UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of voting stock held by non-affiliates of the Registrant on June 30, 2024, based on the closing price of $10.95 for shares of the Registrant's common stock as reported on the Nasdaq Capital Market, was approximately $25.8 million. Shares of common stock beneficially owned by each executive officer, director, and holder of more than 10% of our common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's common stock outstanding as of March 25, 2025 was 3,281,169.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this Annual Report on Form 10-K for the year ended December 31, 2024, or the Annual 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 Annual 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-413, SZN-8141, SZN-8143, SZN-113 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 Annual 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 Annual Report.

This Annual Report contains references to trademarks, trade names and service marks belonging to other entities. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business.

Overview

We are a biotechnology company committed to discovering and developing drug candidates to selectively modulate the Wnt pathway, a critical mediator of tissue repair with a current focus in ophthalmology. We are located in South San Francisco, California.

Our mission is to transform the treatment of serious disease by fully exploiting the Wnt pathway. 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 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 multiple product candidates. We believe that ophthalmology indications are particularly well-suited for Wnt modulating therapeutics.

SZN-8141 for Retinal Diseases

In the third quarter of 2024, we nominated SZN-8141 as a development candidate which combines Frizzled 4, or Fzd4, agonism and Vascular Endothelial Growth Factor, or VEGF, antagonism. SZN-8141 has the potential to provide benefits over treatment with single agents for Diabetic Macular Edema, or DME, and neovascular Age-Related Macular Degeneration, or wet AMD. 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, Fzd4 monotherapy has demonstrated proof of concept in DME in clinical trials. We believe SZN-8141 has the potential to treat multiple retinopathy indications and be differentiated from existing therapies. Data generated in preclinical models of retinopathy demonstrated that SZN-8141 stimulated Wnt signaling and induced normal retinal vessel regrowth while suppressing pathological vessel growth.

SZN-8143 for Retinal Diseases

In the third quarter of 2024, we nominated SZN-8143 as a development candidate which combines Fzd4 agonism, VEGF antagonism, and interleukin-6, or IL-6, antagonism. SZN-8143 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, Fzd4 monotherapy has demonstrated proof of concept in these indications in clinical trials. We believe SZN-8143 has the potential to treat multiple retinopathy indications and be differentiated from existing therapies. Data generated in preclinical models of retinopathy demonstrated that SZN-8143 stimulated Wnt signaling and induced normal retinal vessel regrowth while suppressing pathological vessel growth.

SZN-113 for Fuchs' Endothelial Corneal Dystrophy and Geographic Atrophy

SZN-113 targets Fzd127 and is in development 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.

SZN-413 for Retinal Diseases

In the first quarter of 2022, we nominated SZN-413, a Fzd4, targeted bi-specific antibody, as a development candidate for the treatment of retinal vascular associated diseases. 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 the ability to induce normal retinal vessel regrowth while suppressing pathological vessel growth. In October 2022, we executed a Collaboration and License 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.

SZN-043

In the first quarter of 2025, we discontinued development of SZN-043 in severe alcohol associated hepatitis. While in clinical trials, treatment with SZN-043 was safe and well-tolerated and demonstrated positive changes in liver function assays, there was not a sufficient early signal of clinical benefit to warrant further investment given the challenges associated with an acutely ill target population and a lengthy clinical development path.

Fundamental Importance of the Wnt Pathway and Our Founders' Roles in Its Discovery

The Wnt pathway holds significant therapeutic promise in view of its ability to regulate stem cell renewal, proliferation and differentiation, and its central role in tissue regeneration. Over the past 30 years our founders and advisors have helped establish the fundamental importance of the Wnt pathway in tissue regeneration. Each has been on the forefront of the Wnt signaling pathway research, and their discoveries are the foundation of our approach to therapeutic development.

Wnt proteins exert a wide variety of effects on target cells during development. Fundamentally, Wnts are growth stimulatory factors that promote cell proliferation. Compared to other growth factors, two distinctive aspects of Wnt proteins are their lack of specificity and their ability to give shape to growing tissues while inducing cells to proliferate, acting in the process as directional growth factors. Wnt signals can instruct new cells in such a way that organized body plans are generated. Moreover, Wnt proteins employ a number of receptor isoforms and sub-families, generating an array of combinatorial Wnt signaling critical for correctly shaping tissues during development, maintaining tissue architecture in adult life and repairing tissue injury.

Dr. Roel Nusse and Dr. Harold Varmus discovered the first Wnt gene in 1982. Wnt signaling has now been shown to be critical to many essential normal functions. Dr. Nusse is a founder of our company and a member of our Scientific Advisory Board.

Past Limitations in Targeting the Wnt Pathway for Drug Discovery

Although modulation of Wnt signaling has held significant promise for decades, a number of characteristics of Wnt signaling have created obstacles to conventional protein therapeutic approaches. The key obstacles to drug development targeting the Wnt signaling pathway are described below:

Potent Pathway Activation: While the activity of naturally occurring Wnt pathway agonists is well established, previous attempts to engineer synthetic Wnt ligands have not resulted in selective, potent activation of Wnt signaling.

Selectivity: Naturally occurring Wnt ligands are not selective in their interactions. Moreover, components of the Wnt signaling pathway, which can be targeted with small molecules, are widely expressed and therefore cannot be selectively targeted.

Manufacturing: Wnt ligands are highly hydrophobic, making them difficult to express, solubilize and purify and therefore difficult to manufacture.

Our Wnt Therapeutics Platform

Our Scientific Capabilities

We believe that our breakthrough discoveries and technologies will enable us to overcome the challenges facing drug developers targeting the Wnt pathway. We believe we are potentially the first developer to manufacture synthetic, soluble Wnt mimetics. To date, we have developed potent, selective and manufacturable Wnt mimetics that are designed to replicate the role of naturally occurring Wnt proteins. In pursuit of our goal to develop a portfolio of Wnt product candidates that can repair tissue damage and regenerate functional tissues for patients, we are continuing to expand our platform through the development of novel technologies and capabilities required to research, develop, manufacture and ultimately commercialize therapeutic products that address unmet medical needs. Our core capabilities are described below:

Wnt Biology Expertise: We have established a deep understanding of the Wnt pathway and its role in disease biology and have invested significantly in our people and technologies that enable us to selectively modulate Wnt signaling. Our research and

development organization is led by world-class scientists. We have partnered with key thought leaders in the field, including those on our Scientific Advisory Board, and have developed significant expertise in various areas of biology relevant to the Wnt signaling pathway.

Proprietary Antibody Discovery and Research Technologies: We have developed proprietary antibody discovery capabilities that have led to the discovery of antibody technologies that enable us to potently and selectively modulate the Wnt pathway. Our SWAP (Surrozen Wnt signal Activating Protein) technology enables the design and development of Wnt-mimetics. Importantly, our approach provides a flexible and robust platform that has generated multiple antibodies that possess either tissue or cell selectivity based on preclinical studies.

Additional Novel Wnt Modulating Technologies: We have developed and filed patent applications for additional Wnt modulating antibody technologies, and are committed to continuously integrating new insights, tools, technologies and capabilities to apply to additional diseases and areas.

Genetic Mapping of Wnt Signaling: The role of Wnt signaling in disease and the differential expression of genes involved in Wnt signaling have not been well characterized across many disease states. We isolate RNA for gene expression to identify potential deficiencies in Wnt signaling in specific diseases. Through our genetic mapping, we have increased our understanding of Wnt biology in numerous diseases and Wnts' involvement in diseases that had previously not been well-characterized.

Protein Science Capabilities: We have invested in building capabilities in key areas of antibody discovery which include: *in vitro* and *in vivo* binder discovery, antibody optimization including humanization, structural biology, cell line construction, upstream and downstream process development and purification, bioanalytical characterization, developability assessments including stability and formulatability. These capabilities enable discovery of novel structures and sequences and optimization for pharmacokinetics, potency, selectivity, manufacturability and other drug-like properties.

Our Scientific Approach

By combining our Wnt biology expertise with our proprietary technologies and capabilities, we have been able to establish a broad array of therapeutic opportunities. Our approach includes:

Identifying and characterizing areas where Wnt biology is critical to tissue structure and function. To date, we have investigated the importance of Wnt signaling in over 20 different tissue types and have prioritized multiple tissue types for further exploration, with a plan to continue to expand our efforts.

Prioritizing disease opportunities where there is significant evidence based on our proprietary model systems and tool compounds that Wnt activation could play a role in tissue repair in severe disease.

Focusing efforts and investments in diseases where the strength of our capabilities can potentially address key limitations of existing therapeutic approaches.

Seeking to limit or eliminate the potential oncogenic risk from Wnt pathway activation through our selective activation in the target disease tissue, we focus on severe disease, limited treatment exposure, and mimicking a physiologic repair process that is self-limiting. In preclinical studies, we have observed that the predominant response to Wnt signaling is in diseased tissue.

Our Platform

Our proprietary platform, SWAPs, enables us to potently and selectively modulate Wnt signaling through the generation of Wnt mimetics. Using this technology, we design and develop antibodies that modulate Wnt signaling. Product candidates generated by these technologies have demonstrated the ability to repair tissue damage in multiple preclinical models. We have developed specific candidate molecules for each disease area based on the associated tissue biology, the role of Wnt signaling in disease versus normal tissue, and a functional assessment of our candidate molecules.

Wnt Activation: SWAP (Surrozen Wnt signal Activating Protein)

Our SWAP molecules are designed to mimic the activity of naturally occurring Wnt proteins. They are bispecific full-length human (IgG) antibodies that, like Wnt proteins, directly activate the Wnt-signaling pathway in target tissue by binding to two of its natural co-receptors, Fzd and Lrp. With our SWAP technology, we combine Fzd and Lrp antibody-binding domains into bispecific antibodies to selectively activate Wnt signaling. We have generated and validated a broad library of SWAPs that have successfully activated Wnt-signaling. Our product candidate, SZN-413, utilizes our SWAP technology and is designed to activate the Wnt pathway in injured tissue where certain Fzd receptors are expressed and the natural Wnt ligand is disturbed.

Key characteristics of our SWAP technology include:

Potency: Our Wnt mimetics are multivalent, designed to bind one or more Fzd receptors and one or more Lrp receptors. We demonstrated that the ability to bind to one or more receptors leads to highly potent Wnt signal activation as compared to a protein that can only bind to one Lrp receptor and one Fzd receptor.

Selectivity: Our antibody-based proteins are capable of selective binding to individual Fzd and Lrp receptor isoforms and selective isoform binding has the potential to confer tissue selectivity.

Manufacturability: Our antibody platform is designed to produce molecules with properties suitable for manufacturing and to overcome the challenges of Wnt protein derivates. Unlike our antibodies, Wnt proteins are highly hydrophobic, making them difficult to express, solubilize and purify.

Dr. Christopher Garcia, a Howard Hughes Medical Institute Investigator and one of our founders, enabled our SWAP approach through the discovery of surrogate Wnt agonists. His surrogate ligands were water soluble, consisted of two domains and provided the building blocks for our SWAP technology.

Subsequent discoveries made at Surrozen improved the potency and selectivity of the surrogate ligands discovered by Dr. Garcia. Our technology allows for targeting of Fzd and Lrp receptors, and we believe we can identify an optimized ratio of Fzds and Lrps required to activate Wnt signaling. We have also discovered that binding two different Fzds together with Lrp leads to efficient Wnt signal activation. Figure 1 below compares natural Wnt signaling to how our SWAP product candidates engage receptors on the cell surface to trigger Wnt signal activation.

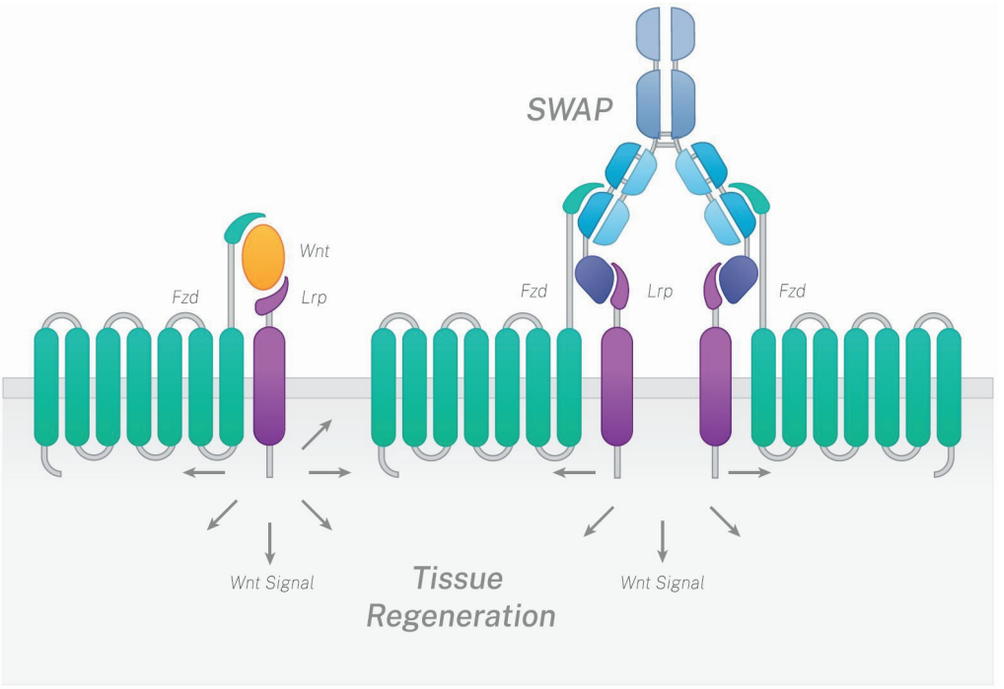


Figure 1. Like endogenous Wnt (left side), our SWAP technology activates Wnt signaling by binding specific Fzd and Lrp receptors (right side)

Our Product Candidates and Research Programs

We believe that our platform has the potential to generate a portfolio of product candidates that can harness the tissue repair activity of the Wnt pathway for a broad spectrum of severe eye diseases.

