UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

o **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 001-39813

TRISALUS LIFE SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-3009869**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6272 W 91st Ave, Westminster, CO	80031
(Address of Principal Executive Offices)	(Zip Code)

(303) 426-1222
Registrant's telephone number, including area code
N/A (Former name, former address and former fiscal year, if changed since last report)

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	**TLSI**	**Nasdaq Global Market**
Warrants, each whole warrant exercisable for one share of registrant's common stock at an exercise price of $11.50 per share	**TLSIW**	**Nasdaq Global Market**

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

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 and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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. (Check one):

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	x

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. o

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

The registrant had 26,316,681 shares of common stock outstanding as of November 12, 2023.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This includes, without limitation, statements regarding the financial position, business strategy and the plans and objectives of management for future operations. These statements constitute projections, forecasts and forward-looking statements, and are not guarantees of performance. We have based these forward-looking statements on our current expectations and projections about future events. Any statements that refer to projections, forecasts or other characterizations of future events or circumstances are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "could," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words or phrases.

These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements in this section, to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q.

We caution you that these forward-looking statements are subject to numerous risks and uncertainties, most of which are difficult to predict and many of which are beyond our control. Some factors that could cause actual results to differ include:

- our ability to recognize the anticipated benefits of the Business Combination (see Note 3 to the condensed consolidated financial statements accompanying this Quarterly Report on Form 10-Q for more information about the Business Combination);
- our ability to maintain the listing of our Common Stock and warrants on the Nasdaq Global Market, and the potential liquidity and trading of such securities;
- changes in applicable laws or regulations;

- our ability to raise financing in the future;
- our ability to retain or recruit, or changes required in, our officers, key employees or directors;
- our ability to successfully commercialize any product candidates that we successfully develop and that are approved by applicable regulatory authorities;
- our expectations for the timing and results of data from clinical trials and regulatory approval applications;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our business, operations and financial performance including:
- our history of operating losses and expectations of significant expenses and continuing losses for the foreseeable future;
- our ability to execute our business strategy, including the growth potential of the markets for our products and our ability to serve those markets;
- our ability to grow market share in our existing markets or any new markets we may enter;
- our ability to develop and maintain our brand and reputation;
- our ability to partner with other companies;
- the size of the addressable markets for our product candidates;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our ability to manage our growth effectively;
- the outcome of any legal proceedings that may be instituted against us; and
- unfavorable conditions in our industry, the global economy or global supply chain, including financial and credit market fluctuations, international trade relations, pandemics, political turmoil, natural catastrophes, warfare and terrorist attacks.

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Should one or more of the risks or uncertainties described in this Quarterly Report on Form 10-Q occur, or should underlying assumptions prove incorrect, actual results and plans could differ materially from those expressed in any forward-looking statements. 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.”

Except to the extent required by applicable law, we are under no obligation (and expressly disclaim any such obligation) to update or revise their forward-looking statements whether as a result of new information, future events, or otherwise. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results, levels of activity and performance as well as other events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

SUMMARY RISK FACTORS

The following is a summary of select risks and uncertainties that could materially adversely affect us and our business, financial condition and results of operations. Before you invest in our common stock, you should carefully consider all the information in this Quarterly Report on Form 10-Q, including matters set forth under the heading “Risk Factors.” These risks include the following, among others:

- We have a limited operating history, have incurred significant losses since our inception and anticipate incurring increasing expenses and continuing losses for the foreseeable future. Our independent registered public accountants and management have expressed substantial doubt as to our ability to continue as a going concern.
- The Asset Purchase Agreement, dated July 31, 2020, we entered into with Dynavax Technologies Corporation (“Dynavax”) in connection with our purchase of SD-101 requires us to make potentially significant payments to Dynavax before we will have regulatory approval of SD-101 and be able to generate revenue from sales of SD-101.
- Until we are able to generate significant revenues or achieve profitability through product sales, we will require substantial additional capital to finance our operations and continue development of our product candidates. We cannot be certain that such additional financing will be available on terms favorable to us, or at all, which could limit our ability to grow and jeopardize our ability to continue our business operations.

- Our revenue is primarily generated from sales of our TriNav device and we are therefore highly dependent on it for our success. Failure to achieve continued market acceptance of TriNav for any reason will harm our business and future prospects.
- TriNav is currently subject to an uncertain reimbursement environment, and any change to TriNav's reimbursement status that reduces its level of reimbursement could cause TriNav revenue to materially decline.
- We currently have a limited marketing, sales and distribution organization. If we are unable to successfully grow our marketing, sales and distribution capabilities, our product revenues related to TriNav, results of operations and financial condition will suffer.
- We are early in our pharmaceutical development efforts and have only one pharmaceutical product candidate, SD-101, in early clinical development. If we are unable to advance our product candidates, including SD-101, in clinical development for any reason (including due to lack of funding), obtain regulatory approval and ultimately commercialize our product candidates, or experiences significant delays in doing so, our business, results of operations, financial condition and prospects may be materially adversely affected.
- Clinical development is a lengthy and expensive process with an uncertain outcome. In addition, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. Failure can occur at any stage of clinical development.
- Changes in existing third-party coverage or our inability to secure advantageous reimbursement codes may impact our ability to sell our products, which would materially and adversely impact our business, results of operations, financial condition and prospects.
- The business and industry in which we participate in are highly competitive. If we are unable to compete effectively, we will not be able to establish our products in the marketplace or grow our products' market share in the marketplace, and as a result, our business and results of operations will be adversely impacted.
- We are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.
- The complexity of a combination product that includes a drug and a medical device, presents additional, unique development and regulatory challenges, which may adversely impact our development plans and our ability to obtain regulatory approval or clearance of our product candidates.
- Failure to obtain, adequately protect, maintain or enforce our intellectual property rights could substantially harm our business and results of operations.
- The expiration or loss of patent protection may adversely affect our future revenues.
- We have limited experience operating as a United States public company and may not be able to adequately develop and implement the governance, compliance, risk management and control infrastructure and culture required for a public company, including compliance with the Sarbanes Oxley Act.
- Our management has identified material weaknesses in its internal control over financial reporting and may identify additional material weaknesses in the future. If we fail to remediate the material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations.
- The price of our Common Stock and Public Warrants has been and may continue to be volatile.

