UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

☒

For the quarterly period ended September 30, 2024

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

☐

For the transition period from to

Commission File Number: 001-39635

Surrozen, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**30-1374889**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
171 Oyster Point Blvd , Suite 400 , South San Francisco , California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 489-9000

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the

Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
	☒	Smaller reporting company	
Non-accelerated filer			☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 4, 2024, there were

3,249,798
shares of common stock, par value $0.0001 per share, issued and outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2024, or the Quarterly Report, constitute forward-looking statements within the meaning of the federal securities laws. Forward-looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts. These forward-looking statements include statements about future financial and operating results of Surrozen; statements about the plans, strategies and objectives of management for future operations of Surrozen; and statements regarding future performance. In some cases, you can identify these forward-looking statements by the use of terminology such as “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “could,” “seeks,” “approximately,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words or phrases.

The forward-looking statements contained in this Quarterly Report reflect our current views about future events and are subject to numerous known and unknown risks, uncertainties, assumptions and changes in circumstances that may cause its actual results to differ significantly from those expressed in any forward-looking statement. There are no guarantees that the transactions and events described will happen as described (or that they will happen at all). The following factors, among others, could cause actual results and future events to differ materially from those set forth or contemplated in the forward-looking statements:

- the initiation, cost, timing, progress and results of research and development activities, preclinical and clinical trials with respect to SZN-043, SZN-413 and potential future drug candidates;
- our ability to develop and expand our drug discovery and development capabilities;
- our ability to obtain the necessary capital to fund our operations while we conduct clinical trials, seek regulatory approval for our product candidates, and complete the product development process;
- our ability to identify, develop and commercialize drug candidates;
- the successful development and commercialization of products that compete with our product candidates or receive regulatory approval in advance of our product candidates;
- changes in personnel and availability of qualified personnel;
- our ability to manage growth and expand business operations effectively;
- the effects of macroeconomic conditions, volatile market conditions, and global events and the actions of U.S. and foreign governments to respond to these events;
- whether the few stockholders who own a large number of shares of our common stock exercise their voting power in a manner that adversely affects us or our stockholders; and
- the increasingly competitive environment in which we operate.

In addition, statements that “Surrozen believes” or “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and such statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

While forward-looking statements reflect our good faith beliefs, they are not guarantees of future performance. Except to the extent required by applicable law, we are under no obligation (and expressly disclaim any such obligation) to update or revise our forward-looking statements whether as a result of new information, future events, or otherwise. For a further discussion of these and other factors that could cause our future results, performance or transactions to differ significantly from those expressed in any forward-looking statement, please see the section titled “*Risk Factors*.” You should not place undue reliance on any forward-looking statements, which are based only on information currently available to us (or to third parties making the forward-looking statements) as of the date of this Quarterly Report.

Unless the context otherwise requires, references in this Quarterly Report on Form 10-Q to the “company,” “Surrozen,” “we,” “us” and “our” refer to Surrozen, Inc.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

SURROZEN, INC.
Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
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	$ 47,998	$ 46,080
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	42,331	8,145
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000 shares authorized; no shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 500,000 shares authorized as of September 30, 2024 and December 31, 2023; 3,250 and 2,063 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
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	$ 47,998	$ 46,080

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	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)
Unrealized (loss) gain on marketable securities, net of tax	—	(4)	—	242
Comprehensive loss	$ (1,434)	$ (10,449)	$ (35,525)	$ (33,887)
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

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SURROZEN, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2023	2,063	$ —	$ 259,630	$ (221,695)	$ 37,935
Vesting of restricted stock units	44	—	—	—	—
Vesting of early exercised stock options	—	—	1	—	1
Stock-based compensation expense	—	—	1,030	—	1,030
Net loss	—	—	—	(8,830)	(8,830)
Balance at March 31, 2024	2,107	—	260,661	(230,525)	30,136
Issuance of common stock in the Private Placement	1,092	—	—	—	—
Issuance of common stock upon employee stock purchase plan	7	—	42	—	42
Stock-based compensation expense	—	—	1,145	—	1,145
Net loss	—	—	—	(25,261)	(25,261)
Balance at June 30, 2024	3,206	—	261,848	(255,786)	6,062
Vesting of restricted stock units	44	—	—	—	—
Stock-based compensation expense	—	—	1,039	—	1,039
Net loss	—	—	—	(1,434)	(1,434)
Balance at September 30, 2024	3,250	$ —	$ 262,887	$ (257,220)	$ 5,667

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SURROZEN, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2022	2,006	$ —	$ 254,895	$ (241)	$ (178,653)	$ 76,001
Repurchase of early exercised stock options	(1)	—	—	—	—	—
Vesting of early exercised stock options	—	—	13	—	—	13
Stock-based compensation expense	—	—	1,129	—	—	1,129
Other comprehensive income	—	—	—	191	—	191
Net loss	—	—	—	—	(14,297)	(14,297)
Balance at March 31, 2023	2,005	—	256,037	(50)	(192,950)	63,037
Issuance of common stock under employee stock purchase plan	33	—	187	—	—	187
Vesting of early exercised stock options	—	—	8	—	—	8
Stock-based compensation expense	—	—	1,158	—	—	1,158
Other comprehensive income	—	—	—	55	—	55
Net loss	—	—	—	—	(9,387)	(9,387)
Balance at June 30, 2023	2,038	—	257,390	5	(202,337)	55,058
Issuance of common stock upon option exercises	—	—	3	—	—	3
Vesting of early exercised stock options	—	—	6	—	—	6
Stock-based compensation expense	—	—	913	—	—	913

Other comprehensive loss	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(10,445)	(10,445)
Balance at September 30, 2023	2,038	$ —	$ 258,312	$ 1	$ (212,782)	$ 45,531

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SURROZEN, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Operating activities:		
Net loss	$ (35,525)	$ (34,129)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,120	1,460
Stock-based compensation	3,214	3,200
Non-cash operating lease expense	1,072	937
Amortization of discount on marketable securities, net	—	(688)
Transaction costs allocated to pre-funded warrants and warrants in connection with the Private Placement	1,507	—
Loss on issuance of common stock, pre-funded warrants and warrants	20,397	—
Change in fair value of warrant liabilities	(1,851)	(83)
Loss on foreign currency remeasurement	(44)	—
Changes in operating assets and liabilities:		
Accounts receivable	(10,000)	—
Prepaid expenses and other current assets	859	955
Other assets	51	38
Accounts payable	(249)	(371)
Accrued and other liabilities	192	(2,728)
Operating lease liabilities	(1,852)	(1,643)
Net cash used in operating activities	(21,109)	(33,052)

Investing activities:

Purchases of property and equipment	(7)	(398)
Purchases of marketable securities	—	(28,044)
Proceeds from maturities of marketable securities	—	70,665
Net cash (used in) provided by investing activities	(7)	42,223
Financing activities:		
Proceeds from issuance of common stock, pre-funded warrants and warrants in the Private Placement, net of transaction costs	16,043	—
Proceeds from issuance of common stock upon exercise of stock options	—	3
Proceeds from issuance of common stock upon employee stock plan purchases	42	187
Repurchase of early exercised stock options	—	(55)
Net cash provided by financing activities	16,085	135
Net (decrease) increase in cash, cash equivalents and restricted cash	(5,031)	9,306
Cash, cash equivalents and restricted cash at beginning of period	36,731	25,095
Cash, cash equivalents and restricted cash at end of period	$ 31,700	$ 34,401
Supplemental disclosure of noncash investing and financing activities:		
Vesting of early exercises of stock options	$ 1	$ 27

The following table presents a reconciliation of the Company's cash, cash equivalents and restricted cash in the Company's unaudited condensed consolidated balance sheets:

	September 30, 2024	2023
Cash and cash equivalents	$ 31,012	$ 33,975
Restricted cash	688	426
Cash, cash equivalents and restricted cash	$ 31,700	$ 34,401

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SURROZEN, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Organization and Business

Organization

Surrozen, Inc., or the Company, is a clinical stage biotechnology company committed to discovering and developing drug candidates to selectively modulate the Wnt pathway, a critical mediator of tissue repair, in a broad range of organs and tissues. The Company, a Delaware corporation, is located in South San Francisco, California and it operates and manages its business in one operating segment. Surrozen Netherlands, B.V. was incorporated in May 2022 and is located in Amsterdam, Netherlands as a wholly-owned subsidiary of the Company.

Liquidity

The Company has incurred net losses since inception. During the three and nine months ended September 30, 2024, the Company incurred a net loss of $

1.4
million and $

35.5
million, respectively. For the three and nine months ended September 30, 2023, the Company incurred a net loss of $

10.4
million and $

34.1
million, respectively. For the nine months ended September 30, 2024 and 2023, the Company used $

21.1
million and $

33.1
million of cash in operations, respectively. As of September 30, 2024, the Company had cash and cash equivalents of $

31.0
million and an accumulated deficit of approximately $

257.2
million. The Company expects operating expenses to continue to be significant in connection with its ongoing clinical study and anticipates the need to raise additional capital to continue to execute its long-range business plan.

Management believes that the existing cash and cash equivalents, plus a $

10.0
million milestone payment received in October 2024 (see Note 5), are sufficient for the Company to continue operating activities for at least the next 12 months from the date of issuance of its unaudited condensed consolidated financial statements. However, if the Company's anticipated cash burn is greater than anticipated, the Company could use its capital resources sooner than expected which may result in the need to reduce future planned expenditures and/or raise additional capital to continue to fund the operations.

Reverse Stock Split

On December 13, 2023, the Company filed a certificate of amendment to its certificate of incorporation to effect a 1-for-15 reverse stock split of the issued and outstanding common stock, or the Reverse Stock Split. As a result of the Reverse Stock Split, every 15 shares of issued and outstanding common stock was converted into one issued and outstanding share of common stock, without any change in par value per share. The Reverse Stock Split affected all shares of common stock outstanding immediately prior to the effectiveness of the Reverse Stock Split, as well as the number of shares of common stock available for issuance under the equity incentive plans and employee stock purchase plan. In addition, the Reverse Stock Split effected a reduction in the number of shares of common stock issuable upon the exercise of stock options, restricted stock units and warrants outstanding immediately prior to the effectiveness of the Reverse Stock Split with a corresponding increase in the exercise price per share applicable to such stock options and warrants. No fractional shares were issued because of the Reverse Stock Split. Stockholders who would otherwise be entitled to receive a fractional share received a cash payment in lieu thereof. All share and per share amounts in these unaudited condensed consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to the Reverse Stock Split.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited condensed consolidated financial statements and accompanying notes have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP, as determined by the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, and pursuant to the regulations of the U.S. Securities and Exchange Commission, or SEC. As permitted under those rules, certain notes or other financial information that are normally required by U.S. GAAP have been condensed or omitted and accordingly, the consolidated balance sheet as of December 31, 2023 has been derived from the Company's audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete consolidated financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair presentation of the Company's consolidated financial statements. The results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the year ended December 31, 2024 or for any other interim period or future year.

The unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiary. All intercompany transactions and balances have been eliminated.

The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K, filed with the SEC on April 10, 2024.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions made in the accompanying unaudited condensed consolidated financial statements include certain accrued expenses for research and development activities and fair value of warrants issued in connection with the closing of a private placement in April 2024. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could materially differ from those estimates.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist of cash and cash equivalents. The Company's cash is held by financial institutions that may at times exceed federally insured limits. However, the Company's exposure to credit risk in the event of default by the financial institution is limited to the extent of amounts recorded on the unaudited condensed consolidated balance sheets. The Company believes it is not exposed to significant credit risk on cash. The Company's cash equivalents were held in custodial accounts maintained by third-party custodians. The Company's policy is to invest cash in institutional money market funds with high credit quality to limit the amount of credit exposure. The Company has not experienced any losses on its cash equivalents.

Revenue Recognition

The Company records accounts receivable for amounts billed to the customer for which the Company has an unconditional right to consideration. The Company assesses accounts receivable for credit losses and, to date, no credit losses have been recorded.

The Company has a Collaboration and License Agreement, or CLA, with Boehringer Ingelheim International GmbH, or BI, to which the Company licensed certain rights to its intellectual property that is determined within the scope of ASC 606. The terms of the CLA include payments to the Company of a non-refundable upfront payment, development, regulatory and commercial milestone payments and royalties on net sales of licensed products.

The Company determined that the Company's intellectual property granted to BI represented one performance obligation for the purposes of conducting the partnership research and further development on SZN-413. The transaction price was determined to be the non-refundable upfront payment. Variable consideration related to future milestones is fully constrained because the Company cannot conclude that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur, given the inherent uncertainty of success with these future milestones. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded as revenue on a cumulative catch-up basis during the period of adjustment. The Company will recognize sales-based royalties as revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalties that have been allocated have been satisfied (or partially satisfied).

Warrant Liabilities

The Company's warrants are classified as liabilities and measured at fair value. Transaction costs associated with the warrant liabilities are recognized as other expenses when incurred. At the end of each reporting period, any change in fair value during the period are recognized in other income, net within the unaudited consolidated statements of operations and comprehensive loss. The Company will continue to adjust the warrant liabilities for changes in the fair value until the earlier of (a) the exercise or expiration of the warrants or (b) the redemption of the warrants, at which time such warrants will be reclassified to additional paid-in capital.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stock by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive securities. Diluted net loss per share is calculated using the more dilutive of the two-class method or treasury method. The Company's basic net loss per share is the same as diluted net loss per share as the effects of the potentially dilutive securities are antidilutive. The following table presents the potential s hares of common stock outstanding that were excluded from the computation of diluted net loss per share of common stock as of the periods presented because including them would have been antidilutive (in thousands):

	September 30,	
	2024	2023
Common stock issuable upon exercise of stock options	553	317
Unvested restricted stock awards	1	5
Unvested restricted stock units	40	90
Common stock issuable upon exercise of warrants	11,569	394
Total	12,163	806

Recent Accounting Pronouncements

In August 2020, the FASB issued Accounting Standards Update 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40).* This standard eliminates the beneficial conversion and cash conversion accounting models for convertible instruments, amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions, and modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted earning per share calculation. The standard is effective for annual periods beginning after December 15, 2023 for smaller reporting companies, and interim periods within those reporting periods. The Company adopted this standard effective January 1, 2024, using a modified retrospective method. The adoption of the standard did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

In December 2023, the FASB issued Accounting Standards Update 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The standard requires entities to disclose additional categories about federal, state and foreign income taxes in the effective tax rate reconciliation as well as provide annual income taxes paid disaggregated by federal, state and foreign taxes. The standard is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is evaluating the impact of adopting this standard on its unaudited condensed consolidated financial statements and related disclosures.

In November 2023, the FASB issued Accounting Standards Update 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* . The standard improves reportable segment disclosure requirements through enhanced disclosures about significant segment expenses and information used to assess segment performance. All disclosure requirements of the update are required for entities with a single reportable segment. The standard is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and requires retrospective application to all prior periods presented in the financial statements. The Company is evaluating the impact of adopting this standard on its unaudited condensed consolidated financial statements and related disclosures .

Note 3. Fair Value Measurement

The following tables summarize the Company's financial assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	As of September 30, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 28,179	$ —	$ —	$ 28,179
Total financial assets measured at fair value	$ 28,179	$ —	$ —	$ 28,179
Liabilities[2]:				
2021 Public Warrants	$ 50	$ —	$ —	$ 50
2021 PIPE Warrants	—	11	—	11
2024 Pre-Funded Warrants	—	479	—	479
2024 PIPE Warrants	—	—	35,671	35,671
Total financial liabilities measured at fair value	$ 50	$ 490	$ 35,671	$ 36,211

	As of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 33,014	$ —	$ —	$ 33,014
Total financial assets measured at fair value	$ 33,014	$ —	$ —	$ 33,014
Liabilities[2]:				
2021 Public Warrants	$ 53	$ —	$ —	$ 53
2021 PIPE Warrants	—	62	—	62
Total financial liabilities measured at fair value	$ 53	$ 62	$ —	$ 115

(1) Included in cash and cash equivalents on the condensed consolidated balance sheets.

(2) See Note 10.

There were

no

changes to the valuation methods utilized and there were

no

transfers of financial instruments between Level 1, Level 2, and Level 3 during the nine months ended September 30, 2024.

The 2021 Public Warrants (as defined in Note 10 below) are classified as Level 1 due to the use of an observable market quote in an active market. The 2021 PIPE Warrants (as defined in Note 10 below) are classified as Level 2 due to the use of observable market data for identical or similar liabilities. The fair value of each 2021 PIPE Warrant is determined to be consistent with that of a 2021 Public Warrant because the 2021 PIPE Warrants are also subject to the make-whole redemption feature, which allows the Company to redeem both types of warrants on similar terms.

The 2024 Pre-Funded Warrants (as defined in Note 10 below) are classified as Level 2 due to the use of observable market data for similar instruments. The fair value of the 2024 Pre-Funded Warrants is determined to be consistent with the fair value of the Company's common stock due to the nominal exercise price. The 2024 PIPE Warrants (as defined in Note 10 below) are classified as Level 3 because the fair value was measured based on significant inputs that are unobservable in the market. The 2024 PIPE Warrants were initially recorded at fair value and subsequently remeasured at each reporting period using the Black-Scholes option-pricing model. The significant unobservable inputs used in the fair value measurement of the warrants include the timing and probability of achieving the milestones and the expected volatility. The expected volatility was implied from a peer analysis. The expected term was estimated based on the timing of when the milestone is expected to be achieved, and the risk-free interest rate was based on the implied yield available on U.S. Treasury Securities with a maturity equivalent to the expected term. The dividend rate is based on the historical rate, which the Company anticipated remaining at zero.