The chart below represents a summary of our product candidates:

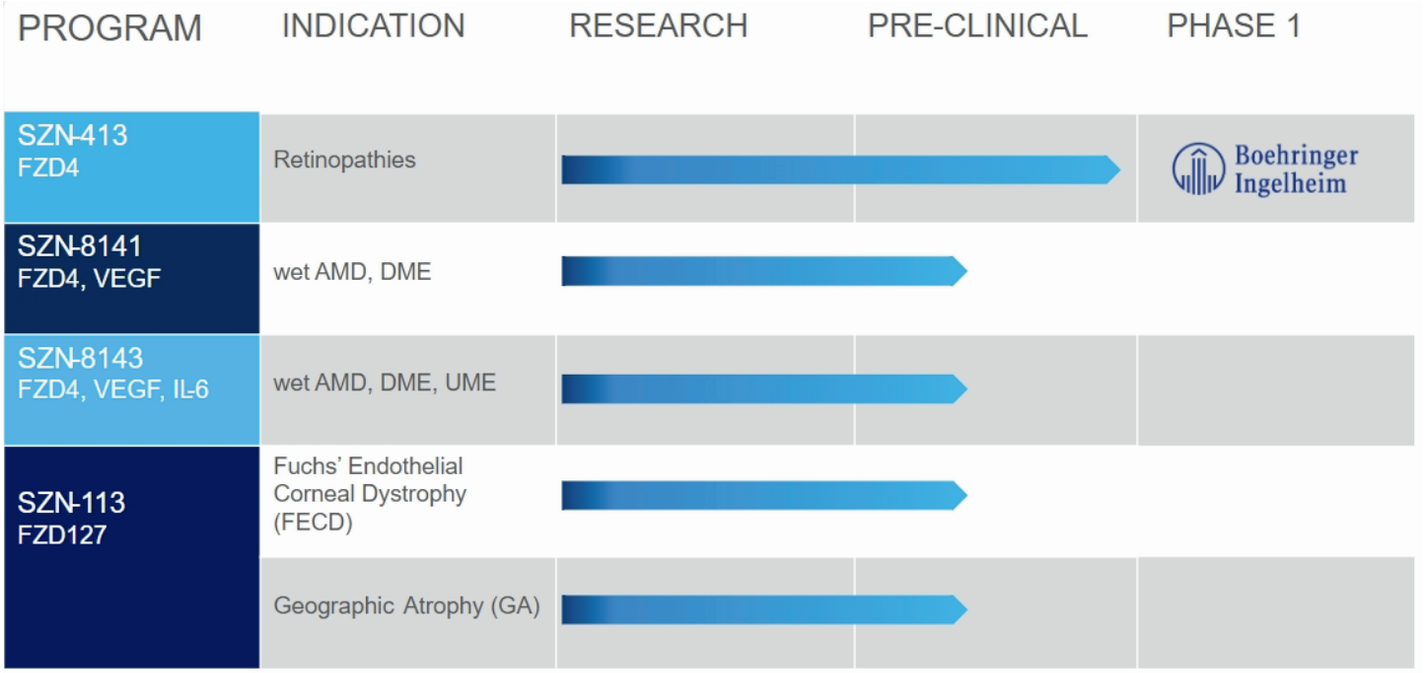


Figure 3. Lead programs

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 License 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. Please see "*Collaboration and Licensing Arrangements"* 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 anti-IL-6 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 an 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.

Our Strategy

Our strategy is to develop a portfolio of product candidates that can repair tissue damage and regenerate functional tissues for a variety of diseases. Consistent throughout our strategy is our goal to activate Wnt signaling only within targeted diseased tissue, focusing on severe diseases, and mimicking the self-limiting physiologic repair process. We plan to achieve this goal by:

- ***Continuing to build on our pioneering research, insights and intellectual property in Wnt pathway modulation.*** Our scientific capabilities and approaches are built upon the groundbreaking work of our academic co-founders and have been developed further by our experienced team. We consider ourselves to be pioneers in the selective modulation of the Wnt signaling pathway and intend to utilize our proprietary insights into Wnt biology and our proprietary technologies to further advance our research and exploration of its therapeutic potential.

- ***Developing novel product candidates and expanding our platform technologies focused in ophthalmology to further our leading position in developing the Wnt signaling pathway modulators.*** Wnt signaling is critical in tissue regeneration throughout the body, including in the eye, intestine, liver, lung, retina, kidney, cochlea, cornea, skin, pancreas and central nervous system. Our research suggests that SWAP will provide us with the opportunity to generate specific modulators of Wnt signaling. We have generated libraries of Wnt receptor binders that have helped us create a broad portfolio of product candidates. We have developed and filed patent applications for additional Wnt modulating antibody technologies and are committed to continuously applying new insights, tools, technologies and capabilities to additional diseases and areas and adding to our platform technologies and pipeline.

- ***Pursuing strategic alliances to maximize the full potential of our pipeline.*** The importance of the Wnt signaling pathway and the potential therapeutic applications of Wnt pathway mimetics are expected to provide us with an abundance of product candidates. We believe this generates an exciting opportunity to enter into strategic alliances to accelerate product development and maximize commercial potential. In October 2022, we executed the CLA with BI to research, develop and commercialize Fzd4 bi-specific antibodies designed using our SWAP technology, including SZN-413.

Wnt Signaling Pathway—A Central Regulator of Tissue Regeneration

As gatekeepers for the maintenance of stem cells and functions, prior attempts at modulating Wnt signaling were hampered by an absence of drug-like properties. Through our technologies, we can modulate Wnt signaling with antibodies, which could open the door for the development of a new classes of drugs with the ability to repair and regenerate damaged tissues.

Signaling through the Wnt pathway can stimulate cell proliferation as well as control cell differentiation and movement. Cell-to-cell communication is needed during embryonic development, and Wnt signaling is essential for development to proceed properly. In both embryonic stem cells and pluripotent stem cells, the Wnt pathway has a dual role in both promoting stem cell renewal and differentiation of certain cell types. In adults, Wnt has a critical role in promoting proliferation and stem cell renewal in multiple tissues. Maintenance of the intestinal surface or epithelium homeostasis, for example, is dependent on Wnt signaling. Wnt signaling is also important for bone formation, retina development and function, liver regeneration and renewal of cells in the lung and pancreas among other tissues.

We believe that several characteristics of the Wnt signaling pathway make this pathway attractive for drug development:

- ***Broad potential for therapeutic intervention***. Signaling through the Wnt pathway is critical in cell fate determination in tissues throughout the body. Aberrant Wnt signaling underlies a broad range of pathologies in humans. In some cases, such as in certain rare bone diseases, mutations in the Wnt signaling pathway are the cause of the disease. Mutations in Wnt signal pathway components are also associated with retina vessel disorders such as Norrie disease and familial exudative vitreoretinopathy, or FEVR, tooth development disorders, and metabolic diseases including diabetes. Preclinical model studies have shown that Wnt signaling is instrumental for liver regeneration, intestine epithelium turnover and injury repair, and plays

a role in maintaining residential stem cells in many more adult tissues including lung, kidney, cochlea, skin and the central nervous system.

- ***Common activation mechanism across Wnt proteins.*** There are 19 Wnt protein genes in the human genome and the genomes of other mammals. Most Wnt proteins bind interchangeably to the 10 different Fzd receptors with little discrimination. Genetic knockouts in mice have shown that individual Wnt protein genes have distinct functions. The differences in biological functions likely arise from discrete localized expression and the relative insolubility of Wnt proteins which limits migration from the site of synthesis. On the other hand, when it comes to biochemical signaling, the different Wnt proteins have very similar activities upon target cells. This, in turn, implies that the same therapeutic approach could be used to address multiple diseases.

- ***Multiple modulators of activity.*** Multiple modulators of the Wnt signaling pathway have been identified that activate, amplify, dampen or inhibit the pathway's activity and limit the potential consequences of either over-activation or inhibition of Wnt signaling. These modulators can serve both as direct targets for therapeutic intervention and as examples of how novel therapeutics could be developed that mimic their action.

The low solubility of Wnt proteins due to the required fatty acid modification limits the ability of natural Wnt proteins themselves to be developed as therapeutic agents. The lack of solubility of Wnt proteins makes them difficult to purify; difficult to formulate into an easily administered drug; and difficult to deliver to various tissues in the body. In contrast, we have developed technologies enabling us to develop activators and amplifiers of Wnt signaling which avoid the low solubility of natural Wnt proteins. These technologies trigger the Wnt pathway to act in a transient manner by mimicking the binding of Wnt proteins and other regulators of the pathway. Our goal is to use our technologies to develop therapeutics that can modulate the naturally occurring Wnt response and promote healing.

Our Wnt Therapeutics Platform

We have discovered proprietary technologies of modulators of Wnt signaling: SWAPs. We have designed and continue to design antibodies that modulate the Wnt signaling pathway by acting as mimetics of the Wnt protein. Product candidates generated by our technologies have demonstrated the ability to repair tissue damage in multiple preclinical retinal disease models. We were able to select a specific candidate molecule and technology for each disease area based on tissue biology, profile of Wnt signaling in disease versus normal, and functional test of molecules. We have multiple ophthalmology candidates in preclinical development.

Wnt Activation: SWAP

The Wnt pathway is equipped with binding sites for two receptors found on the surface of cells that can be triggered by Wnt protein. Binding to just one of these two receptors does not cause activation of the Wnt pathway. But when Wnt protein simultaneously binds to both receptors, this pair of interactions activates several intracellular signaling pathways, as can be seen in Figure 4 below. The two Wnt receptors are called frizzled, or Fzd, and low-density lipoprotein receptor-related protein 5 or 6, or Lrp 5/6. Fzd is an integral membrane protein that binds to Wnt protein, in part, through the fatty acid posttranslational modification on the Wnt protein. The second receptor,

Lrp 5/6, contains an intracellular domain that is chemically modified by Wnt-protein-induced receptor dimerization to initiate the Wnt signaling pathway cascade in cells.

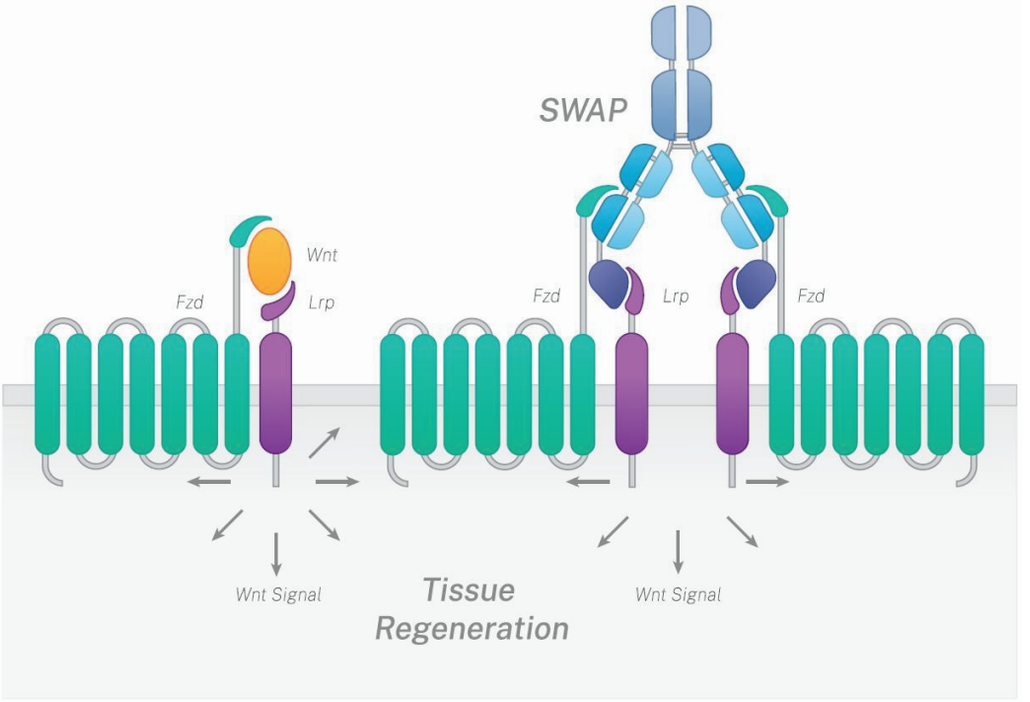


Figure 4. Like endogenous Wnt (left side), our SWAP technology activates Wnt signaling by binding specific Fzd and Lrp receptors (right side)

Published work by Dr. Christopher Garcia, one of our founders and Scientific Advisory Board members, showed that Wnt signaling could be induced by identifying non-Wnt proteins capable of selectively binding to Fzd and Lrp and linking these binding domains together. These non-Wnt proteins led to an activation of Wnt signaling that in many ways was indistinguishable from that induced by Wnt itself. Furthermore, these non-Wnt proteins were soluble and did not require posttranslational modification with fatty acid for activity. These observations revealed the opportunity to develop Wnt-mimetic therapeutics freed from the burden of containing a fatty acid, which decreases their solubility. There was no apparent restriction on the type of interacting domains that could be used to create these molecules. Several categories of molecules, including domains from natural proteins, artificial protein binding domains, and antibodies were all found to be able to function as binding domains for Fzd or Lrp.

We have focused our efforts on developing antibody-binding domains that independently bind to Fzd and to Lrp. Antibody-binding domains provide a potential advantage over other binding domains due to the ability to identify domains with high potency and with high specificity, in addition to the maturing manufacturing process. We have identified antibody-binding domains capable of distinguishing individual Fzd family members, providing an opportunity to selectively activate Wnt signaling in cells expressing specific Fzd receptors—a property that naturally occurring Wnt proteins do not have.

In our SWAP technology, we created multivalent bispecific antibodies that bring together two different sets of antibody-binding domains—one set that binds to Fzd and another set that binds to Lrp. We found that certain recombinant proteins containing these two antibody-binding domains were able to simultaneously bind both Fzd and Lrp, however, inducing the simple bimolecular interaction of one Fzd and one Lrp was, in most cases, insufficient to induce Wnt signaling, as can be observed in Figure 5.

In Figure 5 below, in an assay measuring protein concentration (x-axis) against Wnt pathway activation (as measured by relative light units, or RLU, y-axis), we have demonstrated that a simple bivalent antibody containing a single Fzd binding domain (F1) (the blue

line) and a single Lrp binding domain (L2) (the red line) did not significantly induce the Wnt signaling pathway. At similar concentrations, naturally-occurring Wnt (Wnt3a) (the green line) demonstrated pathway activation.

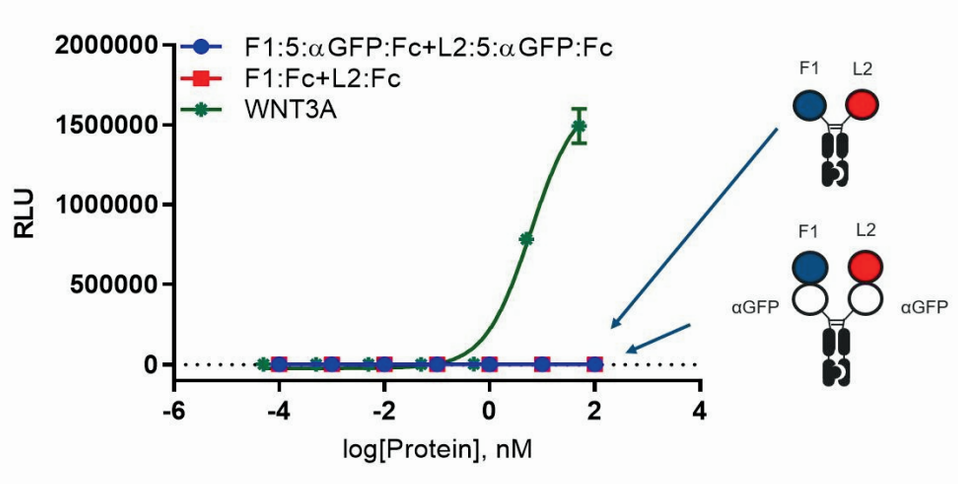


Figure 5. A simple bivalent antibody containing a single Fzd binding domain (F1) and a single Lrp binding domain (L2) did not significantly induce the Wnt signaling pathway. At similar concentrations, naturally-occurring Wnt (Wnt3a) demonstrated pathway activation.

However, multivalent antibodies that contained multiple binding domains, either two Fzd-binding domains with one Lrp binding domain (the blue line in Figure 6 below) or two of each binding domain (the light green line), led to activation of the Wnt signaling pathway at concentrations that were 100 times or lower than required for activation by Wnt3a (the dark green line), as can be observed in Figure 6. For comparison, an antibody with a single Fzd binding domain (the red line) did not demonstrate significant activity.