Part I - Financial Information

Item 1. Financial Statements

TRISALUS LIFE SCIENCES, INC.

Condensed Consolidated Balance Sheets
(in thousands except share and per share data)

	September 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Assets		
Cash and cash equivalents	$ 21,383	$ 9,414
Accounts receivable	3,052	1,557
Inventory, net	1,629	1,471
Prepaid expenses	2,977	4,772
Total current assets	29,041	17,214
Property and equipment, net	1,897	2,231
Right-of-use assets	1,252	1,381
Intangible assets, net	997	802
Other assets	367	367
Total assets	$ 33,554	$ 21,995
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Trade payables	$ 1,899	$ 4,947
Accrued liabilities	6,600	6,377
Series B-2 tranche liabilities	—	4,702
Series B-3 warrant liabilities	—	15,819
Short-term lease liabilities	379	370
Other current liabilities	427	142
Total current liabilities	9,305	32,357
Long-term lease liabilities	1,318	1,593
Contingent earnout liability	9,023	—
Warrant liabilities	5,421	369
Total liabilities	25,067	34,319
Commitments and contingencies		
Convertible preferred stock	—	164,006
Stockholders' equity (deficit):		
Preferred stock, Series A, $0.0001 par value per share, $10.00 liquidation value per share. Authorized 10,000,000 and 0 shares at September 30, 2023, and December 31, 2022, respectively; issued and outstanding, 4,015,002 and 0 shares at September 30, 2023, and December 31, 2022, respectively	1	—
Common stock, $0.0001 par value per share. Authorized 400,000,000 and 30,898,162 shares at September 30, 2023, and December 31, 2022, respectively; issued and outstanding, 26,316,681 and 347,926 shares at September 30, 2023, and December 31, 2022, respectively	2	—
Additional paid-in capital	221,351	10,028
Accumulated deficit	(212,867)	(186,358)
Total stockholders' equity (deficit)	8,487	(176,330)
Total liabilities and stockholders' equity (deficit)	$ 33,554	$ 21,995

See accompanying notes to condensed consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

Condensed Consolidated Statements of Operations
(unaudited, in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	$ 5,193	$ 3,923	$ 12,790	$ 9,172
Cost of goods sold	589	701	2,023	1,442
Gross profit	4,604	3,222	10,767	7,730
Operating expenses:				
Research and development	9,367	4,808	21,871	15,091
Sales and marketing	4,689	3,030	11,430	8,881
General and administrative	9,025	3,495	17,498	8,425
Loss from operations	(18,477)	(8,111)	(40,032)	(24,667)
Interest income	116	49	187	75
Interest expense	(4)	—	(13)	—
Loss on equity issuance	—	—	(4,171)	—
Change in fair value of tranche and warrant liabilities	(2,812)	—	660	21
Change in fair value of contingent earnout liability	19,904	—	19,904	—
Other expense, net	(13)	(31)	(56)	(71)
Loss before income taxes	(1,286)	(8,093)	(23,521)	(24,642)
Income tax expense	—	—	8	3
Net loss available to common stockholders	$ (1,286)	$ (8,093)	$ (23,529)	$ (24,645)
Deemed dividend related to Series B-2 preferred stock down round provision	$ —	$ —	$ (2,981)	$ —
Undeclared dividends on Series A preferred stock	$ (458)	$ —	$ (458)	$ —
Net loss attributable to common stockholders	$ (1,744)	$ (8,093)	$ (26,968)	$ (24,645)
Net loss per common share, basic and diluted	$ (0.13)	$ (25.95)	$ (5.68)	$ (82.17)
Weighted average common shares outstanding, basic and diluted	13,173,422	311,823	4,749,849	299,936

See accompanying notes to condensed consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(unaudited, in thousands except share data)

	Nine months ended September 30, 2023						
	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount	Shares	Amount			
At December 31, 2022	—	$ —	347,926	$ —	$ 10,028	$ (186,358)	$ (176,330)
Exercise of options	—	—	95,842	—	50	—	50
Stock-based compensation	—	—	—	—	73	—	73
Deemed dividend	—	—	—	—	959	(959)	—
Net loss	—	—	—	—	—	(8,268)	(8,268)
At March 31, 2023	—	—	443,768	—	11,110	(195,585)	(184,475)
Exercise of options	—	—	4,592	—	16	—	16
Stock-based compensation	—	—	—	—	69	—	69
Deemed dividend	—	—	—	—	2,022	(2,022)	—
Net loss	—	—	—	—	—	(13,974)	(13,974)
At June 30, 2023	—	—	448,360	—	13,217	(211,581)	(198,364)
Exercise of options	—	—	50,646	—	29	—	29
Stock-based compensation	—	—	—	—	259	—	259
Impact of Business Combination							
Conversion of redeemable convertible preferred stock into common stock in connection with the Business Combination	—	—	21,500,867	2	204,234	—	204,236
Assumption of warrants to purchase common stock in connection with the Business Combination	—	—	—	—	(2,568)	—	(2,568)
Issuance of common stock upon closing the Business Combination, net of expenses	—	—	4,316,808	—	957	—	957
Contingent earnout liability recognized upon closing of the Business Combination	—	—	—	—	(28,927)	—	(28,927)
Assumption of preferred stock in connection with the Business Combination	4,015,002	1	—	—	34,150	—	34,151
Net loss	—	—	—	—	—	(1,286)	(1,286)
At September 30, 2023	4,015,002	$ 1	26,316,681	$ 2	$ 221,351	$ (212,867)	$ 8,487

	Nine months ended September 30, 2022				
	Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount			
At December 31, 2021	264,978	$ —	$ 6,738	$ (136,342)	$ (129,604)
Exercise of options	33,747	—	61	—	61
Stock-based compensation	—	—	62	—	62
Net loss	—	—	—	(7,873)	(7,873)
At March 31, 2022	298,725	$ —	$ 6,861	$ (144,215)	$ (137,354)
Exercise of options	9,393	—	5	—	5
Stock-based compensation	—	—	70	—	70
Net loss	—	—	—	(8,679)	(8,679)
At June 30, 2022	308,118	$ —	$ 6,936	$ (152,894)	$ (145,958)
Exercise of options	12,128	—	7	—	7
Stock-based compensation	—	—	119	—	119
Net loss	—	—	—	(8,093)	(8,093)
At September 30, 2022	320,245	$ —	$ 7,062	$ (160,987)	$ (153,925)