The fair value of the 2024 PIPE Warrants may change significantly as additional data is obtained, impacting the Company's assumptions to estimate the fair value of the liabilities. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The key inputs into the fair value measurement of the 2024 PIPE Warrants were as follows at the initial measurement and September 30, 2024:

	September 30, 2024	April 4, 2024
Expected term (in years)	0.3 - 4.5	0.8 - 5.0
Expected volatility	95 %	100 %
Risk-free interest rate	3.6 % - 4.8 %	4.4 % - 5.2 %
Dividend yield	—	—

	2024 PIPE Warrants
Balance, December 31, 2023	$ —
Issuance in the Private Placement	37,494
Change in fair value upon remeasurement[1]	(5,004)
Balance, June 30, 2024	32,490
Change in fair value upon remeasurement[1]	3,181
Balance, September, 30, 2024	$ 35,671

[1] Included in other (expense) income, net on the condensed consolidated statement of operations.

Assets that are Measured at Fair Value on a Nonrecurring Basis

The Company's non-financial assets such as property and equipment and operating lease right-of-use assets, are adjusted to fair value on a nonrecurring basis when an impairment has occurred. As of December 31, 2023, the Company identified an indicator of impairment of its long-lived assets due to a sustained decline in the trading price of the Company's common stock over the preceding year, resulting in the Company's market capitalization being below its net asset value. The Company concluded that the carrying value of its long-lived assets was not recoverable and recognized an impairment loss of $

0.2

million during the fourth quarter of 2023 based on the fair value of the individual assets.

To determine the fair value of the individual assets, the Company utilized the discounted cash flow method of the income approach based on market participant assumptions with Level 3 inputs. These represent a Level 3 nonrecurring fair value measurement. Calculating the fair value of the assets involves significant estimates and assumptions. These estimates and assumptions include, among others, projected future cash flows, risk-adjusted discount rates and market conditions. Changes in the factors and assumptions used could materially affect the amount of impairment loss recognized in the period the asset was considered impaired.

The Company is not aware of any identified events or changes in circumstances that would have a significant adverse effect on the carrying value of its long-lived assets for the nine months ended September 30, 2024.

Note 4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Prepaid research and development expenses	$ 715	$ 1,751
Prepaid insurance	632	606
Other	731	580
Prepaid expenses and other current assets	$ 2,078	$ 2,937

Accrued and Other Liabilities

Accrued and other liabilities consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued payroll and related expenses	$ 2,443	$ 2,508
Accrued research and development expenses	1,626	1,261
Accrued professional service fees	87	65
Other	161	292
Accrued and other liabilities	$ 4,317	$ 4,126

Note 5. Collaboration and License Agreements

Collaboration and License Agreement with Boehringer Ingelheim International GmbH

In October 2022, the Company executed the CLA with BI to research, develop and commercialize Frizzled 4, or Fzd4, bi-specific antibodies designed using the Company's SWAP technology, including SZN-413. The Company and BI are conducting partnership research focused on SZN-413 during a one-year period, which BI extended for an additional six-month period. The Company granted BI an exclusive, royalty-bearing, worldwide, sublicensable license, under the applicable patents and know-how, to develop, manufacture and commercialize, for all uses, one lead and two back-up Fzd4 bi-specific antibodies selected by BI. After an initial period of joint research, BI shall be responsible for all further research, preclinical and clinical development, manufacturing, regulatory approvals, and commercialization of licensed products at its expense. Unless terminated earlier, the CLA will remain effective, on a country-by-country and product-by-product basis, until the expiration of BI's royalty obligations. BI has the right to terminate the CLA for any reason after a specified notice period. Each party has the right to terminate the CLA on account of the other party's bankruptcy or material, uncured breach.

Under the terms of the CLA, BI agreed to pay a non-refundable upfront payment of $

12.5

million less any applicable withholding tax, success-based milestone payments up to a total of $

587.0

million and mid-single digit to low-double digit royalties on net sales of the licensed products should any reach commercialization. The royalty payments will be subject to reduction due to patent expiration, generic competition and payments made under certain licenses for third-party intellectual property. The Company received $

10.5

million of the upfront payment from BI in November 2022. The associated withholding tax of $

2.1

million is expected to be refunded to the Company in 2024 and recognized as accounts receivable. In September 2024, a milestone was achieved as BI decided to move forward with the development of SZN-413, which entitled the Company to receive a $

10.0

million non-refundable and non-creditable payment from BI pursuant to the terms of the CLA. The milestone payment of $

10.0

million was recognized as revenue and accounts receivable on the condensed consolidated financial statements for the nine months ended September 30, 2024 and was received in October 2024.

The Company determined that the CLA is within the scope of ASC 606. The Company evaluated the promised goods and services and determined that the license to the Company's intellectual property granted to BI represented one performance obligation for the purposes of conducting the partnership research and further development on SZN-413. The transaction price was determined to be $

12.5

million at the inception, which is the non-refundable upfront payment. Variable consideration related to future milestones is fully constrained because the Company cannot conclude that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur, given the inherent uncertainty of success with these future milestones. For sales-based royalties, the Company determined that the license is the predominant item to which the royalties relate to. Accordingly, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied). The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Note 6. License Agreements

Stanford License Agreements

In March 2016, the Company entered into a license agreement with Stanford University, or the 2016 Stanford Agreement, which was amended in July 2016, October 2016 and January 2021, pursuant to which the Company obtained from Stanford a worldwide, exclusive, sublicensable license under certain patents, rights, or licensed patents and technology related to its engineered Wnt surrogate molecules to make, use, import, offer to sell and sell products that are claimed by the licensed patents or that use or incorporate such technology, or licensed products, for the treatment, diagnosis and prevention of human and veterinary diseases. The Company agreed to pay Stanford

(i) nominal annual license maintenance fees which are creditable against earned royalties owed to Stanford for the same year, (ii) an aggregate of up to $

0.9

million for the achievement of specified development and regulatory milestones, and (iii) an aggregate of up to $

5.0

million for achievement of specified sales milestones. Stanford is also entitled to receive royalties from the Company equal to a very low single digit percentage of the Company's and its sublicensees' net sales of licensed products that are covered by a valid claim of a licensed patent. Additionally, the Company agreed to pay Stanford a sub-teen double digit percentage of certain consideration the Company receives as a result of granting sublicenses to the licensed patents. However, the Company and Stanford may be able to negotiate a lower non-royalty sublicense percentage based on then-current value of the licensed patents for each sublicense product. If the Company is acquired, it agreed to pay a one-time change of control fee in the low six figures. Stanford retains the right under the 2016 Stanford Agreement, on behalf of itself, Stanford Hospital and Clinics, the University of Washington and all other non-profit research institutions, to practice the licensed patents and technology for any non-profit purpose. The licensed patents and technology are additionally subject to a non-exclusive, irrevocable, worldwide license held by the Howard Hughes Medical Institute to practice the licensed patents and technology for its research purposes, but with no right to assign or sublicense.

In June 2018, the Company entered into another license agreement with Stanford, or the 2018 Stanford Agreement, pursuant to which the Company obtained from Stanford a worldwide, exclusive, sublicensable license under certain patent rights related to its surrogate R-spondin proteins, or the licensed patents, to make, use, import, offer to sell and sell products that are claimed by the licensed patents, or licensed products, for the treatment, diagnosis and prevention of human and veterinary diseases, or the exclusive field. Additionally, Stanford granted the Company a worldwide, non-exclusive, sublicensable license under the licensed patents to make and use licensed products for research and development purposes in furtherance of the exclusive field and a worldwide, non-exclusive license to make, use and import, but not to offer to sell or sell licensed products in any other field of use. The Company agreed to pay Stanford an aggregate of up to $

0.4

million for the achievement of specified development and regulatory milestones. Stanford is also entitled to receive royalties from the Company equal to a sub-single digit percentage of the Company's and its sublicensees' net sales of licensed products. Additionally, Stanford is entitled to receive a one-time payment in the low six figures for each sublicense of the licensed patents that the Company grants to a third party and, if the Company is acquired, a one-time nominal change of control fee.

For the three and nine months ended September 30, 2024 and 2023, the Company incurred de minimis research and development expenses under the Stanford agreements.

No

milestones have been achieved as of September 30, 2024.

UCSF License and Option Agreements

In September and October 2016, the Company entered into two separate license and option agreements with The Regents of the University of California, or the UCSF Agreements, pursuant to which the Company obtained exclusive licenses from UCSF for internal research and antibody discovery purposes and an option to negotiate with UCSF to obtain an exclusive license under UCSF's rights in the applicable library to make, use, sell, offer for sale and import products incorporating antibodies identified or resulting from the Company's use of such library, or licensed products.

In January 2020, the Company amended and restated the UCSF Agreements to provide non-exclusive licenses to make and use a certain human Fab naïve phage display library and to make and use a certain phage display llama VHH single domain antibody library for internal research and antibody discovery purposes and an option to negotiate with UCSF to obtain a non-exclusive commercial license under UCSF's rights in the applicable library to make, use, sell, offer for sale and import products incorporating antibodies identified or resulting from the Company's use of such library, or licensed products.

In March 2022, the Company exercised the option under the UCSF Agreements and entered into a non-exclusive commercial license agreement to make and use licensed products derived from the phage display llama VHH single domain antibody library. In August 2024, the Company exercised the option under the UCSF Agreements and entered into a non-exclusive commercial license agreement to make and use licensed products derived from the human Fab naïve phage display library. Under the commercial license agreements, the Company paid UCSF a nominal license issue fee and agreed to pay a nominal annual license maintenance fee, five- to six-digit payments per licensed product upon achievement of a regulatory milestone, nominal minimum annual royalties, and earned royalties equal to a sub-single digit percentage of the Company's and the Company's sublicensees' net sales of licensed products.

For the three and nine months ended September 30, 2024 and 2023 the Company incurred de minimis research and development expenses under the UCSF Agreements and the commercial license agreement.

No

milestones have been achieved as of September 30, 2024.

Distributed Bio Subscription Agreement

In September 2016, the Company entered into, and in January 2019, the Company amended, an antibody library subscription agreement with Charles River Laboratories International, Inc., formerly known as Distributed Bio, Inc., or the Distributed Bio Agreement, in which the Company obtained from Distributed Bio a non-exclusive license to use Distributed Bio's antibody library to identify antibodies directed to an unlimited number of the Company's proprietary targets and to make, use, sell, offer for sale, import and exploit products incorporating the antibodies that the Company identifies, or licensed products. The Company agreed to pay Distributed Bio an annual fee in the low six figures after the first three years. Additionally, the Company agreed to pay Distributed Bio an aggregate of $

5.9

million for each licensed product that achieves specified development, regulatory and commercial milestones and royalties equal to a very low single digit percentage of the Company's and its sublicensees' net sales of licensed products. The Company's obligation to pay royalties will end for each licensed product ten years after its first commercial sale.

In September 2023, the Company amended the Distributed Bio Agreement to cease its use of Distributed Bio's antibody library and terminate the Company's obligation to pay the respective annual fee. The obligations to make milestone and royalty payments for use of each licensed product remain in full force and effect.

For the three and nine months ended September 30, 2024, the Company did not incur research and development expenses under the Distributed Bio Agreement, respectively. For the three and nine months ended September 30, 2023, the Company incurred $

0.1

million and $

0.2

million of research and development expenses under the Distributed Bio Agreement, respectively. The Company achieved a milestone with regard to the initiation of the Phase 1 clinical trial for SZN-1326 in May 2022.

Note 7. Restructuring

In January 2023, the Company implemented a restructuring plan approved by the board of directors to prioritize and focus its resources on key clinical and discovery programs. The plan included a reduction of the Company's overall workforce by approximately

25

% in the first quarter of 2023. In connection with the workforce reduction, the Company incurred one-time restructuring charges, including employee severance and other termination benefits, of approximately $

1.2

million in the first quarter of 2023.

In July 2023, the Company implemented a restructuring plan approved by the board of directors to further reduce its overall workforce by approximately

38

% to better align its workforce with the business needs and focus more of its capital resources on its clinical stage programs. The Company completed the workforce reduction in 2023 and incurred one-time restructuring charges, including employee severance and other termination benefits, of approximately $

1.5

million to be recognized ratably over the requisite service period from July 2023 through March 2024.

The outstanding restructuring liabilities are included in accrued and other liabilities on the condensed consolidated balance sheet. The following tables summarize activity during the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Employee Severance and Other Benefits
Balance, December 31, 2023	$ 74
Cash payments	(44)
Personnel adjustments	(30)
Balance, September 30, 2024	$ —

	Employee Severance and Other Benefits

Balance, December 31, 2022	$ —
Restructuring charges	1,207
Cash payments	(726)
Balance, March 31, 2023	481
Cash payments	(457)
Balance, June 30, 2023	24
Restructuring charges	1,505
Cash payments	(1,304)
Balance, September 30, 2023	$ 225

Note 8. Commitments and Contingencies

Lease Agreement

In August 2016, the Company entered into a lease agreement for office and lab space, which consists of approximately

32,813

square feet of rental space in South San Francisco, California. The office space lease is classified as an operating lease. The initial lease term commenced in May 2017 and ends in April 2025, with rent payments escalating each year. The Company has options to extend the lease for additional years, but the exercise of the option was not reasonably certain. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of $

0.4

million, which is recorded as restricted cash in the condensed consolidated balance sheets.

The operating lease expense for each of the three and nine months ended September 30, 2024 and 2023 was $

0.4

million, $

1.2

million, $

0.4

million and $

1.2

million, respectively.

Aggregate future minimum rental payments under the operating leases as of September 30, 2024, were as follows (in thousands):

Remaining three months ending December 31, 2024	$	668
Year ending December 31, 2025		891
Total lease payments		1,559
Less: Imputed interest		(32)
Operating lease liabilities	$	1,527

Note 9. Stockholders' Equity

Private Placement

In April 2024, the Company entered into a securities purchase agreement with certain institutional investors, or the Investors, and certain members of management whereby the Company issued and sold in a private placement, or the Private Placement: (i)

1.1

million shares of common stock, (ii) pre-funded warrants to purchase up to

40,000

shares of common stock, and (iii) warrants to purchase up to

11.1

million shares of common stock for aggregate gross proceeds of approximately $

17.5

million. The purchase price of common stock and pre-funded warrants to the Investors was $

15.50

per share and $

15.4999

per share, respectively. The pre-funded warrants and warrants were issued with an initial fair value of $

37.9

million, which was greater than the aggregate gross proceeds in the private placement. The excess of $

20.4
million was recorded as loss on issuance of common stock, pre-funded warrants and warrants on the condensed consolidated statements of operations and comprehensive loss. The Company incurred transaction costs of $

1.5
million, consisting of placement agent fees and other expenses, all of which were allocated to the warrant liabilities associated with the pre-funded warrants and warrants issued, and recognized the allocated transaction costs as other expenses when incurred. See Note 10 for more information regarding the warrants issued and sold to the Investors in the Private Placement and Note 11 for more information regarding the shares of the Company's common stock and the warrants issued and sold to management in the Private Placement.

Equity Purchase Agreement

In February 2022, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, or the Equity Purchase Agreement, pursuant to which Lincoln Park is obligated to purchase up to $

50.0
million shares of the Company's common stock.

Upon execution of the Equity Purchase Agreement, the Company issued nominal shares of common stock to Lincoln Park with the fair value of $

0.3
million as consideration for Lincoln Park's commitment to purchase the Company's common stock. In the event that the Company sells an aggregate of $

30.0
million shares of its common stock under the Equity Purchase Agreement, the Company shall pay an additional commitment fee of $

0.1
million in cash to Lincoln Park. As of September 30, 2024, the Company has

no
t sold any shares of common stock under the Equity Purchase Agreement.

At-the-Market Sales Agreement

In December 2022, the Company entered into a sales agreement with Guggenheim Securities, LLC to issue and sell up to $

23.0
million shares of the Company's common stock, or the 2022 ATM. The compensation payable to Guggenheim is equal to

3.0
% of the gross sales price of any shares sold through it pursuant to the sales agreement. As of September 30, 2024, the Company has

no
t sold any shares of common stock under the 2022 ATM.