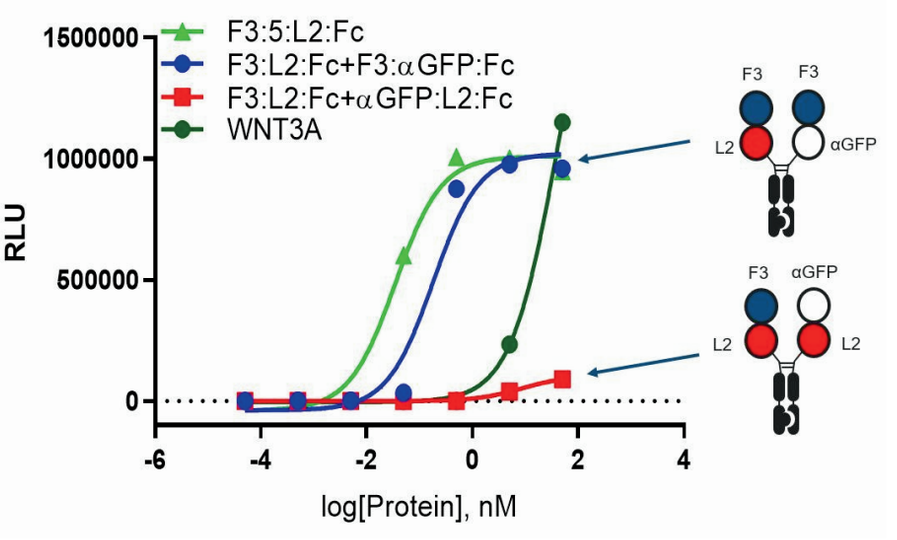


Figure 6. Multivalent antibodies with two Fzd binding domains (F3) and at least one Lrp binding domain (L2) led to more potent activation of the Wnt signaling pathway.

We are developing a series of product candidates based on the SWAP technology, which combines binding domains for specific Fzd receptors and binding domains for specific Lrp receptors. Our current SWAP product candidate, SZN-413, is for the treatment of retinal vascular associated diseases. In addition, we are developing other product candidates for the potential treatment of ocular diseases.

We plan to address multiple serious diseases of the eye (retinopathies) with a novel approach to restoring tissues that may complement or replace existing treatments:

- Neovascular or “Wet” Age-Related Macular Degeneration (Wet AMD)

- Dry Age-Related Macular Degeneration (Dry AMD) or Geographic Atrophy (GA)
- Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)
- Uveitic Macular Edema (UME)

AMD is the progressive degradation of the part of the eye responsible for visual acuity, causing a loss of central vision. AMD is the leading cause of blindness in individuals who are over 65 years old. As the chances of experiencing any form of AMD increase with age, treatment of this disease is becoming even more important as life expectancy continues to rise in most regions of the world.

In the normal functioning eye, the retinal pigment epithelium, or RPE, helps to transport nutrients to the photoreceptors while also helping to eliminate lipids, proteins, and other cellular waste products. Over time, the RPE becomes less efficient in its ability to degrade and remove these wastes, causing them to build up in the Bruch's membrane rather than being transported to the capillaries within the choroid. The build-up of lipids and proteins forms yellow deposits referred to as drusen, a hallmark of early and intermediate AMD. The hardness, size, and number of drusen can help determine the level of disease progression.

As patients with intermediate AMD progress to the advanced or late stage, the disease can take on two forms: dry AMD (also known as geographic atrophy or non-exudative AMD), or wet AMD (also known as exudative AMD or neovascular AMD).

In advanced dry AMD, there is a reduction in the number of functioning photoreceptors and the gradual loss of visual acuity. Dry AMD, with a US prevalence of over 15 million sufferers, accounts for around 90% of AMD cases and can progress to wet AMD. GA is an advanced form of dry AMD with an estimated US prevalence of 1.3 million. GA is a slowly progressive disease that involves degeneration of the retinal pigment epithelial layer of cells below the retina, which affects the health of rod and cone photoreceptor cells. Other than vitamin supplementation, there have not been any treatments for GA/Dry AMD up until recently. Complement inhibitors were approved in 2023 based on their ability to slow the decline of GA through inhibition of the complement cascade, however, these therapies have seen slow adoption by ophthalmologists due to their modest effect on vision decline, frequent IVT injections and potential for rare, but significant side effects. Importantly, physicians regularly cite the need for more effective, safer medications for Dry AMD/GA.

Approximately 10% of all AMD patients will experience a more drastic vision loss as their condition progresses to wet AMD. In wet AMD, vessels grow abnormally within the choroid layer, called choroidal neovascularization, or CNV, and penetrate through the Bruch's membrane, or in some cases even further through the RPE into the subretinal space. These newly formed vessels are highly permeable and leak blood and fluid as they penetrate through the layers of the retina. This leads to the thickening of the retina and the misalignment of photoreceptors, causing blurred or distorted vision. An increase in disease prevalence will contribute to market growth. Analysts at Datamonitor estimate that in 2023, there were 2.7 million total prevalent cases of wet AMD in adults aged 50 years and older in the US, Japan, and five major European markets (France, Germany, Italy, Spain, and the UK) and this market is forecasted to continue to increase. Due to their ability to improve clinical outcomes and treat a more comprehensive patient population, VEGF inhibitors, or "anti-VEGFs", have become the standard treatment used in wet AMD. With newer agents utilizing a combination of mechanisms, further improvements in the standard of care have occurred. However, unmet medical need still exists as anti-VEGF medications have limitations in terms of duration of efficacy and the need for frequent dosing in this large ($10B US in 2024) global market in wet AMD and Diabetic Retinopathies.

Diabetic retinopathy is a microvascular complication of diabetes and is a major cause of vision loss and disability in the middle-aged population. In the US, the prevalence of DR is almost 10 million people. The pathogenesis of DR leads to vascular leakage, which causes diabetic macular edema, and capillary occlusion causing retinal ischemia. The longer a person has Type-1 or Type-2 diabetes, the more likely they are to develop DME. DME is a complication of DR, characterized by fluid buildup in the macula resulting in vision loss if untreated. DME occurs in approximately 15% of patients with DR, or almost 1.4 million people in the US. There remains a significant opportunity to improve on current treatment approaches.

UME is a serious complication of uveitis, an inflammatory condition affecting the uvea (the middle layer of the eye). In the U.S., estimates range widely from 80,000 to 168,000 cases of uveitis each year. It is estimated that up to 30% of all uveitis patients may develop macular edema, or UME.

UME manifests as fluid accumulation in the macula, the central part of the retina responsible for sharp, detailed vision. This leads to significant vision loss, impacting patients' quality of life and creating a substantial burden on healthcare systems. The main treatment

for UME is steroid medications which can work well at controlling inflammation and preventing fluid build-up. However, steroids can cause serious side effects affecting the eyes and general health, particularly in children, and their long-term use is not recommended. Anti-VEGF therapies are also used in UME but show only modest efficacy. Inflammatory markers, like IL-6 and VEGF, are elevated in UME patients, so targeted therapies that can address these multiple aspects of UME are being tested.

Our Solution

Surrozen is developing SZN-8141 that combines Fzd4 agonism and VEGF antagonism which has the potential to provide benefits over treatment with single agents for DME and wet AMD. 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, Fzd4 monotherapy has demonstrated proof of concept in clinical trials. We believe SZN-8141 has the potential to treat multiple retinopathy indications and be differentiated from existing therapies. Data generated in preclinical models of retinopathy demonstrated that SZN-8141 stimulated Wnt signaling and induced normal retinal vessel regrowth while suppressing pathological vessel growth and reduce vascular leakage.

Surrozen is developing SZN-8143 that combines Fzd4 agonism, VEGF antagonism, and interleukin-6 (IL-6) antagonism which may have benefits over single agents for treatment of DME/wet AMD/uveitic macular edema (UME). 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, Fzd4 monotherapy has demonstrated proof-of-concept in clinical trials. We believe SZN-8143 has the potential to treat multiple retinopathy indications and be differentiated from existing therapies. Data generated in preclinical models of retinopathy demonstrated that SZN-8143 stimulated Wnt signaling and induced normal retinal vessel regrowth while suppressing pathological vessel growth.

Surrozen is developing SZN-113 which targets Fzd127 for FECD and 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.

Intellectual Property

We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in our field and other fields that are or may be important for the development of our business. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and our product candidates that are important to the development and implementation of our business.

Collaboration and Licensing Arrangements

Collaboration and License Agreement with Boehringer Ingelheim International GmbH

In October 2022, we executed the CLA with BI to research, develop and commercialize Fzd4 bi-specific antibodies designed using our SWAP technology, including SZN-413. We and BI conducted partnership research focused on SZN-413 during a 1.5-year period. We granted BI an exclusive, royalty-bearing, worldwide, sublicensable license, under our 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. For five years after the effective date of the CLA, we are prohibited from preclinically and clinically developing or commercializing Fzd4 bi-specific antibodies that have certain properties for any diseases of the eye, and BI is prohibited from clinically developing or commercializing licensed products for any purpose other than diseases of the eye. 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 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.

Stanford License Agreements

In March 2016, we entered into a license agreement with Stanford University, or the Stanford Agreement, which was amended in July 2016, October 2016 and January 2021, pursuant to which we obtained a worldwide, exclusive, sublicensable license under certain patents, rights, or licensed patents and technology related to our 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 Stanford Agreement covers two patent families and any patents that grant from these families are predicted to expire in 2035 and 2037, absent any patent term adjustments or extensions. In consideration for this license, we paid Stanford a nominal upfront fee and issued nominal shares of our common stock to Stanford, the University of Washington and two co-inventors of the licensed patents. In addition, we agreed to pay Stanford nominal annual license maintenance fees which are creditable against earned royalties owed to Stanford for the same year, an aggregate of up to $0.9 million for the achievement of specified development and regulatory milestones, and an aggregate of up to $5.0 million for the achievement of specified sales milestones. Stanford is also entitled to receive royalties from us equal to a very low single digit percentage of our and our sublicensees' net sales of licensed products that are covered by a valid claim of a licensed patent. Our obligation to pay royalties will continue, on a country-by-country basis, until the last-to-expire valid claim of a licensed patent covering a licensed product in the country of manufacture or sale. Additionally, we agreed to pay Stanford a sub-teen double digit percentage of certain consideration we receive as a result of granting sublicenses to the licensed patents. However, we and Stanford may be able to negotiate a lower non-royalty sublicense percentage based on the then-current value of the licensed patents for each sublicense product. If we are acquired, we agreed to pay a one-time change of control fee in the low six figures. Stanford retains the right under the 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.

Under the Stanford Agreement, we agreed to use commercially reasonable efforts to develop and commercialize licensed products and we agreed to achieve certain funding and development milestones by certain dates. Unless earlier terminated, Stanford Agreement will continue until the expiration of the patents licensed under such Stanford Agreement. We may terminate Stanford Agreement at any time for any reason by providing at least 30 days' written notice to Stanford. Stanford may terminate Stanford Agreement if we breach certain provisions and fail to remedy such breach within 90 days after written notice of the breach by Stanford.

Research Collaboration Agreement with TCGFB, Inc.

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 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 agreed to 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 and is controlled by entities affiliated with The Column Group. The agreement constitutes a related party transaction because entities affiliated with The Column Group hold more than 5% of our common stock and Dr. Kutzkey, a member of our board of directors, serves as Managing Partner of The Column Group.

Patents and Other Proprietary Rights

As of December 31, 2024, our patent portfolio consisted of over 20 pending patent application families, including 18 families that have entered national phase in the United States and/or other countries, three families with pending Patent Cooperation Treaty, or PCT, applications, and three families with pending U.S. provisional applications. These patent applications are directed to, for example, the SWAP platform, the out-licensed SZN-413, as well as methods of treating disorders of the liver, intestine, retina, cornea, lacrimal gland, lung and kidney.

SWAP Platform Technology

As of December 31, 2024, we solely own or exclusively license 15 patent families related to our SWAP platform. These patent families are directed to compositions of matter and/or methods of use, and relate to Wnt mimetics that bind to both a FZD receptor and an LRP receptor, and binding domains and uses thereof. Any patents that issue from these patent families are predicted to expire between 2035 and 2044 absent any patent term adjustment or extension.

We have exclusively licensed two patent families from The Board of Trustees of the Leland Stanford Junior University, or Stanford, related to our SWAP platform. One patent family has been granted in Australia, Europe, Japan and the United States and is pending in the United States and Canada, and any patents that grant from this patent family are predicted to expire in 2035 absent any patent term adjustment or extension. The other patent family is pending in the United States, and any patents that grant from this patent family are predicted to expire in 2037 absent any patent term adjustment or extension.

The actual term of any patent that may issue from the above-described patent applications claiming one of our product candidates could be longer than described above due to patent term adjustment or patent term extension, if available, or shorter if we are required to file terminal disclaimers. The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we may rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses, or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future product candidates may have an adverse impact on us. If third parties have prepared and filed patent applications prior to March 16, 2013 in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention. For more information, please see the section titled "*Risk Factors—Risks Related to Our Intellectual Property*."

Competition

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. 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 successfully commercialized, it is likely that we will face increased competition as a result of other companies pursuing development of products to address similar diseases.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of retinal diseases for which we have product candidates. Certain of our competitors have commercially approved products for the treatment of retinal diseases that we are pursuing or may pursue in the future, including Roche, Regeneron and Novartis for the treatment of wet AMD, DME, DR and retinal vein occlusion. For Dry AMD/ Geographic Atrophy, Apellis and Astellas have commercially approved products. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to educate these parties on the benefits of switching to any product candidates developed by us. Companies are developing and/or commercializing therapeutics in the retinal disease area include large companies with significant financial resources, such as Roche, Novartis, Bayer and Regeneron, AbbVie, Boehringer Ingelheim, Amgen, and Samsung Bioepis. In addition to competition from other companies targeting retinal indications, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies and drug delivery devices.

Merck's Restoret (gained through its acquisition of EyeBio), an investigational tri-specific Wnt agonist antibody, is in a Phase 2/3 clinical trial in patients with treatment-naïve diabetic macular edema and treatment-naïve neovascular age-related macular degeneration. Recently acquired by Roche, AntlerA Therapeutics was a preclinical stage company developing Wnt antibody-like molecules (ANTs) that activate specific Fzd receptor complexes and are designed to control tissue stem cells and promote tissue repair and rejuvenation. To our knowledge, neither Merck nor Roche has announced any development stage Wnt agonist compounds in retinal diseases.

For additional information on the competitive risks we face, please see the section of this Annual Report titled "*Risk Factors—Risks Related to Our Business—We face competition from entities that have developed or may develop product candidates for the treatment of the diseases that we may target...*"

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological products, such as our product candidates and any future product candidates. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Regulatory Approval in the United States

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or PHSA, and other federal, state, local and foreign statutes and regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with the FDA's Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;

- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice, or GCP, requirements and other clinical trial-related regulations to establish the safety, purity and potency of the product candidate for each proposed indication;
- preparation and submission to the FDA of a biologics license application, or BLA, after completion of all clinical trials;
- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with current cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical Studies

Before testing any biological product candidates in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted.

If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well- designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

For purposes of BLA submission and approval, clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the safety, dosage tolerance, absorption, metabolism and distribution of the product candidate in humans, the side effects associated with increasing doses, and, if possible, early evidence of effectiveness.

- Phase 2 clinical trials generally involve studies conducted in a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide statistically significant evidence of clinical efficacy of the product for its intended use, further evaluate its safety and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic.

The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biologic does not undergo unacceptable deterioration over their shelf life.