See accompanying notes to condensed consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(unaudited, in thousands)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss available to common stockholders	$ (23,529)	$ (24,645)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	500	452
Change in fair value of warrant and tranche liabilities	(660)	(21)
Change in fair value of contingent earnout liability	(19,904)	—
Loss on equity issuance	4,171	—
Stock-based compensation expense	402	251
Loss on disposal of fixed assets	60	50
Milestone payments to Dynavax	1,000	1,000
Changes in operating assets and liabilities:		
Accounts receivable	(1,477)	(936)
Inventory	(158)	6
Prepaid expenses	1,041	(1,306)
ROU assets	130	38
Trade payables, accrued expenses and other liabilities	(2,772)	1,108
Net cash used in operating activities	(41,196)	(24,003)
Cash flows from investing activities:		
Purchases of property and equipment	(216)	(451)
Milestone payments to Dynavax	(1,000)	(1,000)
Cash paid for intellectual property and licenses	(205)	(63)
Net cash used in investing activities	(1,421)	(1,514)
Cash flows from financing activities:		
Proceeds from the issuance of preferred stock	9,189	3,499
Refundable prepayments for Series B-2 preferred stock	—	3,986
Proceeds from exercise of preferred stock warrants	9,630	—
Proceeds from Business Combination	36,854	—
Offering costs related to Business Combination	(1,116)	—
Payments on finance lease liabilities	(65)	(4)
Cash proceeds from the exercise of stock options	94	73
Net cash provided by financing activities	54,586	7,554
Increase (decrease) in cash, cash equivalents and restricted cash	11,969	(17,963)
Cash, cash equivalents and restricted cash, beginning of period	9,664	30,301
Cash, cash equivalents and restricted cash, end of period	$ 21,633	$ 12,338
Supplemental disclosures of cash flow information:		
Supplemental disclosure of noncash items:		
Transfer of warrant liability to preferred stock upon exercise of warrants	$ 25,409	$ —

See accompanying notes to condensed consolidated financial statements.

TriSalus Life Sciences, Inc.

Notes to Condensed Consolidated Financial Statements
(in thousands, except share and per share data)
(Unaudited)

(1) Nature of Business

On August 10, 2023 (the "Closing Date"), TriSalus Life Sciences, Inc., a Delaware corporation (the "Company," "TriSalus," "we," "us"), formerly known as MedTech Acquisition Corporation ("MTAC"), consummated the previously announced merger pursuant to the Agreement and Plan of Merger, dated as of November 11, 2022, as amended by that certain First Amendment to Agreement and Plan of Merger, dated as of April 4, 2023, the Second Amendment to Agreement and Plan of Merger, dated as of May 13, 2023, and the Third Amendment to Agreement and Plan of Merger, dated as of July 5, 2023 (as amended, the "Merger Agreement"), by and between MTAC Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of MTAC ("Merger Sub") and TriSalus Operating Life Sciences, Inc. (formerly known as TriSalus Life Sciences, Inc.), a Delaware corporation ("Legacy TriSalus"), whereby Merger Sub merged with and into Legacy TriSalus with the separate corporate existence of Merger Sub ceasing (the "Merger" and, together with the other transactions contemplated by the Merger Agreement, the "Business Combination") and TriSalus Life Sciences, Inc. becoming the surviving company. The closing of the Business Combination is herein referred to as "the Closing." In connection with the consummation of the Merger, on August 10, 2023, Legacy TriSalus changed its name from TriSalus Life Sciences, Inc. to TriSalus Operating Life Sciences, Inc., and MTAC changed its name from MedTech Acquisition Corporation to TriSalus Life Sciences, Inc., the surviving company ("New TriSalus"). As further described in Note 3, Legacy TriSalus was deemed to be the accounting acquirer and predecessor company in the Business Combination. Thus, the prior periods presented in these consolidated financial statements are of Legacy TriSalus.

Description of the Business

We are engaged in the research, development, and sales of innovative drug delivery technology and immune-oncology therapeutics to improve outcomes in difficult to treat liver and pancreatic cancer. Our technology is utilized in the delivery of our therapeutics and administered by interventional radiologists. We are developing and marketing two product lines — Pressure Enabled Drug Delivery ("PEDD™) infusion systems, in use today, and an investigational agent, SD-101, which shows potential to enhance immune system response in the treatment of hepatocellular cancer, pancreatic cancer and other liver solid tumors. The combination of our PEDD technology with SD-101, is focused on solving the two main barriers in the tumor micro environment that inhibits the success of immunotherapy. The first barrier (mechanical) is comprised of high intratumoral pressure within tumors that limits drug uptake and the second barrier (biological) is the reversal of intratumoral immunosuppression. Our PEDD with SmartValve™ is the only technology designed to work in synchrony with the cardiac cycle to open collapsed vessels in the tumor to enable deeper perfusion and improve therapeutic drug delivery in tumors with high intratumoral pressure. PEDD with SmartValve has been shown in prospective and retrospective clinical studies and in multiple pre-clinical models to improve therapy uptake and tumor response.

TriNav™ is the newest therapy delivery device with SmartValve technology for the proprietary PEDD approach. Current sales consist of the TriNav Infusion System, introduced in 2020, and a family of related guiding catheters. In 2020, we gained transitional pass-through payments ("TPT") approval from the Centers for Medicare & Medicaid Services ("CMS"), which allows hospitals to cover the cost of using TriNav. The approval is scheduled to expire at the end of 2023. On June 1, 2023, TriSalus applied for a new technology Ambulatory Payment Classifications ("APC") code with CMS and met with CMS on June 26, 2023, to review the application. If granted, the new technology APC code would allow for continuing reimbursement for the TriNav device at similar reimbursement rates for the period beginning January 1, 2024, but there can be no assurance that such code will be granted or that continuing reimbursement will be available at similar reimbursement rates, or at all. SD-101 has a dual mechanism of action in solid tumors which includes the alteration of the tumor microenvironment by reducing immunosuppressive myeloid derived suppressor cells while simultaneously activating immune response and recruiting T cells to the tumor, allowing checkpoint inhibitors to work more effectively.