Note 10. Common Stock Warrants

The following table sets forth the common stock warrants outstanding as of September 30, 2024 and December 31, 2023 (in thousands, except exercise price per warrant):

Type	Classification	Exercise Price per Share — Investor	Exercise Price per Share — Management	September 30, 2024	December 31, 2023
2024 Pre-Funded Warrants	Liability	$ 0.0001	N/A	40	—
2024 PIPE Warrants – Series A	Liability	15.50	$ 16.96	1,132	—
2024 PIPE Warrants – Series B	Liability	14.25	15.71	1,231	—
2024 PIPE Warrants – Series C	Liability	16.00	16.00	4,386	—
2024 PIPE Warrants – Series D	Liability	16.00	16.00	4,386	—
2021 Public Warrants	Liability	172.50	N/A	4,883	2,733
2021 PIPE Warrants	Liability	172.50	N/A	1,024	3,174
Total				17,082	5,907

2024 Pre-Funded Warrants and 2024 PIPE Warrants

As described in Note 9, in April 2024, the Company entered into a securities purchase agreement with Investors and certain members of management whereby the Company issued and sold in a private placement: (i) common stock, (ii) pre-funded warrants to purchase common stock, or the 2024 Pre-Funded Warrants, and (iii) warrants to purchase common stock, or the 2024 PIPE Warrants. The purchase price per share of common stock and per Pre-Funded Warrant includes $

1.25

for the following accompanying common stock warrants issued to the Investors:

- Series A common stock warrants to purchase up to

  1.1

  million shares of common stock with an exercise price of $

  15.50

  per share, for aggregate gross proceeds of up to approximately $

  17.5

  million, exercisable immediately upon issuance for five years .

- Series B common stock warrants to purchase up to

  1.2

  million shares of common stock with an exercise price of $

  14.25

  per share, for aggregate gross proceeds of up to approximately $

  17.5

  million, exercisable immediately upon issuance until the fifth trading day following the Company's announcement that (i) it has completed the

enrollment of at least

15

patients with a 30-day mortality rate less than 30% in the Company's SZN-043 Phase 1b clinical trial for the treatment of severe alcohol-associated hepatitis, with no recommended changes by the safety review committee to the study design, including changes related to dose or schedule, and (ii) safety review committee approval for the Company to advance to a higher dose cohort.

• Series C common stock warrants to purchase up to

4.4

million shares of common stock with an exercise price of $

16.00

per share, for aggregate gross proceeds of up to approximately $

70

million, exercisable for 30 days following the Company's announcement of final data from the SZN-043 phase 1b clinical trial for the treatment of severe alcohol-associated hepatitis. The Series C common stock warrants will also become exercisable in the event of a fundamental transaction as defined in the warrants.

• Series D common stock warrants to purchase up to

4.4

million shares of common stock with an exercise price of $

16.00

per share, for aggregate gross proceeds of up to approximately $

70

million, exercisable for 30 days following the Company's announcement of the enrollment of at least

50

patients in the SZN-043 Phase 2/3 clinical trial for the treatment of severe alcohol-associated hepatitis. The Series D common stock warrants will also become exercisable in the event of a fundamental transaction as defined in the warrants.

The holders of the 2024 Pre-Funded Warrants and the 2024 PIPE Warrants are entitled to receive dividends if the Company declares or makes a dividend to holders of shares of common stock while such warrants are outstanding. If a purchaser fails to exercise such purchaser's Series B common stock warrants in full, then all warrants issued to such purchaser are subject to mandatory transfer and to the extent not transferred shall automatically be cancelled and cease to be exercisable. If a purchaser fails to exercise such purchaser's Series C common stock warrants in full, then the Series D common stock warrants issued to such purchaser shall automatically be cancelled and cease to be exercisable.

2021 Public Warrants

Given the effect of the Reverse Stock Split as described in Note 1, every

15
shares of common stock that may be purchased pursuant to the Company's outstanding public warrants, or the 2021 Public Warrants, immediately prior to the Reverse Stock Split represents

1
share of common stock that may be purchased pursuant to such warrants immediately following the Reverse Stock Split at a price of $

172.50
per share, at any time commencing on November 23, 2021 and terminating at the earlier of August 12, 2026 or upon redemption or liquidation. The exercise price and number of shares issuable upon exercise of the 2021 Public Warrants may be adjusted in the event of a share dividend, extraordinary dividend or recapitalization, reorganization, merger or consolidation. The Company would not be obligated to deliver any shares of common stock pursuant to the exercise of a 2021 Public Warrant and would have no obligation to settle such 2021 Public Warrant exercise unless a registration statement under the Securities Act with respect to the common stock underlying the 2021 Public Warrants is then effective. If the Company fails to have maintained an effective registration statement, the 2021 Public Warrant holders have the right to exercise the 2021 Public Warrants on a cashless basis until such time as there is an effective registration statement.

The Company may redeem the outstanding 2021 Public Warrants at a price of $

0.01
per warrant if the closing price of common stock equals or exceeds $

270.00
per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and similar transactions). Additionally, the Company may redeem the outstanding 2021 Public Warrants at a price of $

0.10
per warrant if the closing price of common stock equals or exceeds $

150.00
per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and similar transactions). Notice of redemption shall be mailed to the 2021 Public Warrant holders no less than 30 days prior to the redemption date, or the Redemption Period. If the closing price of common stock equals or exceeds $

150.00
per share and is less than $

270.00
per share, during the Redemption Period, the 2021 Public Warrant holders may elect to exercise their 2021 Public Warrants on a cashless basis based on a make-whole table.

2021 PIPE Warrants

At September 30, 2024, the Company's outstanding warrants that were issued in connection with a private placement occurring in 2021, or the 2021 PIPE Warrants, are the same in all respects as the 2021 Public Warrants. On March 31, 2023, the Company entered into an amended and restated warrant agreement with Continental Stock Transfer & Trust Company as warrant agent, or the PIPE Warrant Agreement. The 2021 PIPE Warrants may be converted into 2021 Public Warrants on transfer pursuant to the terms of the PIPE Warrant Agreement. As of September 30, 2024,

2.1
million 2021 PIPE Warrants had been converted into 2021 Public Warrants.

Classification

In no event will the Company be required to net cash settle outstanding warrants. The holders of all of the Company's warrants do not have the rights or privileges of common stockholders and any voting rights until they exercise warrants and receive common stock. All of the Company's outstanding warrants are classified as liabilities and recorded at fair value with subsequent change in their respective fair value recognized in other income, net within the unaudited condensed consolidated statements of operations and comprehensive loss. See Note 3 for discussion of warrant valuations.

Note 11. Related Party Transactions

Private Placement

As described in Note 9, the Company entered into a securities purchase agreement with Investors and certain members of management in April 2024, whereby the Company issued and sold to members of management

2,948
shares of common stock, at a purchase price of $

16.96
per share for aggregate gross proceeds of $

0.1
million. The purchase price per share of common stock includes $

1.25
for the following 2024 PIPE Warrants:

- Series A common stock warrants to purchase up to

2,948
shares of common stock with an exercise price of $

16.96
per share.

- Series B common stock warrants to purchase up to

3,206
shares of common stock with an exercise price of $

15.71
per share.

- Series C common stock warrants to purchase up to

11,424
shares of common stock with an exercise purchase price of $

16.00
per share.

- Series D common stock warrants to purchase up to

11,424
shares of common stock with an exercise price of $

16.00
per share.

The terms of the 2024 PIPE Warrants held by management are the same as those held by the Investors. See Note 10 for the terms of the 2024 PIPE Warrants.

Sublease

In April 2024, the Company entered into a related party transaction with Nura Bio, Inc., or Nura Bio, to sublease approximately

6,102

square feet of the Company's office and laboratory space. The sublease term is on a month-to-month basis and the monthly base rent is approximately $

35,000

, escalating at

3

% per annum. Nura Bio is also responsible for its share of real estate taxes, utilities and other operating expenses applicable to the subleased space. During the three and nine months ended September 30, 2024, the Company recognized sublease income of $

0.2

million and $

0.3

million, respectively, as reductions to operating expenses.

Note 12. Stock-Based Compensation Plans

The Company maintains the 2021 Equity Incentive Plan, or the 2021 Plan, which provides for the granting of stock awards to employees, directors and consultants. Options granted under the 2021 Plan may be either incentive stock options or nonqualified stock options. Options granted under the 2021 Plan expire no later than 10 years from the date of grant. Options and restricted stock awards, or RSAs, under the 2021 Plan generally vest over four years. Restricted stock units, or RSUs, granted under the 2021 Plan generally vest in one year. As of September 30, 2024, there were

0.1

million shares of common stock available for issuance under the 2021 Plan.

The Company maintains the 2021 Employee Stock Purchase Plan, or the ESPP, which allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to

15

% of their eligible compensation, subject to plan limitations. An offering period under the ESPP consists of four six-month purchase periods, unless otherwise determined by the Company. The eligible employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the purchase day . As of September 30, 2024, there were

28,000

shares of common stock available for issuance under the ESPP. During the nine months ended September 30, 2024, approximately

7,000

shares of common stock were issued under the ESPP.

Stock Options

A summary of stock option activity is set forth below (shares in thousands):

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding – December 31, 2023	311	$ 27.70	7.99	
Granted	258	9.64		
Forfeited	(9)	24.31		
Expired	(7)	30.74		
Outstanding – September 30, 2024	553	19.29	8.28	$ 786

Exercisable – September 30, 2024	240	25.72	7.16	224

The aggregate intrinsic value of options outstanding and exercisable are the difference between the exercise price of the options and the fair value of the Company's common stock at September 30, 2024.

During the nine months ended September 30, 2024 and 2023, the Company granted options with a weighted-average grant-date fair value of $

7.45
and $

9.47
per share.

No options were exercised during the nine months ended September 30, 2024. During the nine months ended September 30, 2023, the intrinsic value of options exercised was de minimis.

The fair value of options is estimated at the grant date using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected term (in years)	—	6.02	6.00	5.85
Expected volatility	—	84.66 %	91.59 %	85.86 %
Risk-free rate	—	4.19 %	4.63 %	3.89 %
Dividend yield	—	—	—	—

Restricted Stock Awards

The following table summarizes the Company's RSAs activity (shares in thousands):

	Number of Shares	Weighted Average Grant Date Fair Value
RSAs, unvested at December 31, 2023	4	$ 146.92
Vested	(3)	145.22
RSAs, unvested at September 30, 2024	1	149.95

The fair value of RSAs vested during the nine months ended September 30, 2024 and 2023 was de minimis in both periods.

Restricted Stock Units

The following table summarizes the Company's RSUs activity (shares in thousands):

	Number of Shares	Weighted Average Grant Date Fair Value
RSUs, unvested at December 31, 2023	90	$ 7.73
Granted	40	9.17
Vested	(88)	7.73
Cancelled	(2)	7.73
RSUs, unvested at September 30, 2024	40	9.17

The fair value of RSUs vested during the nine months ended September 30, 2024 and 2023 was $ 0.7 million and zero

, respectively.

Stock-Based Compensation

Total stock-based compensation expense recorded in the unaudited condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 291	$ 215	$ 940	$ 882
General and administrative	748	698	2,274	2,318
Total stock-based compensation expense	$ 1,039	$ 913	$ 3,214	$ 3,200

As of September 30, 2024, there was approximately $

4.3
million of stock-based compensation expense to be recognized over a weighted-average period of approximately 2.07 years.

Note 13. Subsequent Events

In October 2024, the Company amended its existing lease agreement to extend the lease term from April 2025 to April 2029. The Company has an option to extend the lease for an additional four-year period and a one-time option to early terminate the lease effective as of April 30, 2026, subject to a termination fee of $

0.4
million. The exercise of either option was not reasonably certain. The total future lease payments under the amendment are approximately $

9.8
million.

In October 2024, the Company entered into a strategic research collaboration with a privately-held company, TCGFB, Inc., or TCGFB, to discover antibody therapeutics targeting transforming growth factor beta, or TGF-β, for the potential treatment of patients with idiopathic pulmonary fibrosis. TCGFB will own all TGF-β product related intellectual property. Under the terms of the agreement, the Company will provide antibody discovery services for a period of up to two years. In exchange for the Company's research services, TCGFB will pay up to $

6.0
million in the aggregate, plus any third-party costs, and issued the Company a warrant exercisable for up to

3.4
million shares of TCGFB common stock at an exercise price of $

0.0001
per share based on certain vesting conditions. TCGFB was founded by The Column Group and the agreement constitutes a related party transaction.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, and our consolidated financial statements and related notes thereto for the year ended December 31, 2023 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on April 10, 2024.

Forward-Looking Statements

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions.

All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. In evaluating these statements, you should specifically consider various factors, including the risks outlined under the caption "Risk Factors" set forth in Item 1A of Part II of this Quarterly Report, as well as those contained from time to time in our other filings with the SEC. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

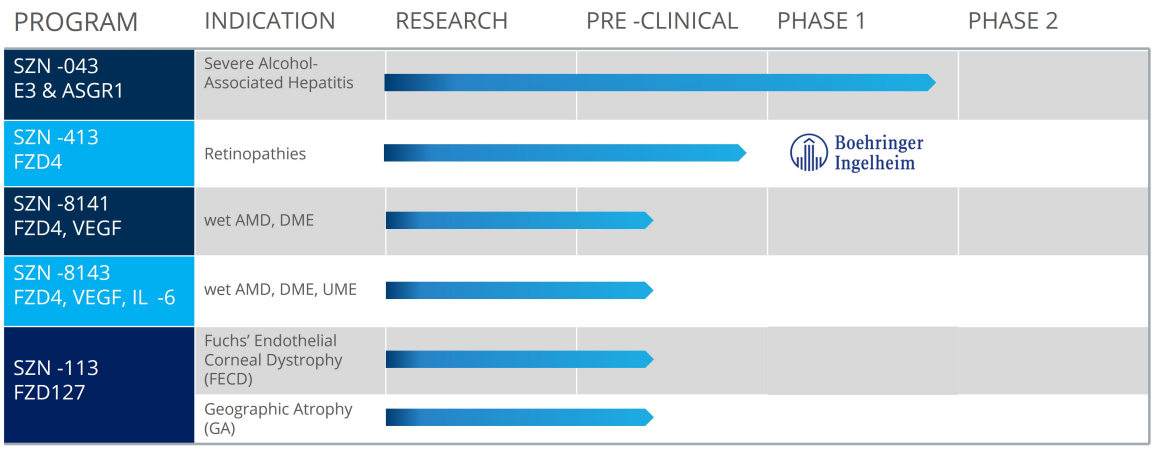
Overview

We are discovering and developing biologic drug candidates to selectively modulate the Wnt pathway, a critical mediator of tissue repair, in a broad range of organs and tissues, for human diseases. Building upon the seminal work of our founders and scientific advisors who discovered the Wnt gene and key regulators of the Wnt pathway, we have made breakthrough discoveries that we believe will overcome previous limitations in harnessing the potential of Wnt biology. These breakthroughs enable us to rapidly and flexibly design tissue-targeted therapeutics that modulate Wnt signaling. As a result of our discoveries, we are pioneering the selective activation of Wnt signaling, designing and engineering Wnt pathway mimetics, and advancing tissue-selective Wnt candidates.

Our lead product candidates are multi-specific, antibody-based therapeutics that mimic the roles of naturally occurring Wnt or R-spondin proteins, which are involved in activation and enhancement of the Wnt pathway, respectively. Given Wnt signaling is essential in tissue maintenance and regeneration throughout the body, we have the potential to target a wide variety of severe diseases, including certain diseases that afflict the intestine, liver, retina, cornea, lung, kidney, cochlea, skin, pancreas and central nervous system. In each of these areas, we believe our approach has the potential to change the treatment paradigm for the disease and substantially impact patient outcomes.

Our strategy is to exploit the full potential of Wnt signaling by identifying disease states responsive to Wnt modulation, design tissue-selective therapeutics, and advance candidates into clinical development in targeted indications with high unmet need. Our unique approach and platform technologies have led to the discovery and advancement of two lead product candidates.

The chart below represents a summary of our product candidates:



SZN-043 is our candidate in development for severe alcohol-associated hepatitis, or sAH. SZN-043, a hepatocyte-specific R-spondin mimetic bispecific fusion protein targeting ASGR1, is the first development candidate using Surrozen's SWEETS™ technology which is designed to mimic the regenerative properties of the protein R-Spondin by enhancing Wnt signaling in a cell-targeted manner. In multiple preclinical animal models of liver injury and fibrosis, SZN-043 has been shown to selectively activate Wnt signaling in the liver, stimulate transient hepatocyte proliferation, improve liver function and reduce fibrosis. The Phase 1a study was completed in February 2024. SZN-043 demonstrated acceptable safety and tolerability in the planned Phase 1b dose range (0.5 mg/kg to 1.5 mg/kg), with evidence of target engagement, Wnt signal activation and effects on liver function. The observed safety, pharmacokinetics and pharmacodynamic activity were the basis for our previous announcement that we planned to initiate enrollment in the Phase 1b study in sAH. We have initiated enrollment in the aforementioned Phase 1b clinical trial and anticipate proof-of-concept data from the Phase 1b clinical trial in the first half of 2025. We successfully completed dosing and 30-day follow-up for cohort 1 in our Phase 1b clinical trial in sAH. No drug related serious adverse events 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 we observed a potential clinical benefit based on reductions in bilirubin and MELD score. A majority of patients experienced improvements in AST and ALT levels.

Ophthalmology Portfolio

Wnt signaling is implicated in multiple diseases and tissues in the eye. We believe our technologies have the potential to generate a portfolio of product candidates that can harness the tissue regenerative activity of the Wnt pathway and potentially bring therapeutic benefit to patients suffering from a broad spectrum of diseases. Our goal in each of these programs is to activate the natural ability of tissues in the body to heal themselves by increasing the Wnt signaling pathway.