FDA Review Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

The cost of preparing and submitting a BLA is substantial. Under the Prescription Drug User Fee Act, or PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

The FDA reviews a submitted BLA to determine if it is substantially complete before the FDA accepts it for filing and may request additional information from the sponsor. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. In this event, the BLA must be resubmitted with any additional information requested. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Under the goals agreed to by the FDA under the PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether such facilities comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety, purity, and potency of the product candidate. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally considers such recommendations carefully when making decisions on approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product is produced, it will issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for FDA to reconsider the application. If a CRL is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may require a REMS to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure a product's safe use, or ETASU. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Among the benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and where preclinical or clinical data demonstrate the potential to address unmet medical needs for the disease condition. Fast track designation applies to combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that

the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Breakthrough therapy designation may be granted for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner. The designation also includes all of the fast track program features, including eligibility for rolling review of BLA submissions if the relevant criteria are met.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA generally does not apply to any biological product for an indication for which orphan designation has been granted. PREA applies to BLAs for orphan-designated biologics if the biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that FDA has determined is substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any exclusivity—patent or non-patent—for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Once a BLA is approved, a product will be subject to certain additional post-approval requirements.

The FDA also may require post-marketing testing, known as Phase 4 testing, may impose a REMS and/or post-market surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Manufacturers are subject to periodic unannounced inspections by the FDA, including those focused on manufacturing facilities to assess compliance with cGMPs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

Under the BPCIA an application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

International Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products.

Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws and Regulations and Legislative Reform

Healthcare Laws and Regulations

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with healthcare providers, physicians, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Our current and future operations are subject to regulation by various federal, state, and local authorities in addition to the FDA, including but not limited to CMS, HHS (including the Office of Inspector General, Office for Civil Rights and the Health Resources and Services Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and

require strict compliance in order to offer protection. Additionally, 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;

- Federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Drug manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- The Health Insurance Portability and Accountability Act, or HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry 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 Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and covered subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- Federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- The federal transparency requirements under the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;

- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

- State and foreign laws that are analogous to each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers, and state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and

- State and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state laws that require the posting of information relating to clinical trials and their outcomes; and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

If our operations are found to be in violation of any of these laws or any other current or future healthcare laws that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our 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 us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Legislative Reform

We operate in a highly regulated industry, and new laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the Affordable Care Act, which included changes to the coverage and reimbursement of drug products under government healthcare programs. Among other things, the Affordable Care Act, among other things, 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 amendments to and executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in the Affordable Care Act 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 through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. Moreover, any significant spending reductions affecting Medicare, Medicaid or other publicly

funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, the IRA, among other things, directs HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare, or the Medicare Drug Price Negotiation Program, 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" under the law, and (ii) imposes rebates under Medicare Part B and 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. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions took effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical 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 healthcare 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 healthcare programs. Further, it is possible that additional governmental action is taken in response to health epidemics. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the recent change in administration.

Environmental Regulations

We are subject to various environmental laws of federal, state and local governments and foreign governments at various levels. We believe we are compliant in all material respects with applicable environmental laws. Compliance with existing laws has not had a material effect on capital expenditures, financial condition, or our competitive position with respect to any of our operations. However, we cannot predict the impact of unforeseen environmental contingencies or new or changed laws or regulations on our business.

Employees and Human Capital Resources

Our Employees

As of March 3, 2025, we had 40 full-time and 1 part-time employees, with 26 in research and development and 15 in general and administrative functions. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we have not experienced any work stoppages. We consider our relationship with our employees to be good.

We believe our total compensation package helps us attract and retain our employees. We offer our employees flexible benefits to meet the individual health and wellness needs of our employees, including competitive pay, equity grants, medical benefits, leave programs, and a 401(k) savings plan.

Our human capital objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Strategic Talent and Culture Vision

We are committed to being a great place to work for enterprising pioneers. We embody these shared values or principles in our work and daily interactions: collaborate, lead, innovate, motivate, and be brave, open and nurturing. These core principles are incorporated in all our people practices including hiring, performance management, and career development. We strive to foster an environment for our employees where:

- we bravely explore and innovate together, with passion for the work and honesty towards each other;
- flexibility in skills, resilience, and adaptability to change are valued;
- we recognize that everyone makes a difference;
- the workplace is fun, supportive and rewarding; and
- patients are at the heart of what we do.

We know how much culture matters to the quality of our work experience, so we are committed to do all we can to strengthen our culture. Our inclusive and pioneering culture creates a sense of belonging, impact, adventure and fun. Our values are not just words on the wall.

Leadership is something that we promote at all levels, encouraging employees to expand their comfort zones through team adventures and enthusiastically celebrate our accomplishments together. Through Surrozen Leadership Academy, we provide training to all employees on various leadership topics that support the long-term growth of the organization.

Employee Engagement

Our engagement strategy focuses on creating a workplace that is reflective of our core values.
We believe that strong employee engagement helps enable higher retention and better business performance.

Employee feedback is gathered through regular conversations with our employees, managers, and through engagement surveys. Feedback informs and shapes our future employee-focused initiatives. Feedback has been incorporated into changes in our compensation, benefits, employee development programs and other culture programs.

Employee Wellness and Safety

It is our goal to provide a safe and healthy workplace for all employees and to eliminate occupational injuries and illnesses. To be successful, the program requires cooperation in all safety and health matters, not only between supervisors and employees, but also between individual employees and their coworkers. It is the obligation of every employee to comply with the requirements of our Injury and Illness Prevention Program at all times. We provide information to employees about workplace safety and health issues through bulletin board postings, memos, training, and online or other written communications. All employees and managers complete workplace harassment and sexual harassment training that includes details on how to report any violation of these policies.

We have taken caution and adhered to local safety guidelines with regard to respiratory viruses (COVID-19, flu and RSV). Policies and practices are in place to ensure the safety of employees within the office, including increasing cleaning procedures, encouraging employees who are able to work from home to do so and implementing mask mandates, social distancing, and additional safety measures as appropriate. We require all U.S. employees to be vaccinated and boosted. For any employee who contracts a virus, we provide sick leave for any affected employee at 100% of their salary or average hourly wages.

In general, we support a flexible workforce. We offer a variety of work arrangements including remote working, hybrid (virtual and on-site) and completely on-site.

Code of Conduct

We are committed to maintaining the highest standards of business conduct and ethics. Our Code of Business Conduct and Ethics reflects the business practices and principles of behavior that support this commitment. We expect every employee, officer and director to read and understand our Code of Business Conduct and Ethics and its application to the performance of his or her business responsibilities.

Corporate Information

Our principal executive offices are located at 171 Oyster Point Blvd., Suite 400, South San Francisco, California 94080 and our telephone number is (650) 489-9000. Our corporate website address is www.surrozen.com. The contents of our website is not incorporated by reference into this Annual Report or in any other report or document we file with the SEC, and any references to our website is intended to be inactive textual references only.

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, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report, including our consolidated financial statements and related notes included elsewhere in this Annual Report and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," 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 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 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 future clinical 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 historically have and may in the future conduct clinical trials 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 our development plans will be delayed, which could materially harm our business.
- 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.

Risks Related to Our Business

We are a 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 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 product candidates advance into 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 development for our lead product candidates, 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.

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 our 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, and our lead product candidates and we will require significant funds to continue to develop our platform 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. Given the volatility in the capital markets, we may not be willing or able to raise equity capital through public or private equity offerings and may 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-413, SZN-8141, SZN-8143, SZN-113 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 develop, or to enter into any collaborations for, our lead 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.

Our 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 our product candidates do not possess certain properties that we believe are beneficial for therapeutic effectiveness and safety. For example, although our lead product candidates 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 our 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-413, SZN-8141, SZN-8143, SZN-113 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.

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, 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 our product candidates 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 in our preclinical toxicology studies and clinical trials, 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 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 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 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. 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. 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 our lead 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 our lead 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-413, SZN-8141, SZN-8143 and SZN-113, 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 retinal vascular associated diseases that our lead product candidates 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-413, SZN-8141, SZN-8143 or SZN-113.

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 our lead product candidates, 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.

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, 2024, we had NOLs of approximately $160.5 million and $5.0 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 $156.8 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 and April 2024. As a result of the annual limitations caused by the ownership changes, it was estimated that approximately $2.6 million of federal tax credit, $8.8 million of federal NOL and $76.5 million of California NOL will expire unutilized for income tax purposes, and such amounts are excluded from the carryforward balances of December 31, 2024. 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.

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 historically have and may in the future conduct clinical trials 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 our 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 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 are 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).

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 confidence 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-413, SZN-8141, SZN-8143, SZN-113 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. 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 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.

Risk of failure for our lead product candidates 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. 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 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-413, SZN-8141, SZN-8143, SZN-113 or potential future product candidates.

SZN-413, SZN-8141, SZN-8143, SZN-113 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.

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 our 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 any of our 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 amendments to and legal and political challenges to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed 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 second Trump 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. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken.

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 biologics that have been on the market for at least 11 years 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, or the Medicare Drug Price Negotiation Program, 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 took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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 our product candidates into the clinic;
- results of preclinical and clinical studies for our 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 existing cash to fund the development of our lead product candidates 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, 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 and March 2025, we issued and sold shares of common stock, pre-funded warrants and warrants to purchase common stock in private placements. Please see Notes 9, 10, 11 and 17 to the consolidated financial statements for further information regarding the private placements and the terms of the warrants. In addition, outstanding options and warrants 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 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 December 31, 2024, and after taking into account our March 2025 private placement, entities affiliated with The Column Group (of which a member of our board of directors, Tim Kutzkey, Ph.D., is a Managing Partner) beneficially owned approximately 21.7% 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.

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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property and confidential information that is proprietary, strategic or competitive in nature. To protect our information systems from cybersecurity threats, we use various security tools that help prevent, identify, escalate, investigate, resolve and recover from identified vulnerabilities and security incidents in a timely manner. These include, but are not limited to, internal reporting and monitoring and detection tools to allow security researchers to assist us in identifying vulnerabilities in our environment before they are exploited by malicious threat actors. We also maintain a third-party security program to identify, prioritize, assess, mitigate and remediate third party risks; however, we rely on the third parties we use to implement security programs commensurate with their risk, and we cannot ensure in all circumstances that their efforts will be successful. We regularly assess risks from cybersecurity and technology threats and monitor our information systems for potential vulnerabilities. We identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and our risk profile using various methods including, for example, using manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and threat actors, conducting scans of the threat environment, evaluating our industry's risk profile, utilizing internal and external audits, and conducting threat and vulnerability assessments. Depending on the environment, we implement and maintain various processes, standards, and/or policies designed to manage and mitigate material risks from

cybersecurity threats to our information system and data, including risk assessments, incident detection and response, vulnerability management, disaster recovery and business continuity plans, internal controls within our accounting and financial reporting functions, encryption of data, network security controls, access controls, physical security, asset management, systems monitoring, vendor risk management program, employee training, and penetration testing.

We work with third-party service providers from time to time that assist us to identify, assess, and manage cybersecurity risks, including professional services firms, consulting firms, threat intelligence service providers, and penetration testing firms. We seek to engage reliable, reputable service providers that maintain cybersecurity programs. We are not aware of any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, which have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. Refer to Item 1A "*Risk Factors*" in this Annual Report on Form 10-K for additional discussion about cybersecurity-related risks.

Governance

Cybersecurity is an important part of our risk management processes and an area of focus for our Board and management. Our audit committee is responsible for the oversight of risks from cybersecurity threats. Members of our audit committee receive updates on a quarterly basis from senior management, including leaders from our Information Technology team regarding matters of cybersecurity. This includes existing and new cybersecurity risks, status on how management is addressing and/or mitigating those risks, cybersecurity and data privacy incidents (if any) and status on key information security initiatives. Our Board members also engage in ad hoc conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs.

Our cybersecurity risk management and strategy processes are overseen by our Information Technology team. Such individuals have an average of over 20 years of prior work experience in various roles involving information technology, including security, auditing, compliance, systems and programming. These individuals are informed about, and monitor the prevention, mitigation, detection and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan, and report to the audit committee on any appropriate items. The audit committee holds quarterly meetings and receives periodic reports from management, concerning our significant cybersecurity threats and risk and the processes we have implemented to address them.

Item 2. Properties.

Our principal executive office is located in South San Francisco, California, pursuant to a lease that expires in April 2029. We believe that our current facility is adequate to meet our ongoing needs and, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock and public warrants are currently listed on the Nasdaq Capital Market under the symbols "SRZN" and "SRZNW", respectively.

Holders

As of March 20, 2025, there were 56 holders of record of our shares of common stock and 11 holders of record of our public warrants. These amounts do not include stockholders for whom shares are held in street name by banks, brokers and other nominees.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item regarding our equity compensation plans is hereby incorporated by reference from Part III, Item 12. "*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters-Equity Compensation Plan Information*" of this Annual Report.

Dividends

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We do not anticipate paying any dividends in the foreseeable future, and we currently intend to retain all available funds and any future earnings for use in the operation of our business, to finance the growth and development of our business and for future repayment of debt.

Future determinations as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Equity Securities

There were no sales of unregistered securities during the period covered by this Annual Report other than those previously reported in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K, or this Annual Report. This discussion includes both historical information and forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including, but not limited to, those discussed in the sections titled "Item 1A. Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" included elsewhere in this Annual Report. Unless otherwise indicated, the terms "Surrozen," "we," "us," or "our" refer to Surrozen, Inc., a Delaware corporation.

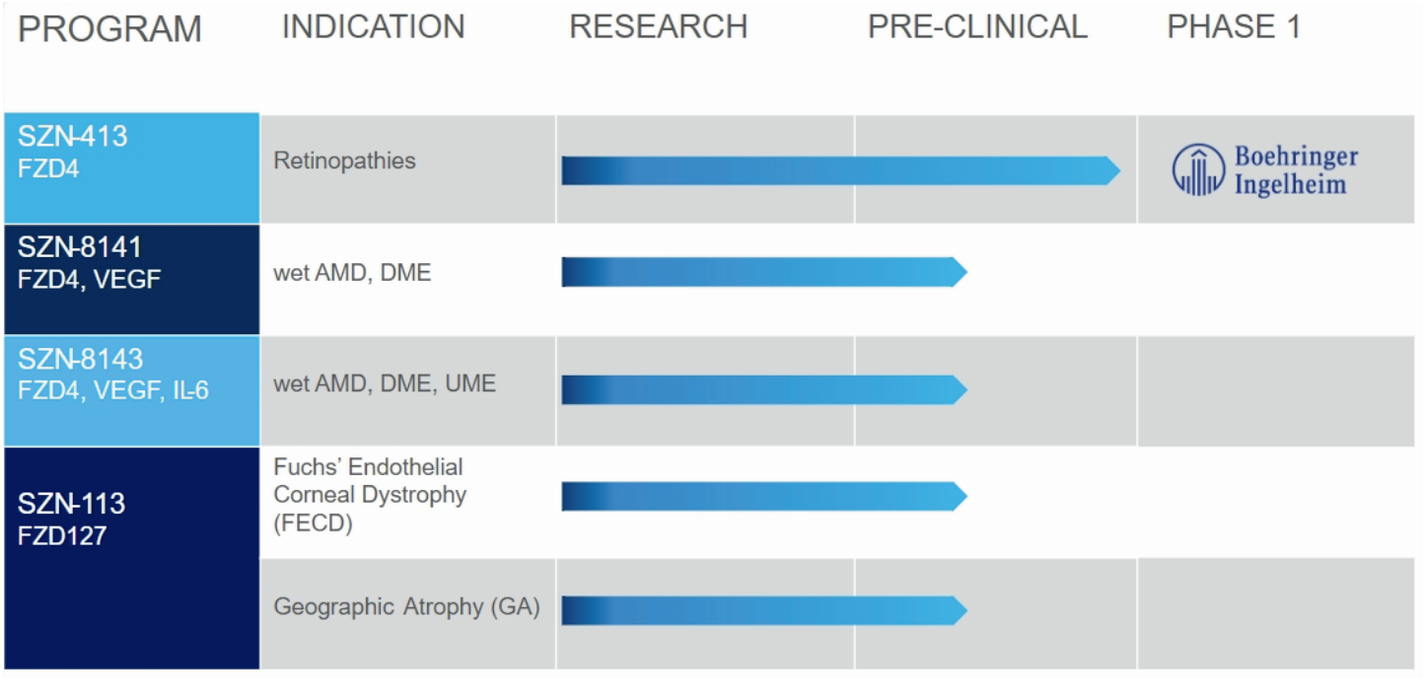
Overview

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 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:



Please see "*Part I, Item I – Business*" for a further discussion of our product candidates and clinical development programs.