We believe the full potential of our technology can be realized through the combination of our drug delivery technology with immune-oncology drugs. In July 2020, we acquired our first immune-oncology drug, SD-101, and began clinical development of SD-101 for treatment of liver and pancreatic cancers.

We have funded operations to date principally with proceeds from the sale of preferred stock, from the issuance of debt and convertible debt, and the closing of the Business Combination. Since inception of the Company in 2009 through September 30, 2023, we have issued for cash $164,364 of preferred stock (of which $36,854 was raised at the closing of the Business Combination, including issuance of Series A convertible preferred stock), which, along with

$551 from common stock and $44,692 from convertible notes and warrants, has funded our accumulated deficit of $212,867. During the nine months ended September 30, 2023, we raised $9,189 in cash through the issuance of Series B-2 preferred stock, $9,630 in cash through the issuance of Series B-3 preferred stock, $94 from the exercise of stock options, and $36,854 from the Business Combination.

As of September 30, 2023, we had cash and cash equivalents of $21,383. The Company is still in its early stage, has yet to generate revenues sufficient to create positive cash flow and has an accumulated deficit of $212,867 as of September 30, 2023. We are currently undergoing a strategic transformation from a company focused solely on the sale of our infusion systems to a therapeutics company whereby our medical devices will be marketed in combination with the pharmaceutical drugs and other treatments that the devices deliver to patients. This transformation requires that we restructure our operating infrastructure, resulting in an increase in operating expenses — including the development of a candidate pharmaceutical — that, in the short term, will not be fully offset by increased revenues. Without additional financing and based on our sales, operations and research and development plans, our management estimates that our existing cash and cash equivalents will be insufficient to fund our projected liquidity requirements for the next 12 months.

In accordance with ASC Topic 205-40, *Presentation of Financial Statements, Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, we are required to evaluate whether there is substantial doubt about our ability to continue as a going concern each reporting period. In evaluating our ability to continue as a going concern, management projected our cash flow sources and needs and evaluated the conditions and events have raised substantial doubt about our ability to continue as a going concern within one year after the date that these consolidated financial statements were issued. Management's plans to address the conditions and events have considered our current projections of future cash flows, current financial condition, sources of liquidity and debt obligations for at least one year from the date of issuance of these consolidated financial statements in considering whether we have the ability to fund future operations and meet our obligations as they become due in the normal course of business.

Our ability to fund future operations and to continue the execution of our long-term business plan and strategy, including our transformation into a therapeutics company, will require that we raise additional capital through a combination collaborations, strategic alliances and licensing arrangements, and issuance of additional equity and/or long-term debt. There can be no assurance that we will be able to raise such additional financing or, if available, that such financing can be obtained on satisfactory terms. If adequate capital resources are not available on a timely basis, we intend to consider limiting our operations substantially. This limitation of operations could include a hiring freeze, reductions in our workforce, reduction in cash compensation, deferring clinical trials and capital expenditures, and reducing other operating costs.

Our current operating plan, which is in part determined based on our most recent results and trends, along with the items noted above, causes substantial doubt to exist about our ability to continue as a going concern and management's plans do not alleviate the existence of substantial doubt. Our financial statements have been prepared assuming we will continue as a going concern, which contemplates the continuity of normal business activities and realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments that might be necessary should we be unable to continue as a going concern.

We are subject to various risks and uncertainties frequently encountered by companies in the early stages of growth, particularly companies in the rapidly evolving market for medical technology-based and pharmaceutical products and services. Such risks and uncertainties include, but are not limited to, a limited operating history, need for additional capital, a volatile business and technological environment, the process to test and obtain approval to market the candidate pharmaceutical, the process to obtain continuing CMS approval and application for a new ACS code for our PEDD product for reimbursement, an evolving business model, and demand for our products. To address these risks, we must, among other things, gain access to capital in sufficient amounts and on acceptable terms, maintain and increase our customer base, implement and successfully execute our business strategy, develop the candidate pharmaceutical, continue to enhance our technology, provide superior customer service, and attract, retain, and motivate qualified personnel. There can be no guarantee that we will succeed in addressing such risks.

Subsequent Event

On October 2, 2023, we entered into a Standby Equity Purchase Agreement (the "Yorkville Purchase Agreement") with YA II PN, Ltd. ("Yorkville"). Yorkville is a fund managed by Yorkville Advisors Global, LP, headquartered in Mountainside, New Jersey.

Pursuant to the Yorkville Purchase Agreement, the Company shall have the right, but not the obligation, to sell to Yorkville up to $30,000 of common stock, par value $0.0001 per share of the Company (the "Common Stock"), at the Company's request any time during the commitment period commencing on October 2, 2023 (the "Effective Date"), and terminating on the first day of the month following the 24-month anniversary of the Effective Date. Each issuance

and sale by the Company to Yorkville under the Yorkville Purchase Agreement (an "Advance") is subject to a maximum limit equal to the greater of: (i) an amount equal to 100% of the average of the daily volume traded of the Company's Common Stock on the Nasdaq Stock Market ("Nasdaq") for the 10 trading days immediately preceding an Advance notice, or (ii) 1,000,000 shares of Common Stock. The shares will be issued and sold to Yorkville at a per-share price equal to, at the election of the Company as specified in the relevant Advance notice: (i) 96% of the Market Price (as defined below) for any period commencing on the receipt of the Advance notice by Yorkville and ending on 4:00 p.m. New York City time on the applicable Advance notice date (the "Option 1 Pricing Period"), and (ii) 97% of the Market Price for any three consecutive trading days commencing on the Advance notice date (the "Option 2 Pricing Period," and each of the Option 1 Pricing Period and the Option 2 Pricing Period, a "Pricing Period"). "Market Price" is defined as, for any Option 1 Pricing Period, the daily volume-weighted average price ("VWAP") of the Common Stock on Nasdaq, and for any Option 2 Pricing Period, the lowest VWAP of the Common Stock on the Nasdaq during the Option 2 Pricing Period. The Advances are subject to certain limitations, including that Yorkville cannot purchase any shares that would result in it beneficially owning more than 4.99% of the Company's outstanding Common Stock at the time of an Advance or acquiring since the Effective Date under the Yorkville Purchase Agreement more than 19.99% of the Company's outstanding Common Stock, as of the date of the Yorkville Purchase Agreement.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2022, included in MTAC's Proxy Statement/Prospectus filed with the SEC on July 18, 2023. Certain information and footnote disclosures, including significant accounting policies, normally included in fiscal year financial statements prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") have been condensed or omitted. The Condensed Consolidated Balance Sheets as of December 31, 2022, was derived from the audited financial statements. We do not have any activity that would be reported on a Statement of Comprehensive Income.