We are currently focused on leveraging our expertise in Wnt signaling to develop potential therapeutics for ocular diseases such as retinopathies and Fuchs' endothelial dystrophy.

SZN-413, a Fzd4 targeted bi-specific antibody, is being developed as a novel treatment for retinal vascular-associated diseases and utilizes our proprietary SWAP technology to activate Wnt signaling. Fzd4 mediated Wnt signaling is known to play a critical role in retinal vascular integrity and function. Data generated in preclinical models of retinopathy demonstrated SZN-413 stimulated Wnt signaling and was able to induce normal retinal vessel regrowth while suppressing pathological vessel growth. In October 2022, we executed a Collaboration and Licensing Agreement, or CLA, with Boehringer Ingelheim International GmbH, or BI, to research, develop and commercialize Fzd4 bi-specific antibodies designed using our SWAP technology, including SZN-413. In September 2024, BI decided to move forward with the development of SZN-413, which triggered a $10.0 million milestone payment to us. See Note 5 to the unaudited condensed consolidated financial statements for further information regarding our licensing and collaboration agreement with BI.

Beyond our work with BI on SZN-413, we also have multiple novel ophthalmology product candidates targeting Fzd4 which have demonstrated proof-of-concept in preclinical studies. These product candidates do not fall within the scope of the CLA with BI and are wholly owned by us. Data generated in preclinical models of retinopathy demonstrated these product candidates stimulated Wnt signaling and induced normal retinal vessel regrowth while suppressing pathological vessel growth. These programs include:

- SZN-8141: Fzd4-antiVEGF product candidate combining Fzd4 agonism and vascular endothelial growth factor, or VEGF, antagonism which may have benefits over treatment with single agents for diabetic macular edema, or DME, and neovascular age related macular degeneration, or wet AMD
- SZN-8143: Fzd4-antiVEGF-antiIL6 product candidate combining Fzd4 agonism, VEGF antagonism, and interleukin-6, or IL-6, antagonism which may have benefits over single agents for treatment of DME/wet AMD/uveitic macular edema, or UME

The current standard of care for diabetic retinopathy (including DME), retinal vein occlusion and wet AMD is intravitreal administration of anti-VEGF monotherapies. In addition, Frz4 and antiIL6 monotherapies have demonstrated proof of concept in clinical trials. We believe SZN-8141 and SZN-8143 have the potential to treat multiple retinopathy indications and differentiate from existing therapies.

SZN-113 targeting Fzd127 is our additional ophthalmology product candidate. We are developing SZN-113 for Fuchs' endothelial corneal dystrophy, or FECD, and geographic atrophy, or GA. In preclinical models of FECD, 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. In preclinical models of GA, 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.

Since our inception in 2015, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, developing and optimizing our Wnt therapeutics platform, identifying potential product candidates, undertaking research and development activities, engaging in strategic transactions, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations. We have incurred net losses since inception. During the three and nine months ended September 30, 2024, we incurred net losses of $1.4 million and $35.5 million, respectively. During the three and nine months ended September 30, 2023, we incurred a net loss of $10.4 million and $34.1 million, respectively. As of September 30, 2024, we had an accumulated deficit of $257.2 million and cash and cash equivalents of $31.0 million.

We expect to continue to incur losses for the foreseeable future and expect to incur increased expenses as we expand our pipeline and advance our product candidates through clinical development and regulatory submissions. Specifically, in the near term we expect to incur substantial expenses relating to our clinical trials, the development and validation of our manufacturing processes, and other research and development activities.

Research Collaboration Agreement

In October 2024, we entered into a strategic research collaboration with a privately-held company, TCGFB, Inc., or TCGFB, to discover antibody therapeutics targeting transforming growth factor beta, or TGF-β, for the potential treatment of patients with idiopathic pulmonary fibrosis. Under the terms of the agreement, we will provide antibody discovery services for a period of up to two years. TCGFB will own all TGF-β product related intellectual property. In exchange for our research services, TCGFB will pay us up to $6.0 million in the aggregate, plus any third-party costs, and issued us a warrant exercisable for up to 3.4 million shares of TCGFB common stock at an exercise price of $0.0001 per share based on certain vesting conditions. TCGFB was founded by The Column Group and the agreement constitutes a related party transaction.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates.

During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies or in the methodology used for estimates from those described under Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our Annual Report on Form 10-K for the year ended December 31, 2023.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes results of operations for the periods presented (dollars in thousands):

	Three Months Ended September 30,		$	%
	2024	2023	Change	Change
Collaboration and license revenue	$ 10,000	$ —	$ 10,000	*
Operating expenses:				
Research and development	5,200	6,112	(912)	-15%
General and administrative	3,568	3,572	(4)	0%
Restructuring	—	1,505	(1,505)	-100%
Total operating expenses	8,768	11,189	(2,421)	-22%
Income (loss) from operations	1,232	(11,189)	12,421	-111%
Interest income	431	661	(230)	-35%
Other (expense) income, net	(3,097)	83	(3,180)	*
Net loss	$ (1,434)	$ (10,445)	$ 9,011	-86%

*Percentage is not meaningful

Collaboration and License Revenue

The increase of $10.0 million in collaboration and license revenue for the three months ended September 30, 2024, compared to the three months ended September 30, 2023 is due to the recognition of a milestone achieved under the CLA in September 2024.

Research and Development Expenses

The following table summarizes research and development expenses for the periods presented (dollars in thousands):

	Three Months Ended September 30,		$	%
	2024	2023	Change	Change
SZN-043	$ 2,597	$ 2,710	$ (113)	-4%
SZN-1326	355	1,288	(933)	-72%
Discovery and preclinical stage programs	2,248	2,114	134	6%
Total research and development expenses	$ 5,200	$ 6,112	$ (912)	-15%

The decrease of $0.1 million, or 4%, in SZN-043 program expenses for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, is primarily due to the workforce reductions we implemented in 2023. The decrease of $0.9 million, or 72%, in SZN-1326 program expenses for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, is also due to the workforce reductions we implemented in 2023, as well as the discontinuation of the clinical development of SZN-1326 in January 2024. The increase of $0.1 million, or 6%, in discovery and preclinical stage program expenses for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, is primarily due to the increase in costs on our ophthalmology product candidates.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2024 are flat compared to those for the three months ended September 30, 2023.

Restructuring

The decrease of $1.5 million, or 100%, in restructuring charges for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, is attributable to the workforce reductions we implemented in 2023.

Interest Income

The decrease of $0.2 million, or 35%, in interest income for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, is primarily due to a decrease in cash equivalents and marketable securities.

Other (Expense) Income, Net

The increase of $3.2 million in other expense, net for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, is primarily attributable to non-cash change in fair value of warrant liabilities.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes results of operations for the periods presented (in thousands):

	Nine Months Ended September 30,		$	%
	2024	2023	Change	Change
Collaboration and license revenue	$ 10,000	$ —	$ 10,000	*
Operating expenses:				
Research and development	15,782	21,135	(5,353)	-25%
General and administrative	11,165	12,209	(1,044)	-9%
Restructuring	—	2,712	(2,712)	-100%
Total operating expenses	26,947	36,056	(9,109)	-25%
Loss from operations	(16,947)	(36,056)	19,109	-53%
Interest income	1,306	1,831	(525)	-29%
Other income, net	513	96	417	*
Loss on issuance of common stock, pre-funded warrants and warrants	(20,397)	—	(20,397)	*
Net loss	$ (35,525)	$ (34,129)	$ (1,396)	4%

*Percentage is not meaningful

Collaboration and License Revenue

The increase of $10.0 million in collaboration and license revenue for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023 is due to the recognition of a milestone achieved under the CLA in September 2024.

Research and Development Expenses

The following table summarizes research and development expenses for the periods presented (in thousands):

	Nine Months Ended September 30,		$	%
	2024	2023	Change	Change
SZN-043	$ 8,162	$ 8,520	$ (358)	-4%
SZN-1326	1,295	4,522	(3,227)	-71%
Discovery and preclinical stage programs	6,325	8,093	(1,768)	-22%
Total research and development expenses	$ 15,782	$ 21,135	$ (5,353)	-25%

The decrease of $0.4 million, or 4%, in total SZN-043 program expense for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023 is primarily due to the workforce reductions we implemented in 2023. The decrease of $3.2 million, or 71%, in SZN-1326 program expenses for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, is also due to the workforce reductions we implemented in 2023, as well as the discontinuation of the clinical development of SZN-1326 in January 2024. The decrease of $1.8 million, or 22%, in discovery and preclinical stage program expenses for the nine months ended September 30, 2024, compared to nine months ended September 30, 2023, is primarily due to the workforce reductions we implemented in 2023 to focus our resources on our clinical stage programs.

General and Administrative Expenses

The decrease of $1.0 million, or 9%, in general and administrative expenses for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, is primarily attributable to reductions in employee-related expenses as a result of the workforce reductions in 2023, as well as lower consulting and professional fees as a result of the restructuring plans we implemented in 2023.

Restructuring

The decrease of $2.7 million, or 100%, in restructuring charges for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, is attributable to the workforce reductions we implemented in 2023.

Interest Income

The decrease of $0.5 million, or 29%, in interest income for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, is primarily due to a decrease in cash equivalents and marketable securities.

Other Income, Net

The increase of $0.4 million in other income, net, for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, is primarily attributable to a $1.8 million increase in non-cash change in fair value of warrant liabilities, offset by $1.5 million related to the transaction costs allocated to the warrants issued in a private placement.

Loss on Issuance of Common Stock, Pre-Funded Warrants and Warrants

The increase of $20.4 million in loss on issuance of common stock, pre-funded warrants and warrants for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, as the fair value of warrants issued was greater than the proceeds received in a private placement closed in April 2024.

Liquidity and Capital Resources

Since inception, we have only generated collaboration and license revenue under the CLA with BI. We incurred significant net operating losses and negative cash flows from operations. Historically, we have financed our operations primarily through the sales of our equity securities and the payment received under our collaboration and license agreement. We anticipate that we will continue to incur net losses for the foreseeable future because of additional costs and expenses related to our research and development activities, including increased expenses from pipeline advancement and advancement of our product candidates into and through clinical developments and associated regulatory submissions. We expect to continue to incur significant costs associated with being a public company, including costs related to compliance with the Nasdaq and SEC requirements.

Lincoln Park Equity Line of Credit

We entered into a purchase agreement and a registration rights agreement with Lincoln Park in February 2022, pursuant to which Lincoln Park is obligated to purchase up to $50.0 million shares of our common stock, subject to the terms of the purchase agreement. To date we have not sold any shares of common stock under the purchase agreement.

Guggenheim “At-the-Market” Program

We entered into an at-the-market sales agreement with Guggenheim Securities, LLC in December 2022, under which we may issue and sell up to $23.0 million shares of our common stock. To date we have not sold any shares of common stock under the sales agreement.

Private Placement

In April 2024, we entered into a securities purchase agreement with certain institutional investors and management whereby we issued and sold in a private placement: (i) 1,091,981 shares of common stock, (ii) pre-funded warrants to purchase up to 40,000 shares of common stock, and (iii) warrants to purchase 11,136,106 shares of common stock. At the closing of the private placement, we received aggregate net proceeds of approximately $16.0 million, after deducting placement agent fees and other expenses. If the warrants are exercised in full we will receive additional gross proceeds of approximately $175.5 million. None of the warrants issued in the private placement have been exercised as of the filing of this Quarterly Report. Please see Notes 9, 10 and 11 to the unaudited condensed consolidated financial statements for further information regarding the private placement.

Sublease

In April 2024, we entered into a related party transaction with Nura Bio, Inc., or Nura Bio, to sublease approximately 6,102 square feet of our office and laboratory space in South San Francisco, California. The sublease term is on a month-to-month basis and the monthly base rent is approximately $35,000, escalating at 3% per annum. Nura Bio is also responsible for its share of real estate taxes, utilities and other operating expenses applicable to the subleased space. Please see Note 11 to the unaudited condensed consolidated financial statements for further information regarding the sublease.

Lease Extension

In October 2024, we amended our existing lease agreement to extend the lease term from April 2025 to April 2029. We have an option to extend the lease for an additional four-year period and a one-time option to early terminate the lease effective as of April 30, 2026, subject to a termination fee of $0.4 million. The total future lease payments under the amendment are approximately $9.8 million.

Funding Requirements

To date, we have only generated revenue from our partnership with BI in connection with the CLA. We have not generated and do not expect to generate any revenue from sales of our products unless and until we obtain regulatory approval and commercialize one of our product candidates, and we do not know when, or if, that will occur. We will continue to require substantial additional capital to develop our products candidates and fund operations for the foreseeable future. Since our inception in 2015, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, developing and optimizing our Wnt therapeutics platform, identifying potential product candidates, undertaking research and development activities, engaging in strategic transactions, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations. We expect our expenses to continue to increase in connection with our ongoing activities as we continue to advance our product candidates through clinical development and regulatory approval. In addition, we will continue to incur additional costs associated with operating as a public company.

As of September 30, 2024, we had cash and cash equivalents of $31.0 million and accumulated deficit of $257.2 million. We believe, based on our current operating plan, that our existing cash and cash equivalents, plus a $10.0 million milestone payment received in October 2024, will be sufficient to fund our operations for at least the next 12 months from the filing date of this Quarterly Report. We expect that in the long-term we will need to raise additional capital through public or private equity offerings, debt financings or other capital sources, including government grants, potential collaborations with other companies or other strategic transactions until we are able to generate revenue on our own. Our ability to continue as a going concern in the long-term is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations. There can be no assurance that sufficient funds will be available to us at all or on attractive terms when needed from these sources. If we are unable to obtain additional funding from these or other sources when needed, we may be necessary to significantly reduce expenses through reductions in staff and delaying, scaling back operations, or stopping certain research and development programs.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and costs of researching and developing our lead product candidates or any future product candidates, conducting preclinical and clinical studies, in particular our current ongoing clinical study of SZN-043;
- the outcome, costs, and timing involved in obtaining regulatory approvals for our product candidates;
- the achievement of milestones that trigger payments to us and the timing, receipt and amount of royalties under the CLA and any collaboration and license agreement we may enter in the future;
- the number and scope of clinical programs we decide to pursue;
- the cost of acquiring, licensing, or investing in product candidates and technologies;
- the costs associated with securing and establishing commercialization;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and medical personnel;
- the effect of competing products and product candidates and other market developments;
- the timing, receipt, and amount of sales from SZN-043 and any other product candidates, if approved;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing of, and success of any collaboration, licensing, or other arrangements which we may enter in the future; and
- the effects of the disruptions to and volatility in the credit and financial markets in the U.S. and worldwide.

In addition, any future financing through sales of equity securities will cause our stockholders to experience dilution. If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others our rights to any of our current or future product candidates or discovery programs in certain territories or indications that we would prefer to develop and commercialize ourselves.

Summary of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	$ (21,109)	$ (33,052)
Net cash (used in) provided by investing activities	(7)	42,223
Net cash provided by financing activities	16,085	135
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (5,031)	$ 9,306

Cash Used in Operating Activities

Cash used in operating activities of $21.1 million for the nine months ended September 30, 2024 was primarily due to the use of funds in our operations, the resulting net loss of $35.5 million and a net change of $11.0 million in our net operating assets and liabilities, offset by $25.4 million in non-cash charges. Cash used in operating activities of $33.1 million for the nine months ended September 30, 2023 was primarily due to the use of funds in our operations, and the resulting net loss of $34.1 million and a net change of $3.7 million in our net operating assets and liabilities, offset by $4.8 million in non-cash charges.

Cash (Used in) Provided by Investing Activities

Cash used in investing activities of $7,000 for the nine months ended September 30, 2024 was related to the purchases of lab equipment. Cash provided by investing activities of $42.2 million for the nine months ended September 30, 2023 was primarily related to $70.7 million of proceeds from maturities of marketable securities, offset by $28.0 million of cash used for the purchase of marketable securities and $0.4 million of cash used for the purchase of laboratory, office, computer equipment and software.

Cash Provided by Financing Activities

Cash provided by financing activities of $16.1 million for the nine months ended September 30, 2024 was primarily related to the issuance and sale of common stock, pre-funded warrants and warrants to investors and certain members of management in a private placement. Cash provided by financing activities of $0.1 million for the nine months ended September 30, 2023 was primarily related to the $0.2 million of proceeds from the issuance of common stock upon employee stock plan purchases, offset by $55,000 of cash used in the repurchase of early exercised options.

Contractual Obligations and Commitments

Other than the extension of our existing lease term as described above and in Note 13 to our unaudited condensed consolidated financial statements contained in Part 1 to this Quarterly Report, our contractual obligations as of September 30, 2024 have not materially changed since December 31, 2023. Please see Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included in our Annual Report on Form 10-K for the year ended December 31, 2023 for information regarding our contractual obligations and commitments.

Emerging Growth Company Status

We are an emerging growth company, or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. The JOBS Act permits companies with EGC status to take advantage of an extended transition period to comply with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our unaudited condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if, as an EGC, we intend to rely on such exemptions, we are not required to, among other things: (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act; (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act; (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board; and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation.