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. For the years ended December 31, 2024 and 2023, we incurred net losses of $63.6 million and $43.0 million, respectively. As of December 31, 2024, we had an accumulated deficit of $285.3 million and cash and cash equivalents of $34.6 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.

Licensing Arrangements

In October 2022, we executed a Collaboration and Licensing Agreement, or the CLA, with Boehringer Ingelheim International GmbH, or BI, to research, develop and commercialize Frizzled 4, or Fzd4, bi-specific antibodies designed using our SWAP technology, including SZN-413. We and BI conducted partnership research focused on SZN-413 during a 1.5-year period. We granted BI an exclusive, royalty-bearing, worldwide, sublicensable license, under our 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. For five years after the effective date of the CLA, we are prohibited from preclinically and clinically developing or commercializing Fzd4 bi-specific antibodies that have certain properties for any diseases of the eye, and BI is prohibited from clinically developing or commercializing licensed products for any purpose other than diseases of the eye.

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, or TCGFB Collaboration. Under the terms of the agreement, we 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 agreed to pay us a fixed monthly fee 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 and is controlled by entities affiliated with The Column Group. The agreement constitutes a related party transaction because entities affiliated with The Column Group hold more than 5% of our common stock and Dr. Kutzkey, a member of our board of directors, serves as Managing Partner of The Column Group.

We also have entered into patent and research license arrangements with third-parties. The license agreements require milestone payments upon the achievement of certain regulatory and developmental stages. In addition, we will be required to pay royalties on sales of certain licensed products. As of December 31, 2024, we have incurred nominal fees and milestone payments under our license agreements. Upon the achievement of further regulatory and developmental milestones and the sale of licensed products, we may incur significant fees and royalties under these licenses.

Please see "*Part I, Item I – Business – Intellectual Property - Collaboration and Licensing Arrangements*" for a further discussion of our collaboration and licensing arrangements.

Components of Results of Operations

Revenue

Collaboration and License Revenue

We had not generated any revenue prior to the execution of the CLA in October 2022. Under the terms of the CLA, BI paid us a non-refundable upfront payment of $12.5 million less applicable withholding tax and agreed to pay success-based milestone payments up to $587.0 million and mid-single digit to low-double digit royalties on net sales of the licensed products should any reach commercialization. In September 2024, a milestone was achieved as BI decided to move forward with the development of SZN-413, and we received 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 collaboration and license revenue for the year ended December 31, 2024.

Research Service Revenue – Related Party

Research service revenue – related party relates to the amounts recognized for the research service performed in 2024 in connection with TCGFB Collaboration.

We do not expect to generate any revenue from the sale of our products unless and until we obtain regulatory clearance or approval.

Operating Expenses

We classify operating expenses into three main categories: (i) research and development expenses, (ii) general and administrative expenses and (iii) restructuring expenses.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities. Our research and development expenses consist of external and internal expenses incurred in connection with our research activities and development programs.

External expenses include:

- costs incurred under agreements with third parties, including CROs and other third parties conducting research and development activities on our behalf;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing drug candidate materials; and
- license and sublicense costs under our license agreements made for intellectual property used in research and development activities.

Internal expenses include:

- personnel-related costs, including salaries, bonuses, benefits and stock-based compensation for individuals involved in our research and product development activities; and
- facilities, depreciation, and other allocated costs, which include rent and insurance.

We track external expenses that are directly attributable to our clinical development candidates. We allocate internal expenses to our clinical development candidates on a program-specific basis. The internal expenses for early-stage research and discovery programs are not allocated as our internal resources, employees and infrastructure are typically deployed across multiple programs. As such, we do not provide financial information regarding the costs incurred for early-stage research and discovery programs on a program-specific basis.

We expect that our research and development expenses will increase for the foreseeable future as we identify and develop product candidates. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the development of our lead product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates, many of which are outside of our control, including those associated with:

- our ability, and the ability of our primary business partners, to hire and retain key personnel;
- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with IND-enabling studies;
- the number of sites and patients included in the clinical trials;
- the countries in which the clinical trials are conducted;
- per patient trial costs;
- successful patient enrollment in, and the initiation of, clinical trials, as well as drop out or discontinuation rates, the availability of alternate treatments and the limited pool of eligible patients in certain disease areas;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the number of trials required for regulatory approval;
- the timing, receipt and terms of any regulatory approvals from applicable regulatory authorities;

- our ability to establish new licensing or collaboration arrangements;
- the performance of our current and future business partners, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work;
- the impact of inflation on our expenses;
- launching commercial sales of our drug candidates, if approved, whether alone or in collaboration with others;
- the effect of products that may compete with our product candidates or other market developments; and
- maintaining a continued acceptable safety profile of the drug candidates following approval.

Any changes in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our drug candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits and stock-based compensation expense for personnel in executive, finance, human resources, business and corporate development, legal, information technology and other administrative functions. General and administrative expenses also include legal, audit, tax and other consulting fees, investor relations services, insurance costs, and facility costs not otherwise included in research and development expenses, and costs associated with compliance with the rules and regulations of the SEC and Nasdaq.

Restructuring Expenses

Restructuring expenses include costs in connection with the workforce reductions implemented in 2023. These costs consist of employee severance and other termination benefits.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of the gain on the change in fair value of warrant liabilities.

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

Loss on issuance of common stock, pre-funded warrants and warrants represents the excess of the initial fair value of common stock, pre-funded warrants and warrants over the aggregate gross proceeds in the private placement consummated in April 2024.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

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

	Year Ended December 31,		$	%
	2024	2023	Change	Change
Collaboration and license revenue	$ 10,000	$ —	$ 10,000	*
Research service revenue - related party	655	—	655	*
Total revenue	10,655	—	10,655	*
Operating expenses:				
Research and development	21,132	27,230	(6,098)	-22%
General and administrative	15,062	15,798	(736)	-5%
Restructuring	—	2,752	(2,752)	-100%
Total operating expenses	36,194	45,780	(9,586)	-21%
Loss from operations	(25,539)	(45,780)	20,241	-44%
Interest income	1,693	2,340	(647)	-28%
Other (expense) income, net	(19,321)	398	(19,719)	*
Loss on issuance of common stock, pre-funded warrants and warrants	(20,397)	—	(20,397)	*
Net loss	$ (63,564)	$ (43,042)	$ (125)	0%

* Percentage is not meaningful

Collaboration and License Revenue

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

Research Service Revenue – Related Party

The increase of $0.7 million in research service revenue – related party for 2024, compared to 2023, is attributable to the research service performed in 2024 in accordance with TCGFB Collaboration.

Research and Development Expenses

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

	Year Ended December 31,		$	%
	2024	2023	Change	Change
SZN-043	$ 10,784	$ 11,240	$ (456)	-4%
SZN-1326	1,462	5,913	(4,451)	-75%
Discovery and preclinical stage programs	8,886	10,077	(1,191)	-12%
Total research and development expenses	$ 21,132	$ 27,230	$ (6,098)	-22%

The decrease of $0.4 million, or 4%, in SZN-043 program expenses for 2024, compared to 2023, is primarily due to the workforce reductions effective in 2023. The decrease of $4.5 million, or 75%, in SZN-1326 program expenses for 2024, compared to 2023, is primarily 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 $1.2 million, or 12%, in discovery and preclinical stage program expenses for 2024, compared to 2023, is primarily due to the workforce reductions implemented in 2023 to focus our resources on our clinical stage programs.

General and Administrative Expenses

The decrease of $0.7 million, or 5%, in general and administrative expenses for 2024, compared to 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 $2.8 million, or 100%, in restructuring charges for 2024, compared to 2023, is attributable to workforce reductions implemented in 2023.

Interest Income

The decrease of $0.6 million, or 28%, in interest income for 2024, compared to 2023, is due to a decrease in cash and cash equivalents.

Other (Expense) Income, Net

The increase of $19.7 million, or 50%, in other expense, net, for 2024, compared to 2023, is primarily attributable to a $18.0 million increase in non-cash change in fair value of warrant liabilities, and $1.5 million related to the transaction costs allocated to the warrants issued in the April 2024 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 2024, compared to 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 revenue and income under the CLA with BI and TCGFB Collaboration. 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, as well as increased general and administrative expenses as we scale our organization as a public company.

Private Placements

In March 2025, we entered into a securities purchase agreement with certain institutional and accredited investors to issue and sell an aggregate of 15,086,236 units in a two-tranche private placement at a purchase price of $11.60 per share and $11.5999 per pre-funded warrant, for gross proceeds of approximately $175.0 million to fund multiple ophthalmology programs through initial Phase 1 safety, tolerability and efficacy studies. Each unit consists of one share of common stock, or pre-funded warrant in lieu thereof, and an accompanying one half of a warrant to purchase common stock, or Series E common stock warrant. At the closing of the first tranche of this private placement on March 26, 2025, (i) 5,213,415 shares of common stock, (ii) pre-funded warrants to purchase up to 1,373,000 shares of common stock, and (iii) Series E common stock warrants to purchase up to 3,293,207 shares of common stock were issued and sold for aggregate gross proceeds of approximately $76.4 million, before deducting placement agent fees and other expenses. None of the warrants issued in the private placement have been exercised as of the filing of this Annual Report. In the second tranche of the private placement, which is contingent upon the public announcement of the receipt of clearance from the U.S. Food and Drug Administration on or prior to October 31, 2026 of our Investigation New Drug Application for SZN-8141, or the second closing milestone, we expect to issue a (i) 6,043,321 shares of common stock, (ii) pre-funded warrants to purchase up to 2,456,500 shares of common stock, and (iii) Series E common stock warrants to purchase up to 4,249,910 shares of common stock; provided that the second tranche may not occur prior to September 27, 2026. If we terminate our SZN-8141 program prior to October 31, 2026, then we will provide written notice to each purchaser, referred to as the Termination Notice, and each purchaser will have the right, but not the obligation, for 30 calendar days following the receipt of such notice, upon written notice to us, to purchase the additional shares of common stock, pre-funded warrants, and Series E common stock warrants subscribed for by such purchaser in the second closing. In addition, at any time prior to October 31, 2026 or the date of the Termination Notice (if earlier), in lieu of the requirement to purchase units in the second closing, each purchaser has the right, but not the obligation, upon five trading days' prior written notice to us to purchase all (but not a portion) of the units subscribed for by such purchaser in the second closing, which we refer to as an optional closing. If a purchaser fails to purchase in full its subscribed for units after the achievement of the second closing milestone in the second closing, or previously at the first closing or an optional closing, then the Series E common stock warrants issued to such purchaser shall automatically be cancelled and cease to be exercisable. Please see Note 17 to the consolidated financial statements for further information regarding this private placement.

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. 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 Annual Report. Please see Notes 9, 10 and 11 to the consolidated financial statements for further information regarding this 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 10 to the 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.

Funding Requirements

To date, we have only generated revenue and income from our partnerships with BI and TCGFB. 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 December 31, 2024, we had cash and cash equivalents of $34.6 million and accumulated deficit of $285.3 million. We believe, based on our current operating plan, that our existing cash, cash equivalents and the gross proceeds of approximately $76.4 million received from the private placement in March 2025 will be sufficient to fund our operations for at least the next 12 months from the date of this Annual 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;
- 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 our lead 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):

	Year Ended December 31,	
	2024	**2023**
Net cash used in operating activities	$ (17,628)	$ (40,363)
Net cash (used in) provided by investing activities	(26)	51,723
Net cash provided by financing activities	16,176	276
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (1,478)	$ 11,636

Cash Used in Operating Activities

Cash used in operating activities of $17.6 million for 2024 was primarily due to the use of funds in our operations and the resulting net loss of $63.6 million and a net change of $0.8 million in our net operating assets and liabilities, partially offset by $46.8 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to a net decrease in accounts payable, accrued and other liabilities and operating lease liabilities.

Cash used in operating activities of $40.4 million for 2023 was primarily due to the use of funds in our operations and the resulting net loss of $43.0 million and a net change of $3.9 million in our net operating assets and liabilities, partially offset by $6.6 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to a net decrease in accounts payable and accrued and other liabilities.

Cash (Used in) Provided by Investing Activities

Cash used in investing activities of $26,000 for 2024 consisted of the purchases of lab equipment

Cash provided by investing activities of $51.7 million for 2023 consisted primarily of $80.2 million of proceeds from the maturities of marketable securities, partially offset by $28.0 million of cash used for the purchases of marketable securities and $0.4 million of cash used for the purchases of property and equipment.

Cash Provided by Financing Activities

Cash provided by financing activities of $16.2 million for 2024 consisted primarily of net proceeds from 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 $0.3 million for 2023 consisted primarily of proceeds from the issuance of common stock under the employee stock purchase plan.

Contractual Obligations and Commitments

As of December 31, 2024, we have lease obligations primarily consisting of one operating lease for our facility. The lease expires in April 2029. Under the terms of our operating leases, we had lease obligations of $10.1 million in payments through 2029 as of December 31, 2024.

We are party to license or subscription agreements pursuant to which we have in-licensed various intellectual property rights. The license agreements obligate us to make certain milestone payments related to achievement of specified events, as well as royalties in the low single-digit percentages based on sales of licensed products. The payment obligations under the license agreements are contingent upon future events, such as our achievement of specified milestones or generating product sales. As of December 31, 2024, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

We enter into contracts in the normal course of business with third-party vendors for preclinical research studies, clinical trials, research supplies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination on notice, and may or may not include cancellation fees. Given that the amount and timing related to such payments are uncertain, they are not considered to be contractual obligations. As of December 31, 2024, we had not accrued for any termination or cancellation charges as these were not considered probable.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our 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 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 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in the notes to our consolidated financial statements included elsewhere in this Annual Report, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Revenue Recognition

We recognize revenue in accordance with ASC 606, *Revenue from Contracts with Customers (Topic 606)*, when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for these goods or services. To determine revenue recognition for the arrangement that is within the scope of ASC 606, we perform the following five steps: (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration that we are entitled to in exchange for the goods or services transferred to the customer.

At contract inception, we assess the goods or services promised within the contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize revenue for the amount of the transaction price that is allocated to the respective performance obligations when or as the performance obligations are satisfied. We constrain the estimate of the transaction price up to the amount (the variable consideration constraint) that a significant reversal of recognized revenue is not probable.

We record accounts receivable for amounts billed to the customer for which we have an unconditional right to consideration. We assess accounts receivable for credit losses and, to date, no credit losses have been recorded.

If a research and development arrangement falls outside of the scope of all accounting standards, we apply ASC 606 by analogy and recognize other income and other receivables related to such arrangement.

Licenses of Intellectual Property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other

promised goods or services, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Services: Service fees are recognized over time based on progress toward complete satisfaction of the performance obligation. For each performance obligation satisfied over time, we assess the proper method to be used for recognition, either an input method to measure progress toward the satisfaction of services or an output method of determining the progress of completion of performance obligation.

Milestone Payments: At contract inception, we use the most likely amount method to evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

Royalties: We 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).