(a) Cash, Cash Equivalents and Restricted Cash

We consider all highly liquid investments with original maturities of three months or less at time of purchase to be cash equivalents. We invest excess cash primarily in money market funds. At September 30, 2023, we had $8,617 invested in a money market fund, which is is a Level 1 instrument.

(b) Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We periodically review our allowance for doubtful accounts and establish reserves based on management's expectations of realization based on historical write-off experience, as well as current general economic conditions and expectations regarding collection. Account balances are charged against the allowance after all reasonable means of collection have been exhausted and the potential for recovery is considered remote.

(c) Inventory

Inventory is carried at the lower of cost or net realizable value. The balance includes the cost of raw material, and finished goods — including direct labor and manufacturing overhead — and is recorded on the first-in-first-out method. Write-downs for excess and obsolete inventory are charged to cost of goods sold in the period when conditions giving rise to the write-downs are first recognized. Valuation reserves are recorded when, in our best judgment, we determine the carrying value of the affected inventory may be impaired or its cost exceeds its net realizable value.

(d) Property and Equipment

Property and equipment are recorded at cost. Repairs and maintenance costs are expensed as incurred. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from 2 to 7 years. Leasehold improvements are amortized on a straight-line basis over the lesser of estimated useful lives or the lease term.

(e) Impairment and Disposal of Long-Lived Assets

We review long-lived assets and intangible assets (principally patents) for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is generally measured by a comparison of the carrying amount of the asset to future net cash flows

expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amounts of the assets exceed the estimated fair values of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to sell.

(f) Leases

We account for leases in accordance with Accounting Standards Codification ("ASC") Topic 842, *Leases*. We determine if an arrangement is or contains a lease at contract inception, and, if it does, the lease is recorded on the Condensed Consolidated Balance Sheets with right-of-use assets ("ROU") representing the Company's right to use an underlying asset for the lease term and lease liabilities representing our obligation to make lease payments. Lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. Lease ROU assets also include the effect of any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. As the implicit rate in our leases is typically unknown, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. When calculating our incremental borrowing rates, we consider our credit risk, the term of the lease, and total lease payments and adjusts for the impacts of collateral as necessary. The lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

We have elected to not separate lease and non-lease components for any leases within our existing classes of assets and, as a result, account for any lease and non-lease components as a single lease component. We have also elected not to apply the recognition requirement for leases with a term of 12 months or less. We recognize an ROU asset and a lease liability at the lease commencement date.

For operating and finance leases, the lease liability is initially measured at the present value of the unpaid lease payments at the lease commencement date. The lease liability is subsequently measured at amortized cost using the effective-interest method.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received.

For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

For finance leases, the ROU asset is subsequently amortized using the straight-line method from the lease commencement date to the earlier of the end of its useful life or the end of the lease term unless the lease transfers ownership of the underlying asset to the Company or the Company is reasonably certain to exercise an option to purchase the underlying asset. In those cases, the ROU asset is amortized over the useful life of the underlying asset. Amortization of the ROU asset is recognized and presented separately from interest expense on the lease liability. Finance lease ROU assets are presented with property and equipment, net in the Condensed Consolidated Balance Sheets.

(g) Warrant and Tranche Liabilities

Freestanding financial instruments that permit the holder to acquire shares that are either puttable by the holder, redeemable or contingently redeemable are required to be reported as liabilities in the financial statements. We present such liabilities on the Condensed Consolidated Balance Sheets at their estimated fair values. Changes in fair value of the liability are calculated each reporting period, and any change in value is recognized in the Condensed Consolidated Statements of Operations. Historically, we have determined that the warrants issued to investors and lenders which are exercisable for shares of our Series B-3 convertible preferred stock, should be classified as liabilities due to contingent redemption features of the underlying convertible preferred stock. See Note 9 for further discussion.

We determined that both the public and private placement warrants do not meet the criteria to be equity classified and should be recorded as liabilities. Our analysis concluded liability classification under ASC 815, *Derivatives and Hedging*, as these warrants include a provision that could allow cash settlement upon an event outside the control of the Company, and such event may not result in a change in control of the Company. In addition, the private placement warrants include a feature that can require an adjustment of the exercise price in certain circumstances after a change of control. As a result, the Private and Public Warrants do not meet the criteria for equity classification. See Note 9 for further discussion.

The Series B-2 Preferred Stock Financing (as described in Note 11) included second and third tranche rights and obligations to investors who participated in the initial B-2 Preferred Stock Financing round. We offered the Series B-2 preferred stock to all of our preferred stockholders at the time of the initial B-2 Preferred Stock Financing round (representing approximately 99.2% of our then-outstanding shares on an as-converted to common stock basis). The second and third tranche rights and obligations were exercisable into shares of our convertible preferred stock at a specified future date. The second and third tranche rights and obligations are considered freestanding financial instruments, and are classified as liabilities under ASC 480. See Note 11 for further discussion.