We will remain an EGC under the JOBS Act until the earliest of (i) the last day of the fiscal year (a) of 2025, (b) the year in which we have total annual gross revenue of at least $1.235 billion, or (c) the year in which we are deemed to be a large accelerated filer; or (ii) the date on which we have issued more than $1 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed consolidated financial statements included in this Quarterly Report for more information about recent accounting pronouncements, the timing of their adoption and our assessment, to the extent they have been made, of their potential impact on our unaudited condensed consolidated financial statements.

Impact of Inflation

Inflation has increased and is expected to continue to increase for the near future. Inflation generally affects us by increasing our labor costs, research and clinical trial costs. While we do not believe that inflation has had a material effect on our financial condition and results of operations during the periods presented, it may result in increased costs in the foreseeable future and adversely affect our business and financial condition. In addition, inflation may cause us to experience greater uncertainty in general economic conditions and additional volatility in the market price of our common stock. If these conditions worsen or do not improve, our ability to raise capital and our stockholders' ability to sell their shares will be adversely affected.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on the evaluation of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarterly period ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. Because of the inherent limitations in all disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that we have detected all our control deficiencies and instances of fraud, if any. The design of disclosure controls and procedures is based partly on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. Before you make an investment decision with respect to our securities, you should carefully consider the risks and uncertainties described below. These risks should be considered along with all of the other information contained in this Quarterly Report, including our unaudited condensed consolidated financial statements and related notes, before deciding to invest in our securities. If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our securities could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Summary of Risk Factors

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Our business involves significant risks that may have a material adverse effect on our business, financial condition, results of operations, prospects and stock price. These risks are more fully described below and include, among others:

- We are a clinical stage biopharmaceutical company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock.
- In our initial Phase 1 clinical trial for SZN-043, treatment-related adverse events have been observed, and if these findings are present in patients with severe alcohol-associated hepatitis and do not represent acceptable safety, we could require additional capital to complete our clinical trial and development efforts for SZN-043 or we may need to delay or abandon development of SZN-043.
- We will need substantial additional funds to advance development of product candidates of our Wnt therapeutics platform, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize our current or potential future product candidates.
- None of our product candidates have received regulatory approval; our ability to achieve and sustain profitability depends on obtaining regulatory approval and successfully commercializing product candidates, either alone or with collaborators.
- If any current or future product candidate, after it begins clinical trials or receives marketing approval, demonstrates undesirable safety or tolerability side effects or safety concerns, our ability to market and derive revenue from the product candidate could be compromised.
- We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.
- Any future equity or debt issuances or other financing transactions may have dilutive or adverse effects on our existing stockholders.
- We rely on third parties to conduct our preclinical studies and our clinical trials, and those third parties may not perform satisfactorily.
- Our clinical development activities could be delayed or otherwise adversely affected for various reasons.
- We cannot predict how difficult it will be to enroll and retain patients for our trials and we may experience difficulties in patient enrollment in our clinical trials for a variety of reasons.
- The manufacturing of our product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.

• We face competition from entities that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel treatments and therapeutic platforms. If these companies develop therapeutics or product candidates more rapidly than we do, or if their therapeutics or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected.

• If we are unable to maintain proper and effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting and the market price of our common stock may be adversely affected.

• Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

• Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, natural disasters and other events on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom it conducts business, including contract manufacturers, contract research organizations, or CROs, shippers and others.

• To the extent we enter into any other collaborations, we may depend on such collaborations for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

• Collaborations are complex and time-consuming to negotiate and document, and if we fail to enter into new strategic relationships, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

• If we are unable to obtain or protect intellectual property rights related to our technology and current or future product candidates, or if our intellectual property rights are inadequate, we may not be able to compete effectively.

• Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

• Clinical development includes a lengthy and expensive process with an uncertain outcome, we may have negative results and results of earlier studies and trials may not be predictive of future trial results.

• We have conducted our clinical trial for our product candidate outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case its development plans will be delayed, which could materially harm its business.

• A few stockholders, including one of our directors, control the voting rights with respect to a large number of shares of our common stock and could exercise their voting power in a manner that adversely affects us or our stockholders.

Risks Related to Our Business

We are a clinical stage biopharmaceutical company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock.

We are a clinical stage biopharmaceutical company with a history of losses. Since our inception, we have devoted substantially all of our resources to research and development, preclinical studies, clinical trials, building our management team and building our intellectual property portfolio, and have incurred significant operating losses. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. To date, we have not generated any revenue from product sales, and have not sought or obtained regulatory approval for any product candidate. Furthermore, we do not expect to generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for our current and potential future product candidates.

We expect our net losses to increase substantially as our lead product candidate, SZN-043, advances through clinical development. However, the amount of our future losses is uncertain. Our ability to achieve or sustain profitability, if ever, will depend on, among other things, successfully developing product candidates, continuing clinical trials for SZN-043, successful development and testing of SZN-413 through our partnership with Boehringer Ingelheim International GmbH, or BI, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, entering into potential future alliances, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient funds to finance business activities. If we, or our current and potential future collaborators, are unable to commercialize one

or more of our product candidates, or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve or sustain profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

In our initial Phase 1 clinical trial for SZN-043, treatment-related adverse events have been observed, and if these findings are present in patients with severe alcohol-associated hepatitis and do not represent acceptable safety, we could require additional capital to complete our clinical trial and development efforts for SZN-043 or we may need to delay or abandon development of SZN-043.

The Phase 1a clinical trial for SZN-043 was completed in February 2024, but Grade 1 and 2 treatment-related asymptomatic transaminase elevations were present in several subjects dosed with SZN-043. The transaminase elevations for these subjects resolved spontaneously, and no serious adverse events were observed during the study. We intend to further analyze available clinical data and monitor future clinical studies to understand and mitigate, if possible, for these observations. If these observations are present and represent unacceptable safety in the intended population of patients with severe alcohol-associated hepatitis, or AH, we may need to pause the trials to perform additional pre-clinical experiments, causing delays in our development plans and requiring additional capital to resume and complete our development efforts and clinical trials for SZN-043. If we are unable to safely continue the trial for SZN-043 and resolve these observations, development of SZN-043 may be substantially delayed or abandoned and adversely affect our financial condition and results of operations.

We will need substantial additional funds to advance development of product candidates of our Wnt therapeutics platform, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize our current or potential future product candidates.

The development of biopharmaceutical product candidates is capital-intensive. If SZN-043 or potential future product candidates advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our Wnt therapeutics platform, SZN-043 and other product candidates and we will require significant funds to continue to develop our platform, continue the clinical trial for SZN-043 and to conduct further research and development, including preclinical studies and clinical trials.

To date, we have primarily financed our operations through the sale of equity securities. Until such time as we can generate sufficient revenue from sales of our product candidates, if ever, we expect to finance our operations through public or private equity offerings, debt financings or other capital sources, including government grants, potential collaborations with other companies or other strategic transactions. In February 2022, we entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $50.0 million of our common stock from time to time over a 36-month period, subject to certain conditions and limitations. We may not be able to receive any or all of the funds from Lincoln Park because of the limitations, restrictions, requirements, events of default and other provisions contained in the purchase agreement that could limit our ability to cause Lincoln Park to purchase our common stock. If our stock price decreases, we also may not be able to sell shares to Lincoln Park at all or in amounts sufficient to obtain necessary financing. In December 2022, we entered into an at-the-market sales agreement with Guggenheim Securities, LLC, or Guggenheim, in connection with a shelf registration statement on Form S-3 filed in December 2022, to issue and sell our common stock with an aggregate maximum offering price of $23.0 million under an at-the-market offering program. To date we have not sold any shares of common stock under the sales agreement. Given the volatility in the capital markets, we may not be willing or able to raise equity capital through such at-the-market offering. We may, therefore, need to turn to other sources of funding that may have terms that are not favorable to us, or further reduce our business operations due to capital constraints.

We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States, and worldwide. The overall impact of these events on our business may be significantly affected by the actions of U.S. and foreign governments. These events and actions could result in severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive.

If we are unable to raise additional capital in sufficient amounts, in a timely manner or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the development of our product pipeline or other research and development initiatives. We also could be required to seek collaborators for our product pipeline and any future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product pipeline and any future product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Our future capital requirements and the period for which we expect existing resources to support our operations may vary significantly from our projections. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of product candidates is highly

uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development of SZN-043, SZN-413 and other potential future product candidates;
- the timing and progress of the development of our Wnt therapeutics platform;
- the price and pricing structure that we are able to obtain from our third-party contract manufacturers to manufacture our preclinical study and clinical trial materials and supplies;
- the extent to which prices for supplies and materials increase due to inflationary pressures and labor market constraints;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current licenses, research and development programs and to establish new collaborations;
- the progress of the development efforts of parties with whom we may in the future enter into collaboration and research and development agreements;
- the costs involved in obtaining, maintaining, enforcing and defending patents and other intellectual property rights;
- the impact of the health epidemics on our business;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company.

If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be harmed, and we will need to significantly modify our operational plans. We may also have to liquidate assets, and the value we receive for any assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

None of our product candidates have received regulatory approval; our ability to achieve and sustain profitability depends on obtaining regulatory approval and successfully commercializing product candidates, either alone or with collaborators.

Before obtaining regulatory approval for the commercial distribution of our product candidates, we or a collaborator must conduct extensive preclinical studies, followed by clinical trials to demonstrate the safety, purity and potency, or efficacy of our product candidates in humans. There is no guarantee that the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities will permit us to conduct clinical trials. Further, we cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs, our clinical protocols or if the outcome of our preclinical studies will ultimately support the further development of our preclinical programs or testing in humans. As a result, we cannot be sure that we will be able to submit Investigational New Drugs, or INDs, or similar applications for our proposed clinical programs on the timeline we expect, if at all, and cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials for any of our product candidates to begin.

We are subject to the risks of failure inherent in the development of product candidates based on novel approaches, targets and mechanisms of action. There is no guarantee that we will be able to proceed with clinical development of our product candidates or that our product candidates will demonstrate a clinical benefit once we further advance these candidates. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties that we have encountered and that are frequently encountered by clinical stage biopharmaceutical companies such as us.

We may not be able to access the financial resources to continue development of, or to enter into any collaborations for, SZN-043 or any potential future product candidates. This may be exacerbated if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, a product candidate, such as:

- negative or inconclusive results from our preclinical or clinical trials (including as described above) or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon any or all of our programs;
- product-related side effects experienced by participants in our clinical trials (such as the asymptomatic transaminase elevations discussed above) or by individuals using drugs or therapeutic antibodies similar to ours, including immunogenicity;
- delays in submitting IND applications or comparable foreign applications, or delays or failures to obtain the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;

- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- chemistry, manufacturing and control, or CMC, challenges associated with manufacturing and scaling up manufacturing of biologic product candidates to ensure consistent quality, stability, purity and potency among different batches used in clinical trials;
- greater-than-anticipated clinical trial costs;
- poor potency or effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory authority inspection and review of a clinical trial or manufacturing site;
- failure of us or Boehringer Ingelheim International GmbH to adequately perform under the Collaboration and License Agreement;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines; or
- the FDA or other regulatory authorities interpreting our data differently than it does.

Further, we and our current and potential future collaborator may never receive approval to market and commercialize any product candidate. Even if we or our current and potential future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as were intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or our current and potential future collaborator may be subject to post-marketing testing requirements to maintain regulatory approval.

SZN-043, SZN-413 and any other of our future product candidates that are tested in humans may not demonstrate the safety, purity and potency, or efficacy, necessary to become approvable or commercially viable.

We may ultimately discover that SZN-043 and SZN-413 do not possess certain properties that we believe are beneficial for therapeutic effectiveness and safety. For example, although SZN-043 exhibited encouraging results in animal studies, they may not demonstrate the same properties in humans and may interact with human physiology in unforeseen, ineffective or harmful ways, as shown by the observations of asymptomatic transaminase elevations discussed above. As a result, we may never succeed in developing a marketable product based on any of our current or future product candidates. If SZN-043, SZN-413 or any of our potential future product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, which could require us to change our focus and approach to antibody-based discovery and development and materially and adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to use and expand our Wnt therapeutics platform to build a pipeline of product candidates.

A key element of our strategy is to use and expand our Wnt therapeutics platform to discover and develop a portfolio of Wnt product candidates that can facilitate the repair and/or regeneration of damaged tissue for patients suffering from a variety of severe diseases. Although our research and development efforts to date have resulted in the discovery and development of SZN-043, SZN-413 and other potential product candidates, our current product candidates may not be safe or effective therapeutics and we may not be able to develop any successful product candidates. Our platform is evolving and may not reach a state at which building a pipeline of product candidates is possible. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. Observations of asymptomatic transaminase elevations in clinical trial of SZN-043 could also impair our ability to build and expand our Wnt platform if we are unable to successfully resolve those observations. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Although a substantial amount of our efforts will focus on the planned clinical trials and potential approval of our existing product candidates and other potential product candidates we are evaluating, a key element of our strategy is to discover, develop and potentially commercialize additional products beyond our current product candidates to treat various conditions and in a variety of therapeutic

areas. We intend to do so by investing in our own drug discovery efforts, exploring potential strategic alliances for the development of new products and in-licensing technologies. Identifying new investigational medicines requires substantial technical, financial and human resources, whether or not any investigational medicines are ultimately identified. Even if we identify investigational medicines that initially show promise, we may fail to successfully develop and commercialize such products for many reasons, including the following:

- the research methodology used may not be successful in identifying potential investigational medicines;
- competitors may develop alternatives that render its investigational medicines obsolete;
- investigational medicines it develops may nevertheless be covered by third parties' patents or other exclusive rights;
- an investigational medicine may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio;
- an investigational medicine may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial patients, the medical community or third-party payors.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

The market may not be receptive to our current or potential future product candidates, and we may not generate any revenue from the sale or licensing of our product candidates.

Even if regulatory approval is obtained for a product candidate, including SZN-043, we may not generate or sustain revenue from sales of approved products. Market acceptance of our current and potential future product candidates, if approved, will depend on, among other factors:

- the timing of its receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our product candidates;
- the success of its physician education programs;
- the availability of coverage and adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If any current or future product candidate, after it begins clinical trials or receives marketing approval, demonstrates undesirable safety or tolerability side effects or safety concerns, our ability to market and derive revenue from the product candidate could be compromised.

Undesirable side effects caused by SZN-043, SZN-413 or any potential future product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. It is also possible that there will be side effects associated with the testing or use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated and the FDA or other regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. For example, certain researchers have noted that therapeutics targeting the Wnt pathway may lead to tumor formation or proliferation as a result of the downstream impacts of Wnt signaling. To date, we have not observed any such tumor formation with SZN-043 in our preclinical toxicology studies and clinical trial, but there can be no guarantee that our current or future product candidates will not result in tumor formation. Any of these occurrences or failure to resolve the findings related to SZN-043 may materially and adversely affect our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature use a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

In the event that any of our current or potential future product candidates receive regulatory approval and we or others identify undesirable side effects caused by one of these products, any of the following adverse events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- regulatory authorities may require additional post-marketing safety studies or registries;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have incurred significant operating losses to date and it is possible we may never generate a profit. We do not expect to realize revenue from product sales or royalties from licensed products for the foreseeable future, if at all, and unless and until our current and potential future product candidates are clinically tested, approved for commercialization and successfully marketed. We expect to continue to incur additional operating losses for the foreseeable future as we continue to develop our product candidates. If the time required to generate significant product revenues and achieve profitability is longer than we currently anticipate or if we are unable to generate liquidity through equity financing or other sources of funding, we may be forced to curtail or suspend our operations.

Any future equity or debt issuances or other financing transactions may have dilutive or adverse effects on our existing stockholders.

The terms of any financing, including our potential financing through Lincoln Park and the at-the-market sales agreement with Guggenheim, may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common stock to decline. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our current and potential future product candidates, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we raise any additional capital through public or private equity or convertible debt offerings, including through any sales of common stock to Lincoln Park or under the at-the-market sales agreement with Guggenheim, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. If we raise additional capital through debt

financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus our efforts on specific research and development programs, including clinical development of SZN-043 and SZN-413. As a result, we may forgo or delay pursuit of other opportunities, including with potential future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaborations, licensing or other royalty arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, preliminary or topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim, preliminary or topline data from our clinical studies. Interim, topline or preliminary data from clinical trials that we may disclose are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of us in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline data that we report differs from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may not be able to enter into strategic transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize current and potential future product candidates, impact our cash position, increase our expense, and present significant distractions to our management.

From time to time, we consider strategic transactions, such as collaborations, acquisitions of companies, asset purchases, joint ventures and out- or in-licensing of product candidates or technologies. For example, in October 2022, we executed a strategic partnership with BI for the research and development of SZN-413 for the treatment of retinal diseases. We will continue to evaluate and, if strategically attractive, seek to enter into collaborations, including with biotechnology or biopharmaceutical companies or hospitals. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. If we are not able to enter into strategic transactions, we may not have access to required liquidity or expertise to further develop our potential future product candidates or our Wnt therapeutics platform. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase its near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business.

We also may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of acquiring such assets. Conversely,

any new collaboration that we enter into may be on terms that are not optimal for us or our product candidates. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses;
- difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business;
- impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and
- the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any current or future partnerships and transactions may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

In addition, to the extent that any current or future collaborators terminate a collaboration agreement, we may be forced to independently develop our current and future product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining, enforcing and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and materially harm its business, financial condition, results of operations and prospects.