The incremental costs of obtaining a customer contract are expensed as and when incurred if the amortization period of the asset that would have been recognized is one year or less.

Research and Development Expenses

Research and development costs are expensed as incurred. A substantial portion of our preclinical studies, clinical trials and contract manufacturing activities is conducted by third-party service providers. We accrue for estimated costs of research and development activities conducted by third-party service providers based upon the estimated services provided but not yet invoiced, and we include these costs in accrued and other liabilities within the consolidated balance sheets. We estimate the amounts incurred in each period based on the information available and our knowledge of the nature of the contractual activities generating such costs. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses until the services are rendered.

If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust accrued expenses or prepaid expenses accordingly, which impacts research and development expenses. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Warrant Liabilities

We account for all outstanding warrants as liabilities and record at fair value. Transaction costs associated with the warrant liabilities are recognized as other expenses when incurred. At the end of each reporting period, changes in fair value during the period are recognized in other (expense) income, net within the consolidated statements of operations and comprehensive loss. We 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.

In April 2024, we issued and sold warrants to purchase common stock in a private placement, or the 2024 PIPE Warrants. The 2024 PIPE Warrants are classified as liabilities, and the fair value is measured using the Black-Scholes option-pricing model. Significant unobservable inputs used in the fair value measurement of such warrants include the timing and probability of achieving the milestones and the expected volatility. The fair value of the 2024 PIPE Warrants may change significantly as additional data is obtained, impacting our 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 our results of operations in future periods.

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 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 consolidated financial statements included in this Annual 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 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 7A. 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, and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

SURROZEN, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Surrozen, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Surrozen, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as "the consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2020.

/s/ Ernst & Young LLP

San Francisco, California
March 31, 2025

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

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 34,565	$ 36,043
Accounts receivable	2,039	2,152
Accounts receivable - related party	502	—
Prepaid expenses and other current assets	1,826	2,937
Total current assets	38,932	41,132
Property and equipment, net	562	1,969
Operating lease right-of-use assets	7,801	1,889
Restricted cash	688	688
Warrant asset	153	—
Other assets	331	402
Total assets	$ 48,467	$ 46,080
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 306	$ 525
Accrued and other liabilities	5,180	4,126
Lease liabilities, current portion	1,829	2,497
Total current liabilities	7,315	7,148
Lease liabilities, noncurrent portion	6,640	882
Warrant liabilities	55,892	115
Total liabilities	69,847	8,145
Commitments and contingencies (Note 5 and Note 14)		
Stockholders' (deficit) equity:		
Preferred stock, $0.0001 par value, 10,000 shares authorized; no shares issued and outstanding as of December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value, 500,000 shares authorized as of December 31, 2024 and 2023; 3,262 and 2,063 shares issued and outstanding as of December 31, 2024 and 2023, respectively	—	—
Additional paid-in-capital	263,879	259,630
Accumulated deficit	(285,259)	(221,695)
Total stockholders' (deficit) equity	(21,380)	37,935
Total liabilities and stockholders' (deficit) equity	$ 48,467	$ 46,080

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

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

	Year Ended December 31,	
	2024	**2023**
Collaboration and license revenue	$ 10,000	$ —
Research service revenue - related party	655	—
Total revenue	10,655	—
Operating expenses:		
Research and development	21,132	27,230
General and administrative	15,062	15,798
Restructuring	—	2,752
Total operating expenses	36,194	45,780
Loss from operations	(25,539)	(45,780)
Interest income	1,693	2,340
Loss on issuance of common stock, pre-funded warrants and warrants	(20,397)	—
Other (expense) income, net	(19,321)	398
Net loss	(63,564)	(43,042)
Unrealized gain on marketable securities, net of tax	—	241
Comprehensive loss	$ (63,564)	$ (42,801)
Net loss per share attributable to common stockholders, basic and diluted	$ (21.67)	$ (21.33)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	2,933	2,018

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

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

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount				
Balance at December 31, 2022	2,006	$ —	$ 254,895	$ (241)	$ (178,653)	$ 76,001
Issuance of common stock under employee stock purchase plan	58	—	332	—	—	332
Issuance of common stock upon option exercises	—	—	3	—	—	3
Redemption of fractional shares due to reverse stock split	—	—	(4)	—	—	(4)
Repurchase of early exercised stock options	(1)	—	—	—	—	—
Vesting of early exercised stock options	—	—	32	—	—	32
Stock-based compensation expense	—	—	4,372	—	—	4,372
Other comprehensive income	—	—	—	241	—	241
Net loss	—	—	—	—	(43,042)	(43,042)
Balance at December 31, 2023	2,063	—	259,630	—	(221,695)	37,935
Issuance of common stock in the Private Placement	1,092	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	15	—	94	—	—	94
Issuance of common stock upon option exercises	4	—	39	—	—	39
Vesting of restricted stock units	88	—	—	—	—	—
Vesting of early exercised stock options	—	—	2	—	—	2
Stock-based compensation expense	—	—	4,114	—	—	4,114
Net loss	—	—	—	—	(63,564)	(63,564)
Balance at December 31, 2024	3,262	$ —	$ 263,879	$ —	$ (285,259)	$ (21,380)

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

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

	Year Ended December 31,	
	2024	**2023**
Operating activities:		
Net loss	$ (63,564)	$ (43,042)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,442	1,911
Stock-based compensation	4,114	4,372
Non-cash operating lease expense	1,522	1,273
Amortization of discount on marketable securities, net	—	(732)
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	—
Non-cash impairment of long-lived assets	—	169
Change in fair value of warrant liabilities	17,830	(211)
Warrant asset recognized in connection with research service revenue	(153)	—
Loss (gain) on foreign currency remeasurement	113	(174)
Changes in operating assets and liabilities:		
Accounts receivable - related party	(502)	—
Prepaid expenses and other current assets	1,111	915
Other assets	71	62
Accounts payable	(228)	(133)
Accrued and other liabilities	1,056	(2,550)
Operating lease liabilities	(2,344)	(2,223)
Net cash used in operating activities	(17,628)	(40,363)
Investing activities:		
Purchases of property and equipment	(26)	(398)
Purchases of marketable securities	—	(28,044)
Proceeds from maturities of marketable securities	—	80,165
Net cash (used in) provided by investing activities	(26)	51,723
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	39	3
Proceeds from issuance of common stock upon employee stock plan purchases	94	332
Repurchase of early exercised stock options	—	(55)
Redemption of fractional shares due to reverse stock split	—	(4)
Net cash provided by financing activities	16,176	276
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,478)	11,636
Cash, cash equivalents and restricted cash at beginning of year	36,731	25,095
Cash, cash equivalents and restricted cash at end of year	$ 35,253	$ 36,731
Supplemental disclosure of noncash investing and financing activities:		
Increase in right-of-use assets and lease liabilities due to a lease modification	$ 7,434	$ —
Purchases of equipment included in accounts payable	$ 9	$ —
Vesting of early exercises of stock options	$ 2	$ 32

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

	December 31,	
	2024	**2023**
Cash and cash equivalents	$ 34,565	$ 36,043
Restricted cash	688	688
Cash, cash equivalents and restricted cash	$ 35,253	$ 36,731

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

Note 1. Organization and Business

Organization

Surrozen, Inc., or the Company, is a biotechnology company committed to discovering and developing drug candidates to selectively modulate the Wnt pathway, a critical mediator of tissue repair with a current focus in ophthalmology. 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 years ended December 31, 2024 and 2023, the Company incurred a net loss of $63.6 million and $43.0 million, respectively. During the years ended December 31, 2024 and 2023, the Company used $17.6 million and $40.4 million of cash in operations. As of December 31, 2024, the Company had cash and cash equivalents of $34.6 million and an accumulated deficit of approximately $285.3 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, cash equivalents and the gross proceeds of approximately $76.4 million received from the private placement in March 2025 (Note 17) are sufficient for the Company to continue operating activities for at least the next 12 months from the date of issuance of its 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 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 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. The consolidated financial statements include the accounts of the Company and its subsidiary. All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of 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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions made in the accompanying consolidated financial statements include certain accrued expenses for research and development activities, valuation of operating lease right-of-use assets and lease liabilities, valuation of warrant asset, 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 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.

Cash and Cash Equivalents

Cash equivalents relate to securities having an original maturity of three months or less at the time of purchase. As of December 31, 2024 and 2023, cash and cash equivalents consisted of bank deposits and money market funds.

Restricted Cash

As of December 31, 2024 and 2023, the Company had $0.7 million of restricted cash consisting of a letter of credit for the Company's facility lease and the collateral associated with the Company's credit card program.

Property and Equipment

Property and equipment, including leasehold improvements, are recorded at cost net of accumulated depreciation and amortization. Major replacements and improvements that extend the useful lives of assets are capitalized, while general repairs and maintenance are charged to expense as incurred. Property and equipment are depreciated and amortized using the straight-line method over the estimated useful lives of the assets as follows:

Asset	Estimated useful life
Leasehold improvements	Shorter of useful life of asset or lease term
Lab equipment	3 years
Furniture and office equipment	3-8 years
Computer equipment and software	3 years

When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the consolidated balance sheet and the resulting gain or loss is recognized in the period realized.

Leases

Material leases with a term longer than one year are recognized as right-of-use, or ROU, assets and lease liabilities in the Company's consolidated balance sheets. The Company determines the lease classification and measurement of its ROU assets and lease liabilities at the lease commencement date and thereafter if modified. The Company uses its incremental borrowing rate, based on the information available at the commencement date, to determine the present value of lease payments if the rate implicit in the lease is not readily available. The ROU asset is based on the measurement of the lease liability and is adjusted for lease incentives provided by the landlord. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. For a lease modification, an evaluation is performed to determine if it should be treated as either a separate lease or a change in the accounting of an existing lease. When a modification does not result in a separate contract, the Company reassesses the lease classification, remeasures the related lease liability using an updated incremental borrowing rate that reflects the modified lease term, and adjusts the related ROU asset.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment and operating lease right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows which the assets are expected to generate. If

such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds their fair value.

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 is recognized in other (expense) income, net within the consolidated statements of operations and comprehensive loss. The Company will continue to adjust the warrant liabilities pertaining to the outstanding warrants 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.

Revenue Recognition

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers (Topic 606)*, or by analogy, when its counterparty obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for these goods or services. To determine revenue recognition for the arrangement that is within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services transferred to the customer. If the counterparty to a research and development arrangement is not a customer, services being provided align with the Company's ordinary activities, and the arrangement falls outside of the scope of all accounting standards, the Company applies ASC 606 by analogy and recognizes revenue related to such arrangement.

At contract inception, the Company assesses the goods or services promised within the contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes revenue for the amount of the transaction price that is allocated to the respective performance obligations when or as the performance obligations are satisfied. The Company constrains its estimate of the transaction price up to the amount (the variable consideration constraint) that a significant reversal of recognized revenue is not probable.

The Company records accounts receivable 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.

Licenses of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Services: Service fees are recognized over time based on progress toward complete satisfaction of the performance obligation. For each performance obligation satisfied over time, the Company assesses the proper method to be used for recognition, either an input method to measure progress toward the satisfaction of services or an output method of determining the progress of completion of performance obligation.

Milestone Payments: At contract inception, the Company uses the most likely amount method evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. 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.

Royalties: The Company recognizes 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).

The incremental costs of obtaining a contract are expensed as and when incurred if the amortization period of the asset that would have been recognized is one year or less.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs consist of external and internal expenses directly attributable to the conduct of research and development programs. The external expenses include the costs of services provided by outside contractors, clinical research organizations and contract manufacturing organizations. The internal expenses include the costs of salaries, bonus, payroll taxes, stock-based compensation, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, and the allocated facility-related costs, such as rent, utilities, insurance, repairs and maintenance, and general support services.

The Company has entered into and may continue to enter into licensing or subscription arrangements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date, none of the Company's license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expense when they are paid or become payable, provided there is no alternative future use of the rights in other research and development projects.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical, clinical, and manufacturing development, which are significant components of research and development expenses, within accrued and other liabilities in the accompanying consolidated balance sheets. A substantial portion of the Company's preclinical studies, clinical trials and contract manufacturing activities is conducted by third-party service providers. The Company accrues for estimated costs of research and development activities conducted by third-party service providers based upon the estimated services provided but not yet invoiced. We estimate the amounts incurred in each period based on the information available and our knowledge of the nature of the contractual activities generating such costs. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses until the services are rendered.

If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts accrued expenses or prepaid expenses accordingly, which impacts research and development expenses. For the years ended December 31, 2024 and 2023, the Company did not have any material differences between accrued costs and actual costs incurred. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for all stock-based awards. For stock awards, stock-based compensation cost is estimated on the grant date based on the closing price of the Company's stock, with consideration of whether there is material nonpublic information that could impact the estimated fair value of awards. Stock-Based compensation cost is recognized as expense on a straight-line basis over the requisite service period. Under the Company's employee stock purchase plan, stock-based compensation cost is measured at the beginning of the offering period and recognized on a straight-line basis over the offering period. Forfeitures are accounted for as they occur.

The Company has elected to calculate the fair value of awards using the Black-Scholes option pricing model, or the Black-Scholes Model. The Black-Scholes Model requires the use of various assumptions including common stock valuation, expected option life and expected stock price volatility. The Company estimates the expected term for stock options using the simplified method as the midpoint between the vesting date and the contractual expiration date of the award as the Company has limited historical exercise information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. Due to the limited trading history of the Company's stock, the Company estimates the volatility using volatilities of a group of public companies in a comparable industry, stage of life cycle, and size. The interest rate is derived from the U.S. Treasury instruments with maturities similar to the expected term of the options. The Company has not declared nor expects to declare dividends. Therefore, there is no dividend impact on the valuation of options.

Comprehensive Income

The Company's comprehensive income consists of unrealized gains on marketable securities.

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 shares 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):

	December 31,	
	2024	**2023**
Common stock issuable upon exercise of stock options	536	311
Unvested restricted stock awards	1	4
Unvested restricted stock units	38	90
Common stock issuable upon exercise of warrants	11,569	394
Total	12,144	799

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates expected to be in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts more likely than not to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is more likely than not of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits require significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to unrecognized tax benefits.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board, or FASB, issued Accounting Standards update 2024-03, *Income Statement Reporting—Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses*. The standard improves the disclosures about a public business entity's expenses and requires more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in expense captions presented on the statement of operations. The guidance will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The standard is to

be applied either prospectively or retrospectively. The Company is evaluating the impact of adopting this standard on its 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 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 adopted this standard effective in 2024. There was no material impact on the Company's reportable segments and the required disclosures have been included in Note 16.

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 earnings 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 consolidated financial statements and related disclosures.

Note 3. Fair Value Measurement

The Company records its financial assets and liabilities at fair value. The carrying amount of the Company's financial instruments, including cash and cash equivalents, accounts receivable, restricted cash, accounts payable, and accrued and other liabilities, approximate their fair value due to their short-term maturities. The accounting guidance for fair value establishes a framework for measuring fair value and a fair value hierarchy that prioritizes the inputs used in valuation techniques. The fair value hierarchy is based on three levels of inputs that may be used to measure fair value as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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 December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds [1]	$ 25,495	$ —	$ —	$ 25,495
Total financial assets measured at fair value	$ 25,495	$ —	$ —	$ 25,495
Liabilities[2]:				
2021 Public Warrants	$ 109	$ —	$ —	$ 109
2021 PIPE Warrants	—	17	—	17
2024 Pre-Funded Warrants	—	574	—	574
2024 PIPE Warrants	—	—	55,192	55,192
Total financial liabilities measured at fair value	$ 109	$ 591	$ 55,192	$ 55,892

	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 consolidated balance sheets as of December 31, 2024 and 2023.