(h) Contingent Earnout Liability

In connection with the execution of the Merger Agreement, MTAC entered into a sponsor support agreement (the “Sponsor Support Agreement”) with MedTech Acquisition Sponsor LLC (the "Sponsor”), Legacy TriSalus and MTAC’s directors and officers (the Sponsor and MTAC’s directors and officers, collectively, the “Sponsor Holders”). Pursuant to the Sponsor Support Agreement, 3,125,000 shares of Common Stock in the Company held by the Sponsor Holders immediately after the Closing Date (such shares, the “Sponsor Earnout Shares”) became unvested and subject to potential forfeiture if certain triggering events are not achieved prior to the 5th anniversary of the Closing Date (the “Earnout Period”). The Sponsor Earnout Shares are classified as a liability in the Company’s Condensed Consolidated Balance Sheets because they do not qualify as being indexed to the Company’s own stock. The earnout liability was initially measured at fair value at the Closing Date and is subsequently remeasured at the end of each reporting period. The change in fair value of the earnout liability is recorded in the Condensed Consolidated Statements of Operations. See Notes 3 and 8 for further detail.

(i) Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ significantly from those estimates. The most significant estimates relate to the valuation of earnout, warrant and tranche liabilities, and the valuation allowance on deferred tax assets.

(j) Concentrations of Credit Risk and Other Risks and Uncertainties

Our cash and cash equivalents are deposited primarily with two financial institutions and one investment institution. At times, the deposits in these institutions may exceed the amount of insurance provided on such deposits. We have not experienced any losses in such accounts and believe that we are not exposed to any significant risk on these balances.

(k) Share-Based Compensation

We account for all employee and non-employee share-based compensation awards by recording expense based on the estimated fair value of the awards at the time of grant using the Black-Scholes-Merton option valuation model (“Black-Scholes”). The determination of fair value using an option-pricing model is affected by the estimated fair value of the Company’s stock, as well as assumptions regarding a number of variables including, but not limited to, the fair value of underlying stock at the grant date, expected volatility of the underlying stock over the term of the awards, projected employee stock option exercise behaviors, and risk-free interest rates. We have elected to not include an estimated forfeiture rate in our share-based compensation expense recognition, in accordance with ASC Topic 718, *Compensation — Stock Compensation*, and we account for forfeitures in the period in which they occur. The estimated fair value of options granted is recognized as compensation expense on a straight-line basis over the expected life for each separately vesting portion of the awards. The fair value of options granted to non-employees is periodically reevaluated and adjusted to current fair value.

(l) Segment Reporting

We have determined, in accordance with ASC Topic 280, *Segment Reporting*, that we operate under one operating segment, and therefore one reportable segment, TriSalus. Our Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of assessing performance and allocation resources. All of our long-lived assets, and all of our customers, are located in the United States.

(m) ***Revenue Recognition***

Our revenue is derived from the shipments of our PEDD infusion systems to our customers. Our customers are generally comprised of hospitals, clinics and physicians. Under ASC Topic 606, *Revenue Recognition*, we evaluate five steps to determine the appropriate timing and amount to recognize revenue. The five steps are:

(a) Identify the contract — We do not maintain long-term contracts with our customers. Typically, customers will submit a purchase order to us for delivery of a quantity of our products, which incorporate enforceable rights and obligations constituting the contract with the customer.

(b) Identify the performance obligation — Our performance obligation is to deliver the ordered products in accordance with the terms of the purchase order, which constitutes a single performance obligation. We do not have any on-going service obligation after delivery.

(c) Determine the transaction price — We maintain a single sales price for each of our products, which is generally fixed. We do not have a history of any significant refunds, allowances or other concessions provided to our customers from the agreed-upon sales price after delivery of the product.

(d) Allocate the transaction price – We do not have multiple performance obligations to complete when we fulfill a purchase order, therefore, the transaction price is fully allocated to the units being sold.

(e) Recognize revenue – We recognize revenue at the point-in-time when the units for a purchase order have been shipped and control of the units has transferred to the customer, as evidenced by the delivery terms on the shipping documents. Typically, we ship Ex Works, so we recognize revenue when the shipment leaves our premises. In a small number of cases, the purchase order specifies alternate shipping terms, usually DAP (delivery at place). In those cases, we defer revenue recognition until we are assured the units have been delivered and control has transferred to the customer.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*. Current GAAP requires an "incurred loss" methodology for recognizing credit losses that delays recognition until it is probable a loss has been incurred. ASU 2016-13 replaces the current incurred loss methodology for credit losses and removes the thresholds that companies apply to measure credit losses on financial statements measured at amortized cost, such as loans, receivables, and held-to-maturity debt securities with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to form credit loss estimates. The determination of the allowance for credit losses under the new standard would typically be based on evaluation of a number of factors, including, but not limited to, general economic conditions, payment status, historical collection patterns and loss experience, financial strength of the borrower, and nature, extent and value of the underlying collateral. For smaller reporting companies, ASU 2016-13 is effective for fiscal years and for interim periods within those fiscal years beginning after December 15, 2022. It requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. We adopted ASU 2016-13 on January 1, 2023. The effect of the adoption had an immaterial impact on our condensed consolidated financial statements.

(3) Business Combination

On August 10, 2023, we consummated the previously announced merger pursuant to the Merger Agreement by and among MTAC, Merger Sub, Inc., and TriSalus Life Sciences, Inc. Upon the closing of the transactions contemplated by the Merger Agreement, Merger Sub merged with and into Legacy TriSalus (the "Business Combination") with Legacy TriSalus surviving the merger as a wholly-owned subsidiary of MTAC, renamed "TriSalus Operating Life Sciences, Inc." In addition, in connection with the consummation of the Business Combination, MTAC was renamed "TriSalus Life Sciences, Inc."

Immediately prior to the effective time of the Merger, each in-the-money warrant of Legacy TriSalus that was unexercised and unexpired was automatically net exercised into the respective series of preferred stock of Legacy TriSalus. Each share of preferred stock of Legacy TriSalus ("Legacy TriSalus Preferred Stock") that was issued and outstanding was then automatically converted into shares of common stock of Legacy TriSalus ("Legacy TriSalus Common Stock") in accordance with the Amended and Restated Certificate of Incorporation of Legacy TriSalus at the then current conversion price, such that each converted share of Legacy TriSalus Preferred Stock was no longer outstanding and ceased to exist, and each holder of Legacy TriSalus Preferred Stock thereafter ceased to have any rights with respect to such securities.