We rely on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily.

We rely on third-party clinical investigators, contract research organizations, or CROs, clinical data management organizations and consultants to design, conduct, supervise and monitor certain preclinical studies and clinical trials. Because we intend to rely on these third parties and will not have the ability to conduct certain preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of such preclinical studies and clinical trials than we would have had it conducted them on its own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and contract manufacturing organizations, or CMOs, and may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, this would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

Our reliance on these third parties for such drug development activities will reduce our control over these activities. As a result, we will have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon its own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, including good laboratory practice, or GLP, good clinical practice, or GCP and current good manufacturing practice, or cGMP, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency, or EMA, or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be

conducted with product candidates produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates FDA regulatory requirements as well as federal or state healthcare laws and regulations or healthcare privacy and security laws.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, they will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in its efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, its costs could increase and our ability to generate revenue could be delayed.

We and our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the time frames that such collaborators announce, which could have an adverse impact on our business and could cause our stock price to decline.

From time to time, we expect that we will make public statements regarding the expected timing of certain milestones and key events, such as the commencement and completion of preclinical and IND-enabling studies in our internal drug discovery programs as well as the commencement and completion of our ongoing and planned clinical trials. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or any future collaborators' drug discovery and development programs, the amount of time, effort and resources committed by us and any future collaborators, and the numerous uncertainties inherent in the development of drugs. As a result, there can be no assurance that we or any current or future collaborators' programs will advance or be completed in the time frames we or they announce or expect. If we or any collaborators fail to achieve one or more of these milestones or other key events as planned, including the milestones in our agreement with BI, our business could be materially adversely affected and the price of common stock could decline.

Clinical trials are expensive, time-consuming and difficult to design and implement, which may cause delays in our development timelines, increase costs, and limit our ability to timely complete our trials.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our current and potential future product candidates are based on new technologies and discovery approaches, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, because of the limited number of drug candidates that target the Wnt pathway, the FDA or other regulatory authorities may require us to perform additional testing before commencing or resuming clinical trials and be hesitant to allow us to enroll patients impacted with its targeted disease indications in Phase 1 trials. If we are unable to enroll patients impacted by the targeted disease indications in our current and planned Phase 1 trials, we may continue to be delayed or would be delayed in obtaining potential proof-of-concept data in humans, which could extend our development timelines. In addition, costs to treat patients and to treat potential side effects that may result from our product candidates may be significant. Accordingly, our clinical trial costs are likely to be high and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our clinical development activities could be delayed or otherwise adversely affected for various reasons.

We may not be able to initiate, resume or continue clinical trials for our current or potential future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. We cannot predict how difficult it will be to enroll and retain patients for our trials. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity and availability of clinical trial sites for prospective patients;
- willingness of physicians to refer their patients to our clinical trials;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we cannot control that may limit patients, principal investigators or staff or clinical site availability.

In addition, our future clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for their clinical trials at such clinical trial sites. Additionally, because some of our clinical trials will be in patients with advanced disease who may experience disease progression or adverse events independent from our product candidates, such patients may be unevaluable for purposes of the trial and, as a result, we may require additional enrollment. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

We have experienced, and may further experience, delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether preclinical studies or clinical trials will begin on time, resume in a timely manner, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of our clinical trials could be substantially delayed or prevented by many factors, including:

- further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, including the endpoint measures required for regulatory approval and our statistical plan;
- the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient quantities or inability to produce quantities of consistent quality, purity and potency of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy or failure to measure a statistically significant clinical benefit within the dose range with an acceptable safety margin during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;

- inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- the impact of, and delays related to, health epidemics;
- the need to suspend, repeat or terminate clinical trials as a result of non-compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and
- the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason by, any future strategic collaborator that have responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by them, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that it currently contemplates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for our current or future product candidates that we may develop. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We may seek orphan drug designation for certain indications for our product candidates in the future. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. The FDA may reduce the seven-year exclusivity if the same drug from a competitor demonstrates clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

The manufacturing of our product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.

Historically engineered antibodies have been particularly difficult to manufacture and CMOs have limited experience in the manufacturing of antibodies to selectively activate Wnt signaling. The process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

All of our engineered antibodies are manufactured by culturing cells from a master cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP standards and regulations, each stored at two sites to reduce risk of loss. It is possible that we could lose multiple cell bank sites and have our manufacturing severely impacted by the need to replace the cell bank sites, and we may fail to have adequate backup should any particular cell bank site be lost in a catastrophic event. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts.

Because we may rely on third parties for manufacturing and supply of our product candidates, some of which may be sole source vendors, for preclinical and clinical development materials and commercial supplies, our supply may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers for our preclinical and future clinical trial product materials and supplies. We do not produce our product candidates in quantities sufficient for preclinical and clinical development, and we do not currently own manufacturing facilities for producing such supplies. Furthermore, some of our manufacturers represent our sole source of supplies of preclinical and future clinical development materials, including our source for the manufacture of SZN-043. Although our current contract manufacturer has multiple sites capable of producing our products (both drug substance and drug product), we cannot assure you that its preclinical or future clinical development product supplies and commercial supplies will not be limited or interrupted, especially with respect to our sole source third-party manufacturing and supply collaborators, or will be of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. For our current and future sole source third-party manufacturing and supply collaborators, we may be unable to negotiate binding agreements with them or find replacement manufacturers to support our preclinical and future clinical activities at commercially reasonable terms in the event that their services to us become interrupted for any reason. We do not always have arrangements in place for a redundant or second-source supply for our sole source vendors in the event they cease to provide their products or services to us or do not timely provide sufficient quantities to us. Establishing additional or replacement sole source vendors, if required, may not be accomplished quickly. Any delays resulting from manufacturing or supply interruptions associated with our reliance on third-party manufacturing and supply collaborators, including those that are sole source, could impede, delay, limit or prevent our drug development efforts, which could harm our business, result of operations, financial condition and prospects.

The manufacturing process for a product candidate is subject to FDA and other regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fails to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, or at all. In some cases, the technical skills or technology required to manufacture our current and future product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We also expect to rely on third-party manufacturers if we receive regulatory approval for any product candidate. We have existing, and may enter into future, manufacturing arrangements with third parties. We will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for any product candidate, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. We or a third party's failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of potential future collaborators;
- subjecting third-party manufacturing facilities or our potential future manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of product candidates; and

- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Our third-party manufacturers may be unable to successfully scale manufacturing of SZN-043 or potential future product candidates in sufficient quality and quantity, which would delay or prevent us from developing our current and future product candidates and, if approved, commercializing product candidates.

In order to conduct clinical trials for SZN-043 as well as any potential future product candidates or commercialize, we will need to manufacture large quantities of these product candidates. We may continue to and currently expect to use third parties for our manufacturing needs. Our manufacturing collaborators may be unable to successfully increase the manufacturing capacity for any current or potential future product candidate in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing collaborators are unable to successfully scale the manufacture of any current or potential future product candidate in sufficient quality and quantity, the development, testing, clinical trials and commercialization of that product candidate may be delayed or infeasible and regulatory approval or commercial launch of any potential resulting product may be delayed or not obtained, which could significantly harm our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in the San Francisco Bay Area. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemics, including any potential effects from power shortage, telecommunication failures, cyberattacks or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of its business operations. Natural disasters or pandemics could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure its investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing, planned or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

If the market opportunities for our current and potential future product candidates, including SZN-043 and SZN-413, are smaller than we believe they are, our future product revenues may be adversely affected and our business may suffer.

Our understanding of the number of people who suffer from certain types of moderate to severe IBD, sAH and retinal vascular associated diseases that SZN-043 and SZN-413, respectively, may be able to treat are based on estimates. These estimates may prove to be incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our current or potential future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for our candidates may further be reduced if its estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from SZN-043 or SZN-413.

Further, there are several factors that could contribute to making the actual number of patients who receive our current or potential future product candidates less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

We face competition from entities that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel treatments and therapeutic platforms. If these companies develop therapeutics or product candidates more rapidly than we do, or if their therapeutics or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. We face potential competition from many different sources, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing, and commercialization of therapies aimed at treating autoimmune, inflammatory, metabolic, and other diseases, including indications that we are pursuing or may pursue in the future. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future.

The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the level of competition and the availability of coverage and adequate reimbursement from third-party payors. If any of our product candidates are approved and commercialized, it is likely that we will face increased competition as a result of other companies pursuing development of products to address similar diseases. For SZN-043 and our earlier stage research programs, we face competition from approved therapies and potential competition from product candidates in development for the indications we are pursuing or may pursue.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop, including if competitors develop a safer and/or more effective Wnt modulation platform. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than us, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market and materially and adversely impact our business.

If we are unable to maintain proper and effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting and the market price of our common stock may be adversely affected.

Effective internal controls are necessary for us to provide reliable financial reports and to protect from fraudulent, illegal or unauthorized transactions. If we cannot provide effective controls and reliable financial reports, our business and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on the effectiveness of our internal control over financial reporting. In the future, our independent registered public accounting firm may also need to attest to the effectiveness of our internal control over financial reporting.

If material weaknesses or control deficiencies occur in the future, we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

Members of our management team have limited experience in managing the day-to-day operations of a public company and, as a result, we may incur additional expenses associated with the management of our company.

Members of our management team have limited experience in managing the day-to-day operations of a public company. As a result, we may need to obtain outside assistance from legal, accounting, investor relations, or other professionals that could be more costly than planned. We also plan to hire additional personnel to comply with additional SEC reporting requirements. These compliance costs will make some activities significantly more time-consuming and costly. If we lack cash resources to cover these costs in the future, our

failure to comply with reporting requirements and other provisions of securities laws could negatively affect our stock price and adversely affect our potential results of operations, cash flow and financial condition.

Our ability to use net operating loss carryforwards, or NOLs, to offset future taxable income may be subject to certain limitations.

Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under current law, NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under current law, NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2023, we had NOLs of approximately $155.7 million and $53.0 million available to reduce future taxable income, if any, for federal and California state income tax purposes, respectively. NOLs generated after 2018 for federal tax reporting purposes of $143.2 million have an indefinite carryforward period. The remaining federal and all state NOLs begin expiring in 2036.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. We have determined that we likely had an ownership change in September 2020. As a result of the annual limitations caused by the ownership changes, it was estimated that approximately $1.3 million of federal tax credit and $27.4 million of California NOL will expire unutilized for income tax purposes, and such amounts are excluded from the carryforward balances of December 31, 2023. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, and some of which are outside our control. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which may result in increased future tax liability to us and could adversely affect our operating results and financial condition.

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Our success largely depends on the continued service of key executive management, advisors and other specialized personnel, including Craig Parker, our President and Chief Executive Officer, and Charles Williams, our Chief Financial Officer and Chief Operating Officer. Our senior management may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our employees. The loss of one or more members of the executive team, management team or other key employees or advisors could delay research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of senior management or other key employees could impede the achievement of research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in the industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist in formulating research and development and commercialization strategies. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue its growth strategy will be limited.

We may experience difficulties in managing growth and expanding operations.

We have limited experience in therapeutic development. As our current and potential future product candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities.

We may also experience difficulties in the discovery and development of potential future product candidates using its Wnt therapeutics platform if we are unable to meet demand as it grows our operations. In the future, we also expect to have to manage additional

relationships with collaborators, suppliers and other organizations. Our ability to manage operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures and secure adequate facilities for operational needs. We may not be able to implement improvements to management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

From time to time, we may implement organizational changes to pursue greater efficiency and realign our business and strategic priorities. In January 2023, we completed certain restructuring actions, or the January Restructuring Plan, designed to reduce operating costs and continue advancing our ongoing commitment to profitable growth, including an initial reduction of the overall workforce by approximately 25%. In July 2023, we implemented another restructuring plan, or the July Restructuring Plan, to reduce our overall workforce by a total of approximately 38% in an effort to better align our workforce with our business needs and focus our capital resources on clinical trials of our product candidates. We may encounter challenges in the execution of these efforts, and these challenges could impact our financial results.

Although we believe that our organizational efforts will further reduce our operating costs, we cannot guarantee that the restructuring plans will achieve or sustain the targeted benefits, or that the benefits, even if achieved, will be adequate to meet our long-term profitability and operational expectations. As a result of these actions, we will incur additional charges in the near term, including those related to employee transition, severance payments, and employee benefits. Additional risks associated with the continuing impact of our organizational charges include employee attrition beyond our intended reduction-in-force and adverse effects on employee morale (which may also be further exacerbated by actual or perceived declining value of equity awards), diversion of management attention, adverse effects to our reputation as an employer (which could make it more difficult for us to hire new employees in the future), and potential failure or delays in the development of our product candidates due to the loss of qualified employees. If we do not realize the expected benefits of our restructuring efforts on a timely basis or at all, our business, results of operations and financial condition could be adversely affected.

If any of our product candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.

We currently have no sales, marketing or distribution capabilities or experience. We will need to develop internal sales, marketing and distribution capabilities to commercialize each current and potential future product candidate that gains, if ever, FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into collaborations with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market any approved products or decide to co-promote products with third parties, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we can make no assurances that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, either on its own or through third parties, our business and results of operations could be materially and adversely affected.

Our international operations may expose us to business, political, operational and financial risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers are located outside of the United States and we have conducted, and anticipate conducting additional future, clinical trials, including our Phase 1 trial for SZN-043, outside of the United States. Furthermore, if we or any current or future collaborator succeed in developing any products, we anticipate marketing them in the European Union, or EU, and other jurisdictions in addition to the United States. If approved, we or any future collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as those relating to privacy, data protection and cybersecurity, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, wars, terrorism, political unrest, outbreak of disease, boycotts, trade wars and other significant events;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or our anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize product candidates in foreign markets for which we may rely on collaborations with third parties. We will not be permitted to market or promote any product candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval for any product candidate. To obtain separate regulatory approval in foreign countries, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of a product candidate, and we cannot predict success in these jurisdictions. If we obtain approval of any current or potential future product candidates and ultimately commercialize any such product candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability, and our inability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

As we conduct preclinical studies and clinical trials of SZN-043, SZN-413 and other potential future product candidates, we are and will be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of these product candidates. Product liability claims could delay or prevent completion of development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, manufacturing processes and facilities or marketing programs and potentially a recall of products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we or any current or future collaborators may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our employees, principal investigators, consultants and commercial collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by employees, principal investigators, consultants and commercial collaborators. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards We may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on

our business and financial condition, including the imposition of significant criminal, civil and administrative fines or other sanctions, such as monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity obligations, reputational harm and the curtailment or restructuring of our operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other information to develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes.

We and any potential future collaborators, partners or service providers may be subject to federal, state and foreign data protection laws, regulations and regulatory guidance, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws or contractual obligations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, such as Health Insurance Portability and Accountability Act, or HIPAA, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of any future potential collaborators or service providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, or if we otherwise violate applicable privacy and data security laws.

International data protection laws, including the EU's General Data Protection Regulation, or GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the EU, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous requirements for the collection, use and disclosure of personal information, including stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information.

In addition, the GDPR includes restrictions on cross-border data transfers. A recent decision by the Court of Justice of the European Union has invalidated the EU-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe in compliance with the GDPR's cross-border data transfer restrictions, and raised questions about whether the European Commission's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner has opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. The United Kingdom, or UK, whose data protection laws are similar to those of the EU, may similarly determine that the EU-U.S. Privacy Shield is not a valid mechanism for lawfully transferring personal information from the UK to the U.S. The European Commission recently proposed updates to the SCCs, and additional regulatory guidance has been released that seeks to impose additional obligations on companies seeking to rely on the SCCs. Given that, at present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the SCCs, any transfers by us or our vendors of personal data from Europe may not comply with European data protection law, which may increase Our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit the transfer of EU personal data outside of the EU (including clinical trial data), and may adversely impact Our operations, product development, and ability to provide our products.

The GDPR has increased the responsibilities and potential liability in relation to personal data processed subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Further, the exit of the UK from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. The UK now is considered a "third country" under the GDPR and transfers of European personal data to the UK will, unless the UK is determined by the EU to provide adequate protection for personal data, require an adequacy mechanism to render such transfers lawful under the GDPR following the expiration or termination of a grace period that presently is scheduled to last for four months from January 1, 2021, with a potential additional two-month extension. Aspects of the relationship between the EU and the UK with respect to data protection, including with respect to cross-border data transfers, remain uncertain. Compliance with the GDPR and applicable laws and regulations relating to privacy and data protection of EU Member States and the UK will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change its business practices, and despite those efforts, there is a risk that We may be subject to fines and penalties, litigation, and reputational harm in connection with Our European activities. In addition, failure to comply with GDPR and applicable laws and regulations relating to privacy and data protection of EU Member States and the UK may result in regulators prohibiting Our processing of the personal information of EU data subjects, which

could impact Our operations and ability to develop our products and provide its services, including interrupting or ending EU clinical trials.