(2) See *Note 11, Common Stock Warrants*.

There were no changes to the valuation methods utilized on existing financial instruments, and there were no transfers of financial instruments between Level 1, Level 2, and Level 3 for the years ended December 31, 2024 and 2023.

The 2021 Public Warrants (as defined in Note 11 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 11 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 11 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 11 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. Particularly, in March 2025, the Company announced its discontinuation of the development of SZN-043 in severe alcohol associated hepatitis. Additionally, in connection with the Company's private placement in March 2025, both the exercise prices

of the Company's outstanding Series A and Series B common stock warrants were reduced to $11.54 per share, except that the exercise prices per warrant for such warrants held by members of management were reduced to $12.45 per share. In addition, the Company's outstanding Series C and Series D common stock warrants were cancelled and no further obligations or rights exist with respect to the Series C and Series D common stock warrants. Please see Note 17 for information regarding the private placement in March 2025.

The key inputs into the fair value measurement of the 2024 PIPE Warrants were as follows at the initial measurement and December 31, 2024:

	December 31, 2024	April 4, 2024
Expected term (in years)	0.5 - 4.3	0.8 - 5.0
Expected volatility	100%	100%
Risk-free interest rate	4.3% - 4.4%	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)]	17,698
Balance, December 31, 2024	$ 55,192

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

Assets that are Measured at Fair Value on a Nonrecurring Basis

Equity investment

The Company received a warrant pursuant to a strategic research collaboration as discussed in Note 10. To determine the value of the warrant at contract inception, the Company utilized the Option Pricing Method, or OPM, based analysis, primarily the OPM backsolve methodology. Within the OPM framework, the backsolve method, for inferring the total equity value implied by a recent financing transaction, involves the construction of an allocation model that takes into account the Company's capital structure and the rights, preferences and privileges of each class of stock, then assumes reasonable inputs for the other OPM variables. The fair value of the warrant at contract inception was determined to be $2.6 million on October 31, 2024. The key assumptions used in the OPM included a probability of contract in effect, an expected holding period of five years, an estimated volatility of 102%, a risk free interest rate of 4.11% and zero dividend yield. These represent a Level 3 nonrecurring fair value measurement.

As the warrant asset does not have a readily determinable fair value, the Company elected to use a measurement alternative for all subsequent measurements. Under such measurement alternative, the warrant is remeasured at fair value when observable transactions involving the underlying security or impairment of the warrant asset occurred. The Company is not aware of any events or changes in circumstances that would have a significant effect on the fair value of the warrant as of December 31, 2024.

Long-lived assets

The Company's long-lived 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. As a result of the sustained decline in the Company's stock price, the Company determined an impairment indicator was present. The Company determined all of its long-lived assets represent a single asset group for the purpose of the long-lived asset impairment assessment. The Company concluded that the carrying value of the single asset group was not recoverable as it exceeded the future net undiscounted cash flows that are expected to be generated from the use and eventual disposition of the assets within the asset group. The implied allocated impairment loss to any individual asset within the long-lived asset group shall not reduce the carrying amount of that asset below its fair value.

To determine the fair value of the individual assets within the asset group, 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. For the year ended December 31, 2023, the Company recognized an impairment loss of $0.2 million, consisting of $0.1 million on the operating lease right-of-use asset and $0.1 million on the leasehold improvements, which is included in research and development expenses and general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

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 year ended December 31, 2024.

Note 4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2024	2023
Prepaid research and development expenses	$ 686	$ 1,751
Prepaid insurance	469	606
Other	671	580
Prepaid expenses and other current assets	$ 1,826	$ 2,937

Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	December 31,	
	2024	2023
Leasehold improvements	$ 1,116	$ 1,116
Lab equipment	6,777	7,703
Furniture and office equipment	316	316
Computer equipment and software	200	202
Total property and equipment	8,409	9,337
Less: accumulated depreciation and amortization	(7,847)	(7,368)
Property and equipment, net	$ 562	$ 1,969

Depreciation expenses for the years ended December 31, 2024 and 2023 was $1.4 million and $1.9 million, respectively. For the year ended December 31, 2023, the Company recorded an asset impairment charge of $0.1 million on its leasehold improvements. Refer to *Note 3, Fair Value Measurement* for more information.

Accrued and Other Liabilities

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

	December 31,	
	2024	2023
Accrued payroll and related expenses	$ 2,929	$ 2,508
Accrued research and development expenses	1,904	1,261
Accrued professional service fees	156	65
Other	191	292
Accrued and other liabilities	$ 5,180	$ 4,126

Note 5. Leases

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. 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 future exercise of either option is not reasonably certain. The total future lease payments under the amendment are approximately $9.8 million.

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 consolidated balance sheets.

The operating lease expense for the years ended December 31, 2024 and 2023 was $1.8 million and $1.6 million, respectively. For the year ended December 31, 2023, the Company recorded an asset impairment charge of $0.1 million on its right-of-use assets. Refer to *Note 3, Fair Value Measurement* for more information.

Aggregate future minimum rental payments under the operating leases as of December 31, 2024, were as follows (in thousands):

Year ending December 31, 2025	$ 2,440
Year ending December 31, 2026	1,797
Year ending December 31, 2027	2,461
Year ending December 31, 2028	2,547
Year ending December 31, 2029	857
Total lease payments	10,102
Less: Imputed interest	(1,633)
Operating lease liabilities	$ 8,469

The following represents supplemental information related to the Company's operating leases:

	December 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	$ 2,670	$ 2,596
Weighted-average remaining lease term (in years)	4.33	1.33
Weighted-average discount rate	8.25%	8.48%

Note 6. 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 1.5-year 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 $2.0 million is expected to be refunded to the Company in 2025 and recognized as accounts receivable. In September 2024, a milestone was achieved as BI decided to move forward with the development of SZN-413, and the Company received 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 collaboration and license revenue for the year ended December 31, 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 7. License Agreements

Stanford License Agreements

In March 2016, the Company entered into a license agreement with Stanford University, or the 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 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.

For the years ended December 31, 2024 and 2023, the Company incurred research and development expenses of approximately $0.1 million, respectively, under the Stanford Agreement. No milestones have been achieved as of December 31, 2024.

Note 8. 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 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 consolidated balance sheet. The following table summarizes activity during the years ended December 31, 2024 and 2023 (in thousands):

	Employee Severance and Other Benefits
Balance, December 31, 2022	$ —
Restructuring charges	2,752
Cash payments	(2,678)
Balance, December 31, 2023	74
Cash payments	(44)
Personnel adjustments	(30)
Balance, December 31, 2024	$ —

Note 9. Stockholders' Equity

2024 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 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 11 for more information regarding the warrants issued and sold to the Investors in the Private Placement and Note 10 for more information regarding the shares of the Company's common stock and the warrants issued and sold to management in the Private Placement.

Note 10. Related Party Transactions

Research Collaboration Agreement with TCGFB, Inc.

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, or TCGFB Collaboration. TCGFB will own all TGF-β product related intellectual property. Under the terms of the agreement, the Company provides antibody discovery services for a period of up to two years and delivers a non-exclusive license as necessary for continued research. TCGFB may terminate this agreement at any time upon prior written notice. Upon termination, TCGFB shall pay to the Company all sums owed for services completed up to the effective termination date. In exchange for the Company's research services, TCGFB pays a fixed monthly service fee 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. 2.4 million shares of the warrant vest monthly over 2 years, 0.5 million shares vest on the 18-month anniversary, and 0.5 million shares vest on the 24-month anniversary. TCGFB was founded and is controlled by entities affiliated with The Column Group. The agreement constitutes a related party transaction because entities affiliated with The Column Group hold more than 5% of the Company's common stock and Dr. Kutzkey, a member of the Company's board of directors, serves as Managing Partner of The Column Group.

While TCGFB is not a customer and the service being provided is consistent with the Company's ordinary activities, the Company determined that the TCGFB Collaboration is in the scope of ASC 606 by analogy. The Company evaluated the promised goods and services and determined that the service to TCGFB and the potential grant of the non-exclusive license represented one combined performance obligation for discovery antibody therapeutics targeting TGF-β. The transaction price was determined to be the fixed monthly service fee plus variable consideration related to the warrant. Revenue is recognized over time for the combined performance obligation using the input method.

The warrant received does not meet the definition of a derivative and account for as an equity investment under ASC 321. Please refer to Note 3 for the fair value measurement of the warrant. The warrant is recognized as warrant asset once the vesting restrictions are lifted.

During the year ended December 31, 2024, the Company recognized $0.7 million as research service revenue – related party for the services rendered, consisting of the fixed cash consideration of $0.5 million as accounts receivable – related party and the variable noncash consideration of $0.2 million as warrant asset on the consolidated balance sheet.

2024 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 11 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 year ended December 31, 2024, the Company recognized sublease income of $0.4 million as reductions to operating expenses. Tim Kutzkey, Ph.D., a member of the Company's board of directors, serves as the chairman of the board of directors of Nura Bio. Dr. Kutzkey also serves as Managing Partner of The Column Group, LLC, which is the general partner of certain limited partnerships which are significant stockholders of Nura Bio. The Column Group holds more than 5% of the Company's common stock. Therefore, the agreement constitutes a related party transaction.

Note 11. Common Stock Warrants

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

Type	Classification	Exercise Price per Share — Investor	Exercise Price per Share — Management	December 31, 2024	December 31, 2023
2021 Public Warrants	Liability	$ 172.50	N/A	5,117	2,733
2021 PIPE Warrants	Liability	172.50	N/A	790	3,174
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	—
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.

In connection with the private placement in March 2025, both the exercise prices of the Company's outstanding Series A and Series B common stock warrants were reduced to $11.54 per share, except that the exercise prices per warrant for such warrants held by members of management were reduced to $12.45 per share, and the Company's outstanding Series C and Series D common stock warrants were cancelled. Please see Note 17 for information regarding the private placement in March 2025.

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 December 31, 2024, the Company's 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 Public Warrants on transfer pursuant to the terms of the PIPE Warrant Agreement. As of December 31, 2024, 2.4 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 (expense) income, net within the consolidated statements of operations and comprehensive loss. See Note 3 for discussion of warrant valuations.

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 two years. As of December 31, 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 December 31, 2024, there were approximately 20,000 shares of common stock available for issuance 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		
Exercised	(4)	9.20		
Forfeited	(19)	18.76		
Expired	(10)	29.16		
Outstanding – December 31, 2024	536	19.45	8.00	$ 1,514
Exercisable – December 31, 2024	262	25.33	7.01	487

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 December 31, 2024.

The intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was de minimis in both periods.

During the years ended December 31, 2024 and 2023, the Company granted options with a weighted-average grant-date fair value of $7.45 per share and $9.47 per share, respectively.

Fair Value of Options

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

	Year Ended December 31,	
	2024	2023
Expected term (in years)	6.00	5.85
Expected volatility	91.59%	85.86%
Risk-free rate	4.63%	3.89%
Dividend yield	—	—

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
Canceled	(4)	8.43
RSUs, unvested at December 31, 2024	38	9.16

The fair value of RSUs vested during the years ended December 31, 2024 and 2023 was $0.7 million and zero, respectively.

Stock-Based Compensation

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

	Year Ended December 31,	
	2024	2023
Research and development	$ 1,165	$ 1,272
General and administrative	2,949	3,100
Total stock-based compensation expense	$ 4,114	$ 4,372

As of December 31, 2024, there was approximately $3.4 million of stock-based compensation expense to be recognized over a weighted-average period of approximately 2.04 years.

Note 13. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2024 and 2023. The Company has incurred net operating losses for all the periods presented. The Company accounts for income taxes in accordance with the asset and liability method, which requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is not likely to be realized and, accordingly, has provided a full valuation allowance.

Significant components of the Company's net deferred tax assets consist of the following (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 34,048	$ 36,398
Section 174 capitalized expense	13,411	12,047
Research and development credits	2,250	4,000
Lease liabilities	1,823	664
Accrual and reserves	599	471
Employee retention credits	—	64
Stock-based compensation	312	322
Capitalized intangible costs	713	160
Fixed assets	449	279
Other	6	6
Gross deferred tax assets	53,611	54,411
Less: valuation allowance	(51,896)	(53,962)
Deferred tax assets, net of valuation allowance	1,715	449
Deferred tax liabilities:		
Right-of-use assets	(1,690)	(397)
Other	(25)	(52)
Gross deferred tax liabilities	(1,715)	(449)
Total net deferred tax assets	$ —	$ —

The net valuation allowance decreased by $2.1 million and increased by $8.6 million for the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, the Company had net operating loss, or NOL, carryforwards of approximately $160.5 million and $5.0 million available to reduce future taxable income, if any, for federal and California state income tax purposes, respectively. NOL carryforwards generated after 2018 for federal tax reporting purposes of $156.8 million have an indefinite carryforward period. The remaining federal and state net operating loss carryforwards begin expiring in 2036.

As of December 31, 2024, the Company had research and development credit carryforwards of approximately zero and $3.8 million available to reduce future taxable income, if any, for federal and California state income tax purposes, respectively. The state credits carry forward indefinitely.

Federal and state laws impose substantial restrictions on the utilization of net operating loss and tax credit carryforwards in the event of an ownership change for tax purposes, as defined in Section 382 of the Internal Revenue Code. As a result of such ownership changes, the Company's ability to realize the potential future benefit of tax losses and tax credits that existed at the time of the ownership change may be limited and may expire unutilized. Such impairment of tax losses and tax credits would reduce the deferred tax asset and corresponding valuation allowance, as a result of the limitation. The Company completed an assessment of the available NOLs under Section 382 and determined that the Company underwent an ownership change in September 2020 and April 2024. As a result of the annual limitations caused by the ownership change, it was estimated the approximately $2.6 million of federal tax credit, $8.8 million

of federal NOL and $76.5 million of California NOL will expire unrealized for income tax purposes, and such amounts are excluded from the carryforward balances as of December 31, 2024.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate assuming the Company continues to maintain a full valuation allowance position. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

A reconciliation of the Company's unrecognized tax benefits is as follows (in thousands):

	December 31,	
	2024	2023
Balance at beginning of the year	$ 1,725	$ 1,628
Additions based on tax positions of prior years	—	97
Deductions for tax positions of prior years	(800)	—
Balance at end of the year	$ 925	$ 1,725

The Company files income tax returns in the U.S. federal and California tax jurisdictions. As of the date these financial statements were issued, the Company is not under examination by any income tax authority. The federal and state income tax returns from December 31, 2016 to December 31, 2024 remain subject to examination.

A reconciliation of the statutory U.S. federal tax rate to the Company's effective tax rate is as follows:

	December 31,	
	2024	2023
Statutory rate	21.00%	21.00%
State tax	(4.33)	—
Tax credits	—	0.64
Stock-based compensation	(1.07)	(1.74)
Change in valuation allowance	3.24	(19.95)
Gain on warrant liabilities	(13.10)	0.10
382 ownership change	(5.66)	—
Other	(0.08)	(0.05)
Total	0.00%	0.00%

Note 14. Commitments and Contingencies

Indemnification

From time to time, the Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship with the Company, (ii) contracts under which the Company must indemnify directors and certain officers for liabilities arising out of their relationship with the Company, (iii) contracts under which the Company may be required to indemnify customers or partners against certain claims, including claims from third parties asserting, among other things, infringement of their intellectual property rights and (iv) procurement, consulting, or license agreements under which the Company may be required to indemnify vendors, consultants or licensors for certain claims, including claims that may be brought against them arising from acts or omissions with respect to the supplied products, technology or services. From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In addition, under these contracts the Company may have to modify the accused infringing intellectual property and/or refund amounts received.