At the Closing Date, by virtue of the Business Combination and without any action on the part of MTAC, Merger Sub, Legacy TriSalus or the holders of any of the following securities:

(a) each share of Legacy TriSalus Common Stock (including shares of Legacy TriSalus Common Stock resulting from the conversion of shares of TriSalus Preferred Stock described above) that was issued and outstanding immediately prior to the Effective Time were exchanged at an exchange ratio of 0.02471853 (the "Exchange Ratio") for an aggregate of 21,999,886 shares of our Common Stock;

(b) each option to purchase shares of Legacy TriSalus Common Stock, whether vested or unvested, converted into an option to purchase shares of our Common Stock ("TriSalus Assumed Option"), with each TriSalus Assumed Option subject to the same terms and conditions as were applicable to the original Legacy TriSalus option and with the resulting exercise price and number of shares of TriSalus Common Stock purchasable based on the Exchange Ratio and other terms contained in the Merger Agreement; and

(c) each Legacy TriSalus restricted stock unit ("RSU") award converted into a restricted stock unit award to receive shares of our Common Stock ("TriSalus Assumed RSU Award"), with each TriSalus Assumed RSU Award subject to the same terms and conditions as were applicable to the original Legacy TriSalus restricted stock unit award, and with the number of shares of TriSalus Common Stock to which the TriSalus Assumed RSU Award relates being based on the Exchange Ratio and other terms contained in the Merger Agreement.

The Business Combination was accounted for as a reverse recapitalization in conformity with accounting principles generally accepted in the United States. Under this method of accounting, MTAC was treated as the "acquired" company for financial reporting purposes. This determination was primarily based on the fact that subsequent to the Business Combination, the Legacy TriSalus stockholders have a majority of the voting power of TriSalus, Legacy TriSalus comprises all of our ongoing operations, Legacy TriSalus has appointed a majority of our governing body, and Legacy TriSalus' senior management comprises all of our senior management. Accordingly, for accounting purposes, the financial statements of the combined entity represented a continuation of the financial statements of Legacy TriSalus with the business combination being treated as the equivalent of Legacy TriSalus issuing stock for the net assets of MTAC, accompanied by a recapitalization. Operations prior to the Business Combination are those of Legacy TriSalus. Reported shares and earnings per share available to holders of the Company's common stock, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination (1.0 share of Legacy TriSalus for approximately 0.02471853 shares of TriSalus).

Proceeds from this transaction totaled $42,854. These proceeds were comprised of $2,704 from the MTAC trust account, and $40,150 received from the assumption of a concurrent private investment in public equity financing ("PIPE Financing"). Pursuant to the terms of the Merger Agreement, $6,000 of the proceeds were used to pay expenses incurred by MTAC related to the merger, resulting in net cash proceeds of $36,854. The Company incurred $6,069 in transaction costs relating to the merger with MTAC, of which $1,742 was recorded as a reduction of equity and the balance of $4,327 was recorded in general and administrative expense.

Pursuant to the terms of the Merger Agreement, the existing stockholders of Legacy TriSalus exchanged their interests for shares of common stock of TriSalus. In addition, MTAC had previously issued public warrants and private placement warrants (collectively, the "MTAC Warrants") as part of its initial public offering in November 2020. None of the terms of the MTAC Warrants were modified as a result of the Business Combination. On the Closing Date, the Company recorded a liability related to the MTAC Warrants of $2,568. During the period from August 10, 2023, to September 30, 2023, the fair value of the MTAC Warrants increased to $5,421, resulting in a loss on the change in fair value of $2,853 and a gain of $660 in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2023, respectively.

Immediately following the Business Combination, there were 26,316,681 shares of our Common Stock outstanding, options and RSUs to purchase an aggregate of 2,816,224 shares of common stock and warrants outstanding to purchase 14,266,605 shares of common stock.

PIPE Financing

On the Closing Date, certain investors agreed to purchase an aggregate of 4,015,002 newly-issued shares of Series A Convertible Preferred Stock at a purchase price of $10.00 per share for an aggregate purchase price of $40,150, pursuant to separate subscription agreements dated June 7, 2023, and July 4, 2023 (collectively, the "Subscription Agreements"). See Note 11 for further discussion.

Sponsor Earnout

In connection with the execution of the Merger Agreement, MTAC entered into the Sponsor Support Agreement. Pursuant to the Sponsor Support Agreement, the 3,125,000 Sponsor Earnout Shares became unvested and subject to potential forfeiture if certain triggering events are not achieved prior to the 5th anniversary of the Closing Date. Pursuant to the Sponsor Support Agreement, (i) 25% of the shares of our Common Stock held by the Sponsor Holders will only vest if, during the five year period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $15.00 for any 20 trading days within a period of 30 consecutive trading days, (ii) 25% of the shares of our Common Stock held by the Sponsor Holders will only vest if, during the five year period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $20.00 for any 20 trading days within a period of 30 consecutive trading days, (iii) 25% of the shares of our Common Stock held by the Sponsor

Holders will only vest if, during the five year period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $25.00 for any 20 trading days within a period of 30 consecutive trading days; and (iv) 25% of the shares of our Common Stock held by the Sponsor Holders will only vest if, during the five year period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $30.00 for any 20 trading days within a period of 30 consecutive trading days. Additionally, the Sponsor Earnout Shares will vest if there is a change in control of our company on or before the 5th anniversary of the Closing Date that results in the holders of our Common Stock receiving a price per share equal to or in excess of the applicable earnout targets. Any such shares held by the Sponsor Holders that remain unvested after the 5th anniversary of the Closing will be forfeited.

(4) Financial Instruments

Our financial instruments consist of cash, cash equivalents, accounts receivable, accounts payable, contingent earnout liability, and warrants to purchase preferred and common stock. The carrying values of these financial instruments (other than warrants and tranche liabilities, which are held at fair value) approximate fair value at September 30, 2023, and December 31, 2022. In general, asset and liability fair values are determined using the following categories:

Level 1 — Inputs utilize quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs include quoted prices for similar assets or liabilities in active markets, and inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly.

Level 3 — Inputs are unobservable inputs and include situations where there is little, if any, market activity for the balance sheet items at period end. Pricing inputs are unobservable for the terms and are based on the Company's own assumptions about the assumptions that a market participant would use.