In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first “GDPR-like” law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and can include any of Our current or future employees who may be California residents) and provide such residents new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches and statutory damages ranging from $100 to $750 per violation, which is expected to increase data breach class action litigation and result in significant exposure to costly legal judgments and settlements. As we expand our operations and trials (both preclinical and clinical), the CCPA may increase compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. In November 2020, California passed the California Privacy Rights Act, or the CPRA, which amends and expands the CCPA. The CPRA creates obligations relating to consumer data beginning on January 1, 2022, with implementing regulations expected on or before July 1, 2022, and enforcement beginning July 1, 2023. The CPRA has created additional uncertainty and may increase our cost of compliance. Other states are beginning to pass similar laws.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in its contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Laws and regulations worldwide relating to privacy, data protection and cybersecurity are, and are likely to remain, uncertain for the foreseeable future. While we strive to comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity to the extent possible, we may at times fail to do so, or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel, collaborators, partners or vendors do not comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity. Actual or perceived failure to comply with any laws and regulations relating to privacy, data protection or cybersecurity in the U.S. or foreign jurisdictions could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect Our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators or service providers obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals’ privacy rights, failed to comply with applicable laws or regulations, or breached its contractual obligations, even if We are not found liable, could be expensive and time consuming to defend, result in regulatory actions and proceedings, in addition to private claims and litigation, and could result in adverse publicity that could harm our business.

We also are, or may be asserted to be, subject to the terms of our external and internal privacy and security policies, representations, certifications, publications and frameworks and contractual obligations to third parties related to privacy, data protection, information security and processing. Failure to comply with any of these, or if any of these policies or any of our representations, certifications, publications or frameworks are, in whole or part, found or perceived to be inaccurate, incomplete, deceptive, unfair, or misrepresentative of its actual practices, could result in reputational harm; result in litigation; cause a material adverse impact to business operations or financial results; and otherwise result in other material harm to our business.

We depend on sophisticated information technology systems and data processing to operate our business. If we experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, we may face costs, significant liabilities, harm to our brand and business disruption.

We rely on information technology systems and data processing that we or our service providers, collaborators, consultants, contractors or partners operate to collect, process, transmit and store electronic information in our day-to-day operations, including a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. Additionally, we, and our service providers, collaborators, consultants, contractors or partners, do or will collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other information to host or otherwise process some data and that of users, develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes. Our internal computer systems and data processing and those of our third-party vendors, consultants, collaborators, contractors or partners, including existing and future CROs may be vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, theft or destruction of intellectual property or other confidential or proprietary information, business interruption or other significant security incidents. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. In addition to traditional computer “hackers,” threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing), phishing and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). These risks may increase as a result of an increase in personnel working remotely.

There can be no assurance that we, our service providers, collaborators, consultants, contractors or partners will be successful in efforts to detect, prevent, or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data. Any failure by us or our service providers, collaborators, consultants, contractors or partners to detect, prevent, respond to or mitigate security breaches or improper access to, use of, or inappropriate disclosure of any of this information or other confidential or sensitive information, including patients' personal data, or the perception that any such failure has occurred, could result in claims, litigation, regulatory investigations and other proceedings, significant liability under state, federal and international law, and other financial, legal or reputational harm to us. Further, such failures or perceived failures could result in liability and a material disruption of our development programs and our business operations, which could lead to significant delays or setbacks in research, delays to commercialization of product candidates, lost revenues or other adverse consequences, any of which could have a material adverse effect on its business, results of operations, financial condition, prospects and cashflow. For example, the loss of clinical trial data from completed, ongoing, or future clinical trials could result in delays in our regulatory approval efforts and significantly increase costs to recover or reproduce the data.

Additionally, applicable laws and regulations relating to privacy, data protection or cybersecurity, external contractual commitments and internal privacy and security policies may require us to notify relevant stakeholders if there has been a security breach, including affected individuals, business partners and regulators. Such disclosures are costly, and the disclosures or any actual or alleged failure to comply with such requirements could lead to a materially adverse impact on the business, including negative publicity, a loss of confidences in our services or security measures by its business partners or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or other data protection obligations related to information security or security breaches.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research, development and manufacturing involves the use of hazardous materials and various chemicals. We maintain quantities of various flammable and toxic chemicals in its facilities that are required for research, development and manufacturing activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing, handling and disposing of these materials in its facilities comply with the relevant guidelines of the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover ourselves for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Although we have some environmental liability insurance covering certain facilities, we may not maintain adequate insurance for all environmental liability or toxic tort claims that may be asserted against us in connection with the storage or disposal of biological or hazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, natural disasters and other events on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom it conducts business, including contract manufacturers, CROs, shippers and others.

Health epidemics could cause significant disruption in our operations and the operations of third-party manufacturers, CROs and other third parties upon whom we rely.

If relationships with suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet desired clinical development and any future commercialization timelines. Although we carefully manage relationships with suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and future clinical trials may be affected by health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to concerns among patients about participating in clinical trials during health epidemics. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site

staff who, as healthcare providers, may experience additional restrictions by their institutions, city or state, preclinical studies and future clinical trial operations could be adversely impacted.

To the extent we enter into any other collaborations, we may depend on such collaborations for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

We may selectively seek additional third-party collaborators for the development and commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates, including our collaboration with BI, pose many risks to us, including that:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or products if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- A collaborator with marketing and distribution rights to one or more product candidates or products may not commit sufficient resources to the marketing and distribution of such drugs;
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

Collaborations are complex and time-consuming to negotiate and document*, *and if we fail to enter into new strategic relationships, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

If we decide to collaborate with any other third parties in connection with any of our development programs or product candidates, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development program or the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our technology and current or future product candidates, or if our intellectual property rights are inadequate, we may not be able to compete effectively.

Our success depends in part on our ability to obtain and maintain protection for our owned and in-licensed intellectual property rights and proprietary technology. We rely on patents and other forms of intellectual property rights, including in-licenses of intellectual property rights and biologic materials of others, to protect current or future discovery platform, product candidates, methods used to manufacture current or future product candidates, and methods for treating patients using current or future product candidates.

We own or in-license patents and patent applications relating to our discovery platform and product candidates. There is no guarantee that any patents covering our discovery platform or product candidates will issue from the patent applications we own or in-licenses, or,

if they do, that the issued claims will provide adequate protection for our discovery platform or product candidates, or any meaningful competitive advantage.

The patent prosecution process is expensive, complex and time-consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection. The patent applications that our own or in-licenses may fail to result in issued patents, and, even if they do issue as patents, such patents may not cover Our current or future technologies or product candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner.

Further, although we make reasonable efforts to ensure patentability of its inventions, we cannot guarantee that all of the potentially relevant prior art relating to our owned or in-licensed patents and patent applications has been found. For example, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our discovery platform, our product candidates, or the use of its technologies. We thus cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or patent applications, or that we or our licensors were the first to file for patent protection of such inventions. There is no assurance that all potentially relevant prior art relating to our owned or in-licensed patent applications has been found. For this reason, and because there is no guarantee that any prior art search is absolutely correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent or to prevent its owned or in-licensed patent applications from issuing as patents. Invalidation of any of our patent rights, including in-licensed patent rights, could materially harm our business.

Moreover, the patent positions of biopharmaceutical companies are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. As a result, the issuance, scope, validity, enforceability and commercial value of our pending patent rights is uncertain. The standards applied by the United States Patent and Trademark Office, or the USPTO, and foreign patent offices in granting patents are not always certain and moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or in-licensed patent applications or narrow the scope of any patent protection it may obtain from its owned or in-licensed patent applications.

Even if patents do successfully issue from our owned or in-licensed patent application, and even if such patents cover our current or any future technologies or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any current or future technologies or product candidates that it may develop. Likewise, if patent applications we own or have in-licensed with respect to our development programs and current or future technologies or product candidates fail to issue, if their breadth or strength is threatened, or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us to develop current or future technologies or product candidates. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain or any loss of patent protection could have a material adverse impact on our business and ability to achieve profitability. We may be unable to prevent competitors from entering the market with a product that is similar or identical to SZN-043, SZN-413 or any future product candidates.

The filing of a patent application or the issuance of a patent is not conclusive as to its ownership, inventorship, scope, patentability, validity or enforceability. Issued patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, our patent applications or patent applications filed by our licensors, or any patents that grant therefrom, may be challenged through third-party submissions, opposition or derivation proceedings. By further example, any issued patents that may result from our owned or in-licensed patent applications may be challenged through reexamination, inter partes review or post-grant review proceedings before the USPTO, or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our owned or in-licensed patent rights; result in the loss of exclusivity; limit our ability to stop others from using or commercializing similar or identical platforms and product candidates; allow third parties to compete directly with us without payment to us; or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength

of protection provided by any patents that might result from our owned or in-licensed patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future platforms or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, future owned and in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent application, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial condition.

Our in-licensed patent rights may be subject to a reservation of rights by one or more third parties, such as the U.S. government. In addition, our rights in such inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our licensors or collaborators. If any of our licensors or collaborators fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering Our product candidates, we could lose our rights to the intellectual property or exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing product candidates. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

In the future, we may enter into agreements involving licenses or collaborations that provide for access or sharing of intellectual property. If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future product candidates.

We currently license, and in the future may continue to license, from third parties' certain patents and other intellectual property relating to our current and future product candidates. We have certain obligations to our existing licensors, and may owe additional obligations in the future to any additional licensors. If we breach any material obligations, including diligence obligations with respect to development and commercialization of product candidates covered by the intellectual property licensed to us, or uses the licensed intellectual property in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed intellectual property or enable a competitor to gain access to the licensed intellectual property.

Disputes may arise between us and our present and future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patents and other rights to third parties, including the terms and conditions therefor;
- our diligence obligations with respect to the development and commercialization of our product candidates that are covered by the licensed intellectual property, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our licensors and us and our collaborators.

If disputes over intellectual property that our licenses in the future prevent or impair our ability to maintain its licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on its business.

In addition, certain of our future agreements with third parties may limit or delay its ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into

license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Further, we or our licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on its business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under license from third parties, it may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to it assuming control over patent prosecution.

Our technology acquired or licensed currently or in the future from various third parties is or may be subject to retained rights. Our predecessors or licensors do and may retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce its rights to licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, it may be unable to successfully develop, out-license, market and sell our product candidates, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies and licensed technology into commercial product candidates. Therefore, any limitations on its ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or product candidates or we could lose certain rights to grant sublicenses.

We are party to an exclusive license agreement with Stanford University covering patents relevant to one or more product candidates, and may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our current and future product candidates we may identify and pursue. The license agreements with Stanford impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. For a more detailed description of the license agreements with Stanford, see the section titled "*Business—Stanford License Agreements*." If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license. License termination could result in our inability to develop, manufacture and sell products that are covered by the licensed technology or could enable a competitor to gain access to the licensed technology. Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. In certain circumstances, our licensed patent rights are subject to reimbursing licensors for their patent prosecution and maintenance costs. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our licensed rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that is the subject of such licensed rights could be materially adversely affected.

Moreover, our current or future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that it is infringing, misappropriating or otherwise violating the licensor's intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of future royalty obligations will depend on the technology and intellectual property we use in products that it successfully develops and commercializes, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on Our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair its ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies or product candidates.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available. Even so, the life of a patent and the protection it affords are limited. As a result, our owned and in-licensed patent portfolio provide us with limited rights that may not last for a sufficient period of time to exclude others from commercializing product candidates similar or identical to us. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. For example, given the large amount of time required for the research, development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Extensions of patent term may be available, but there is no guarantee that we would have patents eligible for extension, or that we would succeed in obtaining any particular extension—and no guarantee any such extension would confer patent term for a sufficient period of time to exclude others from commercializing product candidates similar or identical to us. In the United States, depending upon the timing, duration and specifics of FDA marketing approval of product candidates, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved product or approved indication. In the United States, patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval; only one patent may be extended; and extension is available for only those claims covering the approved drug, a method for using it, or a method for manufacturing it. The applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to its patents, or may grant more limited extensions than we request. An extension may not be granted or may be limited where there is, for example, a failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply before expiration of relevant patents, or some other failure to satisfy applicable requirements. If this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and clinical trials along with our clinical and preclinical data. This could have a material adverse effect on our business and ability to achieve profitability.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current or any future technologies or product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States or elsewhere could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, which could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of any future owned or in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier.

A third party that files a patent application in the USPTO after March 16, 2013, but before we could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. The Leahy-Smith Act also allows third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to challenge the validity of a patent by the USPTO administered post grant proceedings, including derivation, reexamination, inter partes review, post-grant review and interference proceedings. The USPTO developed additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our issued, owned or in-licensed patents, all of which could have a material adverse impact on our business prospects and financial condition.

As referenced above, for example, courts in the U.S. continue to refine the heavily fact-and-circumstance-dependent jurisprudence defining the scope of patent protection available for therapeutics, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This creates uncertainty about our ability to obtain patents in the future and the value of such patents. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in the future and whether patent expiration dates will be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which significantly impacts European patents, including those granted before the introduction of the system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC had the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents under the jurisdiction of the UPC are potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of these changes.

Other companies or organizations may challenge our or our licensors' patent rights, which could require significant time and attention of our management, require costs to defend, and could have a material and adverse impact on our profitability, financial condition, and prospects.

Third parties may attempt to invalidate our or our licensors' intellectual property rights via procedures including but not limited to patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO, U.S. courts, and foreign patent offices or foreign courts. Even if such rights are not directly challenged, disputes could lead to the weakening of our or our licensors' intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management, and could have a material and adverse impact on our profitability, financial condition and prospects or ability to successfully compete.

We or our licensors may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our owned or in-licensed patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to our owned or in-licensed patent or other intellectual property rights, even if resolved in our favor, could be substantial, and any litigation or other proceeding would divert our management's attention. Such litigation or proceedings could materially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Some of our competitors may be able to more effectively sustain the costs of complex patent litigation because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations. Furthermore, because of the substantial amount of discovery required in connection with certain such proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim

proceedings or developments and if securities analysts or investors perceive these results to be negative, such announcements could have a material adverse effect on the price of our common stock.

If we or our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, claiming patent-ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non-enablement, anticipation or obviousness. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our product candidates or certain aspects of our platform technology. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our product candidates and technologies if competitors or third parties design around such product candidates and technologies without legally infringing, misappropriating or violating our owned or in-licensed patents or other intellectual property rights.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents on current or future technologies or product candidates in all countries throughout the world would be prohibitively expensive. Competitors or other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and, further, may export infringing product candidates to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These product candidates may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of any owned and in-licensed patents we may obtain in other countries, or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our owned or in-licensed intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. Such proceedings could also put any owned or in-licensed patents at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against our or out licensors. We or our licensors may not prevail in any lawsuits or other adversarial proceedings that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, we and our licensors' efforts to enforce such intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-licenses.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of its patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business prospects may be materially adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of our potential future collaborators to develop, manufacture, market and sell our current or any future product candidates and to use our proprietary technologies without infringing, misappropriating or violating the proprietary and intellectual property rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO, U.S. courts, foreign patent offices or foreign courts. As the field of antibody-based therapeutics matures, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, there is uncertainty as to when, to whom, and with what claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;

- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in its competitors gaining access to the same technology.

Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. Because patent applications can take many years to issue, there may also be currently pending patent applications that may later result in issued patents that our technology or product candidates may infringe. Further, we cannot guarantee that we are aware of all of patents and patent applications potentially relevant to our technology or products. We may not be aware of potentially relevant third-party patents or applications for several reasons. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until a patent issues. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or platform technologies could have been filed by others without its knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover its platform, our product candidates or the use of our technologies.

Although no third party has asserted a claim of patent infringement against us as of the date hereof, others may hold proprietary rights that could prevent our product candidates from being marketed. We or our licensors, or any future strategic collaborator, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current or any potential future product candidates and technologies, including derivation, reexamination, inter partes review, post-grant review or interference proceedings before the USPTO and similar proceedings in jurisdictions outside of the United States such as opposition proceedings. In some instances, we may be required to indemnify its licensors for the costs associated with any such adversarial proceedings or litigation. Third parties may assert infringement claims against us, our licensors or our strategic collaborators based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic collaborators to enforce or otherwise assert their patent rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a material adverse impact on our ability to utilize our discovery platform or to commercialize our current or any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity by presenting clear and convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence we believe to be clear and convincing, would invalidate the claims of any such U.S. patent.

Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we, or our licensors, or any future strategic collaborators are found to infringe, misappropriate or violate a third-party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney's fees, if we are found to have willfully infringed. In addition, we, or our licensors, or any future strategic collaborators may choose to seek, or be required to seek, a license from a third party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block its ability to further develop and commercialize our current or future product candidates. We could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing our discovery platform or product candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Thus, it is possible that one or more third parties will hold patent rights to which we will need a license, which may not be available on reasonable terms or at all. If such third parties refuse to grant us a license to such patent rights on reasonable terms or at all, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing our product candidates, or to develop or license replacement technology, all of which may not be commercially or technically feasible. In such case, we may not be able to market such technology or product candidates and may not be able to perform research and development

or other activities covered by these patents. This could have a material adverse effect on our ability to commercialize our product candidates and our business and financial condition.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or product candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or product candidates, which may not be available on commercially reasonable terms or at all.