In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results or financial condition. It is not

possible to determine the maximum potential amount under these contracts due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement.

The Company maintains director and officer insurance, which may cover certain liabilities arising from the Company's obligation to indemnify its directors and certain officers.

To the date of the consolidated financial statements were issued, the Company has not incurred any material costs or accrued any liabilities related to indemnification obligations.

Litigation

The Company's industry is characterized by frequent claims and litigation, including claims regarding intellectual property. As a result, the Company may be subject to various legal proceedings from time to time. The results of any future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. Management is not aware of any pending or threatened litigation.

Note 15. 401(k) Plan

The Company adopted a 401(k) retirement savings plan, or the 401(k) Plan for all eligible employees. Each participant may contribute pre- or post-tax compensation, up to annual statutory limits. The 401(k) Plan also permits the Company to make discretionary and matching contributions, subject to established limits and a vesting schedule. Each year, the Company may, at its sole discretion, make contributions to the plan. For the years ended December 31, 2024 and 2023, the Company's contributions were $0.1 million in both periods.

Note 16. Segment Reporting

The Company has one reportable segment relating to the research and development of drug candidates to selectively modulate the Wnt pathway for tissue repair and regeneration. The segment derives its revenue from licensing and research collaborations.

The Company's Chief Executive Officer and the Chief Financial Officer/Chief Operating Officer are together considered the Company's Chief Operating Decision Maker, or CODM, on a consolidated basis. The CODM uses consolidated operating expenses by function to evaluate financial performance, monitor budget versus actual results, and manage the Company's operations for the purposes of allocating resources and establishing business strategies. The measure of segment assets is not reported as it is not regularly provided or reviewed by the Company's CODM.

The table below is a summary of the segment profit or loss, including significant segment expenses (in thousands):

	Year Ended December 31,	
	2024	2023
Total revenue	$ 10,655	$ —
Less:		
Compensation excluding stock-based compensation	(12,720)	(18,096)
Clinical and manufacturing costs	(5,582)	(5,486)
Consultants and third-party services	(3,765)	(4,501)
Rent and facility expenses	(3,965)	(5,072)
Stock-based compensation	(4,114)	(4,372)
Depreciation and amortization	(1,442)	(1,911)
Other (expense) income, including loss on issuance of common stock[1]	(38,026)	2,737
Other segment items[2]	(4,605)	(6,341)
Segment and consolidated net loss	$ (63,564)	$ (43,042)

[1] Other information not reported to CODM includes loss on issuance of common stock, pre-funded warrants and warrants, interest income, and gain/loss on change in fair value of warrant liabilities, which are reported as other expense (income), net on the consolidated statements of operations and comprehensive loss.
[2] Other segment items primarily consist of lab expenses, professional services and information technology costs.

For the year ended December 31, 2024, collaboration and license revenue of $10.0 million is attributed to BI, which is domiciled in Germany; research service revenue – related party of $0.7 million was generated in the United States. As of December 31, 2024 and 2023, all long-lived assets of the Company reside in the United States.

Note 17. Subsequent Events

2025 Private Placement

In March 2025, the Company entered into a securities purchase agreement with certain institutional and accredited investors to issue and sell an aggregate of 15.1 million units in a two-tranche private placement at a purchase price of $11.60 per share unit and $11.5999 per pre-funded warrant unit, for gross proceeds of approximately $175.0 million to fund multiple ophthalmology programs through initial Phase 1 safety, tolerability and efficacy studies. Each unit consists of one share of common stock, or pre-funded warrant in lieu thereof, and an accompanying one half of a Series E common stock warrant. The purchase price per unit includes $0.0625 for the accompanying one half of a Series E common stock warrant. Each pre-funded warrant has an exercise price of $0.0001 per share, is exercisable immediately and will not expire until exercised in full. Each Series E common stock warrant has an exercise price of $11.54 per share, is exercisable immediately and expires five years from the date of issuance.

At the closing of the first tranche on March 26, 2025, (i) 5.2 million shares of common stock, (ii) pre-funded warrants to purchase up to 1.4 million shares of common stock, and (iii) Series E common stock warrants to purchase up to 3.3 million shares of common stock were issued and sold for aggregate gross proceeds of approximately $76.4 million, before deducting placement agent fees and other expenses. None of the warrants issued in the private placement have been exercised as of the filing of this Annual Report. In the second tranche of the private placement, which is contingent upon the public announcement of the receipt of clearance from the U.S. Food and Drug Administration on or prior to October 31, 2026 of the Company's Investigation New Drug Application for SZN-8141, or the second closing milestone, the Company expects to issue a (i) 6.0 million shares of common stock, (ii) pre-funded warrants to purchase up to 2.5 million shares of common stock, and (iii) Series E common stock warrants to purchase up to 4.2 million shares of common stock for aggregate gross proceeds of approximately $98.6 million; provided that the second tranche may not occur prior to September 27, 2026. If the Company terminates its SZN-8141 program prior to October 31, 2026, then it will provide written notice to each purchaser, and each purchaser will have the right, but not the obligation, for 30 calendar days following the receipt of such notice, upon written notice to the Company, to purchase the additional shares of common stock, pre-funded warrants, and Series E common stock warrants subscribed for by such purchaser in the second closing. In addition, at any time prior to October 31, 2026 or the date of the Termination Notice (if earlier), in lieu of the requirement to purchase units in the second closing, each purchaser has the right, but not the obligation, upon five trading days' prior written notice to the Company to purchase all (but not a portion) of the units subscribed for by such purchaser in the second closing, referred to as an optional closing. If a purchaser fails to purchase in full its subscribed for units after the achievement of the second closing milestone in the second closing, or previously at the first closing or an optional closing, then the Series E common stock warrants issued to such purchaser shall automatically be cancelled and cease to be exercisable.

In connection with the private placement, both the exercise prices of the Company's outstanding 2024 Series A and Series B common stock warrants were reduced to $11.54 per share, except that the exercise prices per warrant for such warrants held by members of management were reduced to $12.45 per share, and the Company's outstanding Series C and Series D common stock warrants were cancelled.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

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 December 31, 2024.

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 December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). The Company's internal control over financial reporting is a process designed under the supervision of our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of December 31, 2024, management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the framework established in "*Internal Control—Integrated Framework (2013 Framework)*" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that our internal control over financial reporting was effective as of December 31, 2024.

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 quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Attestation of Independent Registered Public Accounting Firm

This Annual Report does not include an attestation by our independent registered public accounting firm regarding our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) as we qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act.

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 also 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.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated herein by reference to our definitive proxy statement in connection with our 2025 annual meeting of stockholders, or 2025 Proxy Statement, under the sections titled "*Proposal No. 1 Election of Directors*", "*Executive Officers*" and "*Corporate Governance*." 2025 Proxy Statement will be filed with the SEC within 120 days after the end of the year ended December 31, 2024.

Information regarding Section 16(a) beneficial reporting compliance, if any, will be set forth under the section titled "Delinquent Section 16(a) Reports" in the 2025 Proxy Statement and is incorporated herein by reference.

Code of Business Conduct and Ethics

We adopted a Code of Business Conduct and Ethics, or Code of Ethics, applicable to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, in accordance with applicable federal securities laws. The Code of Ethics codifies the business and ethical principles that govern all aspects of our business. The Code of Ethics is available on our website at www.surrozen.com. If we make any substantive amendments to the Code of Ethics or grant any waiver from a provision of the Code of Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

The information concerning our Audit Committee and Audit Committee financial expert is incorporated by reference herein to the information set forth in the section titled "*Corporate Governance – Board Committee – Audit Committee*" in our 2025 Proxy Statement.

Information regarding procedures by which stockholders may recommend nominees to our board of directors is set forth in the section titled "*Corporate Governance - Director Nominations*" in the 2025 Proxy Statement.

Information regarding the insider trading policy is incorporated by reference to our 2025 Proxy Statement under the section titled "*Corporate Governance – Insider Trading Policy.*"

Item 11. Executive Compensation.

Compensation of Directors and Executive Officers

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement under the sections titled "*Executive Compensation*" and "*Director Compensation*."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item with respect to the security ownership of certain beneficial owners and management is incorporated herein by reference to our 2025 Proxy Statement under the section titled "*Security Ownership of Certain Beneficial Owners and Management*."

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement under the section titled "*Securities Authorized for Issuance Under Equity Compensation Plans*."

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement under the sections titled "*Certain Transactions with Related Persons*" and "*Corporate Governance - Director Independence.*"

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement under the section titled "*Proposal No. 2 Ratification of Appointment of Independent Registered Public Accounting Firm*."

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List the following documents filed as a part of the report:

(1) Financial statements:

See Index to Consolidated Financial Statements at Item 8 herein.

(2) Financial Statement Schedules.

All financial statement schedules have been omitted because the required information is included in the consolidated financial statements or the notes thereto or is not applicable or required.

(3) Exhibits:

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
2.1	Business Combination Agreement, dated as of April 15, 2021, by and among CHFW, Perseverance Merger Sub Inc., and Surrozen, Inc.	8-K	001-39635	2.1	4/15/2021	
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	
4.3	Description of Securities					X
10.1	Investors' Rights Agreement, dated as of August 11, 2021, by and among Surrozen, Inc., Consonance Life Sciences, and certain other investors	8-K	001-39635	10.5	8/17/2021	
10.2+	Surrozen, Inc. 2021 Equity Incentive Plan	10-K	001-39635	10.2	4/10/2024	
10.3+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under 2021 Equity Incentive Plan	10-K	001-39635	10.3	4/10/2024	
10.4+	Form of RSU Grant Package under 2021 Equity Incentive Plan	10-Q	001-39635	10.1	11/08/2023	
10.5+	Surrozen, Inc. 2021 Employee Stock Purchase Plan	10-K	001-39635	10.5	4/10/2024	
10.6	Form of Indemnification Agreement	8-K	001-39635	10.8	8/17/2021	
10.7††	Exclusive (Equity) Agreement, dated as of March 23, 2016, by and between the Board of Trustees of the Leland Stanford Junior University and Surrozen, Inc.	S-4/A	333-256146	10.13	6/24/2021	
10.8††	Amendment No. 1 the Exclusive (Equity) Agreement, dated as of July 5, 2016, by and between the Board of Trustees of the Leland Stanford Junior University and Surrozen, Inc.	S-4/A	333-256146	10.14	6/24/2021	
10.9††	Amendment No. 2 to the Exclusive (Equity) Agreement, dated as of October 7, 2016, by and between the Board of Trustees of the Leland Stanford Junior University and Surrozen, Inc.	S-4/A	333-256146	10.15	6/24/2021	
10.10††	Amendment No. 3 to the Exclusive (Equity) Agreement, dated as of January 19, 2021, by and between the Board of Trustees of the Leland Stanford Junior University and Surrozen, Inc.	S-4/A	333-256146	10.16	6/24/2021	
10.11	Lease Agreement, dated as of August 4, 2016, by and between HCP Oyster Point III LLC and Surrozen, Inc	10-K	001-39635	10.20	3/28/2022	
10.12	Collaboration and License Agreement, dated as of September 30, 2022, by and between Boehringer Ingelheim International GmbH and Surrozen Operating, Inc.	10-Q	001-39635	10.1	11/14/2022	
10.13	Sales Agreement, dated as of December 9, 2022, by and between the Company and Guggenheim Securities, LLC	S-3	333-268745	1.2	12/9/2022	
10.14††	Side Agreement No. 2, relating to the exclusive agreement between Surrozen Operating, Inc. and the Board of Trustees of the Leland Stanford Junior University, dated March 23, 2016, as amended	10-Q	001-39635	10.2	5/10/2023	
10.15	First Amendment to Lease, by and between Surrozen Operating, Inc. and HCP Oyster Point III LLC, dated October 1, 2024.	8-K	001-39635	10.1	10/1/2024	
10.16	Sublease Agreement, dated as of April 19, 2024, by and between Surrozen, Inc. and Nura Bio, Inc.	10-Q	001-39635	10.1	5/8/2024	

10.17	Form of Securities Purchase Agreement, dated April 1, 2024, by and among Surrozen, Inc. and each of the several purchasers signatory thereto.	8-K	001-39635	10.1	4/2/2024	
10.18	Form of Pre-Funded Warrant (April 2024)	8-K	001-39635	10.2	4/2/2024	
10.19	Form of Series A Common Warrant	8-K	001-39635	10.3	4/2/2024	
10.20	Form of Series B Common Warrant	8-K	001-39635	10.4	4/2/2024	
10.21	Form of Series C Common Warrant	8-K	001-39635	10.5	4/2/2024	
10.22	Form of Series D Common Warrant	8-K	001-39635	10.6	4/2/2024	
10.23	Form of Registration Rights Agreement, dated April 1, 2024, by and among Surrozen, Inc. and each of the several purchasers signatory thereto.	8-K	001-39635	10.7	4/2/2024	
10.24	Form of Securities Purchase Agreement, dated March 24, 2025, by and among Surrozen, Inc. and each of the several purchasers signatory thereto.	8-K	001-39635	10.1	3/28/2025	
10.25	Form of Pre-Funded Warrant (March 2025).	8-K	001-39635	10.2	3/28/2025	
10.26	Form of Series E Common Warrant.	8-K	001-39635	10.3	3/28/2025	
10.27	Form of Registration Rights Agreement, dated March 24, 2025, by and among Surrozen, Inc. and each of the several Purchasers signatory thereto.	8-K	001-39635	10.4	3/28/2025	
10.28††	Collaboration Agreement, dated as of October 31, 2024, by and between Surrozen Inc. and TCGFB, Inc.					X
19.1	Insider Trading Policy					X
21.1	List of Subsidiaries	10-K	001-39635	21.1	3/31/2023	
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.					X
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
97.1	Incentive Compensation Recoupment Policy	10-K	001-39635	97.1	4/10/2024	
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Documents					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

+ Indicates management contract or compensatory plan or arrangement.

† Schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

†† The company has redacted provisions or terms of this Exhibit pursuant to Regulation S-K Item 601(b)(10). The Company agrees to furnish an unredacted copy of the Exhibit to the SEC upon its request.

* 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 Annual Report on Form 10-K 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.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized**.**

SURROZEN, INC.

Date: March 31, 2025

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Craig Parker and Charles Williams, and each or any one of them, their true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for them and in their name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-facts and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as they might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their substitutes or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Craig Parker **Craig Parker**	President and Chief Executive Officer and Director *(Principal Executive Officer)*	March 31, 2025
/s/ Charles Williams **Charles Williams**	Chief Financial Officer and Chief Operating Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 31, 2025
/s/ David J. Woodhouse, Ph.D. **David J. Woodhouse, Ph.D.**	Chair of the Board of Directors	March 31, 2025
/s/ Anna Berkenblit, M.D. **Anna Berkenblit, M.D.**	Director	March 31, 2025
/s/ Christopher Chai **Christopher Chai**	Director	March 31, 2025
/s/ Eric Bjerkholt **Eric Bjerkholt**	Director	March 31, 2025
/s/ Mace Rothenberg, M.D. **Mace Rothenberg, M.D.**	Director	March 31, 2025
/s/ Mary Haak-Frendscho, Ph.D. **Mary Haak-Frendscho, Ph.D.**	Director	March 31, 2025
/s/ Shao-Lee Lin, M.D., Ph.D. **Shao-Lee Lin, M.D., Ph.D.**	Director	March 31, 2025
/s/ Tim Kutzkey, Ph.D. **Tim Kutzkey, Ph.D.**	Director	March 31, 2025