Because the antibody landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing, misappropriating or violating third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering antibodies generally or covering portions of antibodies that may be relevant for product candidates that we wish to develop. We are aware of third party patents and patent applications that claim aspects of our current or potential future product candidates and modifications that we may need to apply to our current or potential future product candidates. In particular, we are aware of pending patent applications that could result in patents that cover aspects of the SZN-043 product candidate. There are also many issued patents that claim antibodies or portions of antibodies that may be relevant to products we wish to develop. The holders of such patents and patent applications may be able to block or delay our ability to develop and commercialize the applicable product candidate, including SZN-043, unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our current or future technologies product candidates or elements thereof or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies, product candidates unless we successfully pursue litigation to narrow or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or product candidates. If such an infringement claim should successfully be brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or product candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders may also actively bring infringement, misappropriation, or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or product candidates that are held to be infringing, misappropriating or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or product candidates so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on its financial condition and results of operations.

If, in the future, we develop trade secrets and are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our current or future technologies and product candidates, we may in the future consider trade secrets, including confidential and unpatented know-how, to be important to the maintenance of its competitive position. However, trade secrets and know-how can be difficult to protect. If we develop trade secrets, we plan to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as its employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they are obligated to maintain confidentiality and to assign their inventions to it. However, we cannot be certain that such agreements have been entered into with all relevant parties, and

cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Moreover, individuals with whom we have such agreements may not comply with their terms. Any of these parties may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breaches. We may also become involved in inventorship disputes relating to inventions and patents developed by our employees or consultants under such agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret, or securing title to an employee- or consultant-developed invention if a dispute arises, is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions disfavor or are unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using the technology or information to compete with it. If, in the future, any of our trade secrets were to be disclosed to or independently developed by a competitor, its competitive position would be materially and adversely harmed.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

Many of our employees or consultants and our licensors' employees or consultants were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that one or more of these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of former employers. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights or personnel or may be enjoined from using such intellectual property. Any such proceedings and possible aftermath would likely divert significant resources from its core business, including distracting our technical and management personnel from their normal responsibilities. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent it from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against any such claims, litigation or arbitration could result in substantial costs and could be a distraction to management.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes that arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that We may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow it to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, it may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on its business, financial condition, results of operations, and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and in-licensed patents or applications and any patent rights it may own or in-license in the future. The USPTO and various non-U.S. patent offices require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help it comply with these requirements, and we are also dependent

on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical product candidates or platforms, which could have a material adverse effect on our business prospects and financial condition.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Intellectual property rights we have licensed were generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if we determine that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fails to disclose the invention to the government and fails to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we use for name recognition by potential collaborators or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, it may not be able to compete effectively and our business may be materially adversely affected.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect its business. The following examples are illustrative:

- others may be able to make antibodies or portions of antibodies or formulations that are similar to our product candidates, but that are not covered by the claims of any patents that we own, license or control;
- we or any strategic collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own license or control;
- we or our licensors might not have been the first to file patent applications covering certain of our owned and in-licensed inventions;
- others may independently develop the same, similar, or alternative technologies without infringing, misappropriating or violating our owned or in-licensed intellectual property rights;
- it is possible that our owned or in-licensed pending patent applications will not lead to issued patents;
- issued patents that we own, in-licenses, or controls may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, including as a result of legal challenges;

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such trade secrets or know-how; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse impact on our business and financial condition.

Risks Related to Government Regulation

Clinical development includes a lengthy and expensive process with an uncertain outcome, we may have negative results and results of earlier studies and trials may not be predictive of future trial results.

Our product candidate SZN-043 has begun clinical development and its risk of failure is high. It is impossible to predict when or if our candidates or any potential future product candidates will prove effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety, purity, and potency, or efficacy of that product candidate in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain, particularly in light of recent observations relating to clinical trial for SZN-043. Failure can occur at any time during the development process. The results of preclinical studies and clinical trials of any of our current or potential future product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials. We initiated first-in-human trials of SZN-043 in the second quarter of 2022. We have experienced (as described above), and may further experience, delays in initiating our planned clinical studies. We do not know whether planned clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, will enroll patients on time or be completed on schedule, if at all. Our development programs may be delayed for a variety of reasons, including delays related to:

- unfavorable findings or observations that cause us to pause or modify our clinical trial;
- the FDA or other regulatory authorities requiring additional data or imposing other requirements before permitting initiation of a clinical trial;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB or ethics committee, or EC, approval at each clinical trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of our product candidates for use in clinical trials.
- Furthermore, we expect to rely on CROs, collaborators such as BI and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we may have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of current or potential future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of any of our current or potential future product candidates, the commercial prospects of such

product candidate will be harmed, and our ability to generate product revenue from such product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our current or potential future product candidates.

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, be unable to commercialize SZN-043, SZN-413 or potential future product candidates.

SZN-043, SZN-413 and any potential future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our potential future collaborators to begin selling them.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and other regulatory authorities. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in regulatory policy during the period of product development, clinical trials and FDA regulatory review in the United States and other jurisdictions. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are seeking approval. Further, we and our potential future collaborators may never receive approval to market and commercialize any product candidate. Even if we or a potential future collaborator obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as it intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or a potential future collaborator may be subject to post-marketing testing requirements to maintain regulatory approval. If any of our product candidates prove to be ineffective, unsafe or commercially unviable, we may have to re-engineer the product candidates, and our entire pipeline could have little, if any, value, which could require us to change our focus and approach to drug discovery and therapeutic development, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We will also be subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

If we succeed in developing any products, we intend to market them in the United States as well as the European Union and other foreign jurisdictions. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that it will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fails to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced, and our ability to realize the full market potential of our product candidates will be harmed.

We have conducted our clinical trial for our product candidate outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case its development plans will be delayed, which could materially harm its business.

We have conducted and may further conduct clinical trials for our product candidate outside the United States. For example, we have conducted the Phase 1 trial of SZN-043 in New Zealand. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless (i) those data are applicable to the U.S. population and U.S. medical practice; (ii) the studies were performed by clinical investigators of recognized competence; and (iii) the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. For studies that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comments on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of Our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction or permanently halt our development of our product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Even if we receive regulatory approval for any of our current or potential future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or potential future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our current or potential future collaborators obtain for SZN-043, SZN-413 or any potential future product candidate may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including "Phase 4" clinical trials, and surveillance to monitor the safety and efficacy of such product candidate. In addition, if the FDA or any other regulatory authority approves SZN-043, SZN-413 or any of our future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for such product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practices for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product candidate, withdrawal of the product candidate from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic collaborators;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Furthermore, the FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians may prescribe, in their independent professional medical judgment, products for off-label uses as the FDA does not regulate the behavior of physicians in their choice of drug treatments, the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Companies may only share truthful and non-misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory authorities have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. Among the provisions of the ACA, of greatest importance to the pharmaceutical and biotechnology industry are increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been legal and political challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any additional future challenges or the healthcare reform measures of the Biden administration will impact the ACA and our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This

includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and will remain in effect through 2032, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 among other things, reduced Medicare payments to several providers, including hospitals and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. Additionally, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In addition, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug pricing negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. It is unclear whether this executive order or similar policy initiatives will be implemented in the future.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures.

If we or our existing or potential future collaborators, manufacturers or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates and may harm our reputation.

Healthcare providers, physicians and third-party payors, among others, will play a primary role in the prescription and recommendation of any product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers and customers, among others, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which it obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations in the United States and other countries, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, a person or entity from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order, arranging for or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, a violation of the Anti-Kickback Statute can form the basis for a violation of the federal False Claims Act (discussed below);

- federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which provides for civil whistleblower or qui tam actions, that impose penalties against individuals or entities for knowingly

presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a referral made in violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates and covered subcontractors that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act” under the Affordable Care Act, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests of such physicians and their immediate family members; and

- analogous local, state and foreign laws and regulations, such as state anti-kickback and false claims laws that may apply to healthcare items or services reimbursed by third party payors, including private insurers; local, state and foreign transparency laws that require manufacturers to report information related to payments and transfers of value to other healthcare providers and healthcare entities, marketing expenditures, or drug pricing; state laws that require pharmaceutical companies to register certain employees engaged in marketing activities in the location and comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare reporting, privacy, data protection, cybersecurity and other laws and regulations could involve substantial costs. If our operations are found to be in violation of any such requirements, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, individual imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause it to incur significant legal expenses and could divert its management’s attention from the operation of its business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm its business.

Even if we receive marketing and commercialization approval of a product candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after a product is made commercially available, both in the United States and any foreign jurisdiction in which it seeks regulatory approval. The FDA and other regulatory authorities have significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product candidate from the market. The FDA and other regulatory authorities also have the authority to require a Risk

Evaluation and Mitigation Strategy, or a REMS, after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product candidate, manufacturer or facility, including withdrawal of the product candidate from the market. We intend to rely on third-party manufacturers and will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or any of our existing or future collaborators, manufacturers or service providers fails to comply with applicable continuing regulatory requirements in the U.S. or foreign jurisdictions in which we seek to market our products, it or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private health insurers and health maintenance organizations. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost.

Cost-containment is a priority in the U.S. healthcare industry and elsewhere. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product. Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the U.S. can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that it commercializes and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which it obtains marketing approval.

Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay its commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues it is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup its investment in one or more product candidates, even if our product candidates obtain regulatory approval. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm its business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, its employees, representatives, contractors, collaborators, and agents, even if it does not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new product candidates and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact its business.

The ability of the FDA to review and approve new product candidates can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on its business.

Risks Related to Ownership of Our Shares

Our stock price may be volatile and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including the other risks described in this section of the Report titled "*Risk Factors*" and the following:

- our ability, or the ability of our business partners, to advance SZN-043, SZN-413 or potential future product candidates into the clinic;
- results of preclinical and clinical studies for SZN-043, SZN-413 or potential future product candidates, or those of our competitors or current and potential future collaborators;
- the impact of health epidemic on our business;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our future products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization collaborators, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory authorities with respect to our future products, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including, but not limited to, those with our sources of manufacturing supply and our commercialization collaborators;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic alliances, joint ventures or capital commitments;

- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, public health crises and other calamities; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Because our management will have flexibility in allocating our cash, you may not agree with how we use our cash and it may not be invested successfully.

We currently expect to use our current cash to fund the development of SZN-043 through the continuation of first in human trials and to fund our other ongoing research and discovery programs, as well as for working capital and other general corporate purposes. We may also use a portion of our cash to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, other than our CLA with BI, we have no current commitments or obligations to do so. Therefore, our management will have flexibility in allocating our cash. Accordingly, you will be relying on the judgment of our management with regard to the allocation of our cash, and you will not have the opportunity, as part of your investment decision, to assess whether the cash is being allocated appropriately. It is possible that the cash will be invested in a way that does not yield a favorable, or any, return for our company.

We may issue additional shares of common stock or other equity securities without your approval, including pursuant to our employee stock plans, our agreement with Lincoln Park and our agreement with Guggenheim, and holders of warrants and options may choose to exercise their warrants and options requiring us to issue shares of common stock; all of these actions would dilute your ownership interest and may depress the market price of our common stock.

Significant additional capital will be needed in the future to continue our planned operations, including further development of our Wnt therapeutics platform, preparing IND or equivalent filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

In April 2024, we entered into a securities purchase agreement with certain institutional investors and management and issued and sold in a private placement: (i) 1,091,981 shares of common stock, (ii) pre-funded warrants to purchase up to 40,000 shares of common stock, and (iii) warrants to purchase up to 11,136,106 shares of common stock. A significant portion of these warrants may only be exercised in the event we meet certain clinical development milestones, which include patient enrollment. If we achieve these milestones and the warrants are exercised, it will result in significant dilution to our stockholders. In the alternative, we may not achieve these milestones,

in which event we will be required to seek alternative sources of financing to continue the clinical development of our product candidates. Please see Notes 9, 10 and 11 to the unaudited condensed consolidated financial statements for further information regarding the private placement and the terms of the warrants. In addition, outstanding options may be exercised and restricted stock units may vest resulting in the issuance of additional shares of common stock, which will result in further dilution to our stockholders.

We may also issue additional shares of common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances. The issuance of additional shares or other equity securities of equal or senior rank would have the following effects:

- existing stockholders' proportionate ownership interest in us will decrease;
- the amount of cash available per share, including for payment of dividends in the future, may decrease;
- the relative voting strength of each previously outstanding common stock may be diminished; and
- the market price of the common stock may decline.

A few stockholders, including one of our former directors, control the voting rights with respect to a large number of shares of our common stock and could exercise their voting power in a manner that adversely affects us or our stockholders.

As of September 30, 2024, The Column Group (managed by one of our former directors, Tim Kutzkey, Ph.D.) holds approximately 25% of our common stock and can significantly influence any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. Dr. Kutzkey resigned from our board of directors and all committees of the board of directors on which he served, effective as of June 30, 2024.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders, which our company is not obligated to call more than once per calendar year, be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, or DGCL, our certificate of incorporation or our bylaws;
- claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws;
- any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers or other employees that is governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court and certain other state courts have ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If any other court of competent jurisdiction were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our certificate of incorporation and bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, the bylaws and our indemnification agreements that we entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we will be required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

- we will not be obligated pursuant to our bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in the bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

We qualify as an emerging growth company as well as a smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting companies, this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We qualify as an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of our common stock that is held by non-affiliates equals or exceeds $700 million as of the end of that year's second fiscal quarter, (ii) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more during such fiscal year (as indexed for inflation), (iii) the date on which we have issued more than $1 billion in non-convertible debt in the prior three-year period or (iv) December 31, 2025. Investors may find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to opt out of such extended transition period and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

Additionally, we qualify as a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds $250 million as of the end of that year's second fiscal quarter, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates equals or exceeds $700 million as of the end of that year's second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

We may amend the terms of the public warrants in a manner that may be adverse to holders with the approval by the holders of at least 50% of the then-outstanding public warrants. As a result, the exercise price of your public warrants could be increased, the exercise period could be shortened and the number of shares of our common stock purchasable upon exercise of a public warrant could be decreased, all without your approval.

Our public warrants are issued in registered form under an amended and restated warrant agreement by and between Continental Stock Transfer & Trust Company, as the warrant agent, and us, dated as of March 31, 2023, or the Warrant Agreement. The Warrant Agreement provides that the terms of the public warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 50% of the then-outstanding public warrants to make any change that adversely affects the interests of the registered holders of public warrants. Accordingly, we may amend the terms of the public warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding public warrants approve of such amendment. Although our ability to amend the terms of the public warrants with the consent of at least 50% of the then-outstanding public warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the public warrants, convert the public warrants into cash or stock (at a ratio different than initially provided), shorten the exercise period or decrease the number of shares of our common stock purchasable upon exercise of a public warrant.

We may redeem unexpired public warrants prior to their exercise at a time that is disadvantageous to holders, thereby making such public warrants worthless.

We have the ability to redeem outstanding public warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per public warrant, provided that the last reported sales price of our common stock equals or exceeds $270 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date on which we give proper notice of such redemption and provided certain other conditions are met. If and when the public warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding public warrants could force you (a) to exercise your public warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (b) to sell your public warrants at the then-current market price when you might otherwise wish to hold your public warrants or (c) to accept the nominal redemption price which, at the time the outstanding public warrants are called for redemption, is likely to be substantially less than the market value of your public warrants.

In addition, we may redeem public warrants after they become exercisable for a number of shares of common stock determined based on the redemption date and the fair market value of our common stock. Any such redemption may have similar consequences to a cash redemption described above. In addition, such redemption may occur at a time when the public warrants are “out-of-the-money,” in which case, holders of public warrants would lose any potential embedded value from a subsequent increase in the value of our common stock had the public warrants remained outstanding.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

During the nine months ended September 30, 2024, none of our directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any “non-Rule 10b5-1 trading arrangement” as such term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Certificate of Incorporation of Surrozen, Inc.	8-K	001-39635	3.1	8/17/2021	
3.2	Amended and Restated Bylaws of Surrozen, Inc.	8-K	001-39635	3.1	10/13/2023	
3.3	Certificate of Amendment to Certificate of Incorporation of Surrozen, Inc.	8-K	001-39635	3.1	12/13/2023	
4.1	Specimen Warrant Certificate	S-1/A	001-39635	4.3	10/13/2020	
4.2	Amended and Restated Warrant Agreement, dated as of March 31, 2023, between Surrozen, Inc. and Continental Stock Transfer & Trust Company	10-K	001-39635	4.6	3/31/2023	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SURROZEN, INC.

Date: November 6, 2024

By: /s/ Craig Parker
Craig Parker
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2024

By: /s/ Charles Williams
Charles Williams
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Craig Parker, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Surrozen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2024

By: /s/ Craig Parker

Craig Parker
President and Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles Williams, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Surrozen, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2024

By: /s/ Charles Williams
Charles Williams
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Surrozen, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Craig Parker, President and Chief Executive Officer and Director of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 6, 2024

By: /s/ Craig Parker

Craig Parker
President and Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Surrozen, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Charles Williams, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 6, 2024

By: /s/ Charles Williams
Charles Williams
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)