Our warrant, tranche and earnout liabilities are measured at fair value on a recurring basis.

Financial Instruments After Business Combination

The carrying amount of our outstanding MTAC warrants liabilities was $5,421 at September 30, 2023. The carrying amount of outstanding earnout liability was $9,023 at September 30, 2023. These carrying values of the warrant liabilities represent the remeasurement to fair value each reporting period based on Level 1 inputs for the publicly traded MTAC Warrants and Level 2 inputs for the private placement MTAC Warrants. The carrying amounts of the contingent earnout liability represent the remeasurement to fair value each reporting period based on unobservable, or Level 3, inputs, using assumptions made by us, including the market price of our common stock and the observed volatility of a peer group of companies.

At the Closing Date, we assumed warrants to purchase 14,266,605 shares of common stock for $11.50 (see Note 9). Of these, 8,333,272 are traded publicly and 5,933,333 are privately held. At the Closing Date, we determined the fair value of all the warrants to be $2,568 based on the closing price of $0.18 for the publicly traded warrants (Level 1).

At the Closing Date, we determined the fair value of the earnout liability to be $28,927 based on a Monte Carlo simulation of future trading prices for our common stock. See Note 8 for further discussion.

The following tables summarize the changes in fair value of our outstanding earnout liability in the nine months ended September 30, 2023. The warrant and earnout liability were not present in the nine months ended September 30, 2022.

Level 3 Liabilities	Fair Value at December 31, 2022	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Net Transfer In (Out) of Level 3	Fair Value at September 30, 2023
Contingent earnout liability	$ —	$ (19,904)	$ 28,927	$ —	$ 9,023

Financial Instruments Prior to the Business Combination

Our warrants and tranche liabilities are measured at fair value on a recurring basis. The carrying amount of outstanding warrant liabilities was zero and $16,188 at September 30, 2023, and December 31, 2022, respectively. The carrying amount of outstanding tranche liabilities was zero and $4,702 at September 30, 2023, and December 31, 2022, respectively. These carrying values represent the remeasurement to fair value each reporting period based on unobservable inputs, or Level 3 inputs, using assumptions made by us, including the probabilities assigned to a status quo scenario and the potential closing of the Business Combination (see Note 3) scenario, the value of the Series B-3 Warrants (as defined below) upon closing of the Business Combination, the fair value of the Company, the fair value of the underlying preferred stock, the Company's volatility, discount rate, and expected term of the related instrument.

See Note 9 for further discussion. These assumptions require significant judgment on the part of management and actual outcomes may materially differ from those estimated by management.

In March 2023, we sold shares of Series B-2 preferred stock with accompanying warrants to purchase Series B-3 preferred stock as part of the Second Tranche Closings (see Note 9). At issuance, the warrants issued to purchase Series B-3 preferred stock had a fair value of $4,654 and were classified as a liability. The issuance of the Series B-2 preferred stock and accompanying warrants to purchase Series B-3 preferred stock as part of the Second Tranche Closings resulted in a $584 loss on equity issuance.

In June 2023, we sold shares of Series B-2 preferred stock with accompanying warrants to purchase Series B-3 preferred stock as part of the Second Tranche Closings (see Note 9). At issuance, the warrants issued to purchase Series B-3 preferred stock had a fair value of $10,047 and were classified as a liability. The issuance of the Series B-2 preferred stock and accompanying warrants to purchase Series B-3 preferred stock as part of the Second Tranche Closings resulted in a $3,425 loss on equity issuance.

Immediately prior to the exercise of the warrants to purchase Series B-3 preferred stock in February, March, June and July 2023, the associated liabilities were remeasured to fair value.

In July 2023, warrants to purchase 2,239,309 shares of Series B-3 preferred stock were exercised for $4,530.

At the Closing Date of the Business Combination, all in-the-money outstanding warrants and Series B-3 Warrants were remeasured to fair value, net-exercised, converted to shares of common stock of Legacy TriSalus, and then exchanged for shares of TriSalus common stock at the Exchange Ratio. Out-of-the-money warrants expired, resulting in a gain on expiration of $18. The Series B-2 tranche liabilities also expired at the Closing Date of the Business Combination.

The following tables summarize the changes in fair value of our outstanding warrant and tranche liabilities measured using Level 3 inputs in the nine months ended September 30, 2023 and 2022:

Level 3 Liabilities	Fair Value at December 31, 2021	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Net Transfer In (Out) of Level 3	Fair Value at September 30, 2022
Warrant liability	$391	$(19)	$—	$—	$372

Level 3 Liabilities	Fair Value at December 31, 2022	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Net Transfer In (Out) of Level 3	Fair Value at September 30, 2023
Warrant liability	$ 369	$ —	$ (369)	$ —	$ —
Series B-2 tranche liabilities	$ 4,702	$ (3,200)	$ (1,502)	$ —	$ —
Series B-3 Warrant liabilities	$ 15,819	$ (311)	$ (15,508) (1)	$ —	$ —

(1) This amount includes settlements of $25,409, and final net exercise of $4,800, transferred to convertible preferred stock, offset by issuances of $14,701

(5) Cash, cash equivalents and restricted cash

Cash, cash equivalents and restricted cash, as presented in the Condensed Consolidated Statements of Cash Flows, consisted of the following:

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 21,383	$ 9,414
Restricted cash (included in Other assets)	250	250
Total cash, cash equivalents and restricted cash shown in the Condensed Consolidated Statements of Cash Flows	$ 21,633	$ 9,664

Restricted cash is $250 held by our bank to support our corporate credit card program.

(6) Inventory

The components of inventory are summarized as follows:

	September 30, 2023	December 31, 2022
Raw materials	$ 289	$ 753
Finished goods	1,340	718
Inventory, net	$ 1,629	$ 1,471

Finished goods amounts include a reserve for excess or obsolete inventory of nil and $43 as of September 30, 2023, and December 31, 2022.

(7) Accrued Liabilities

Accrued Liabilities consists of the following:

	September 30, 2023	December 31, 2022
Accrued liabilities	$ 3,404	$ 2,905
Accrued bonus	2,706	2,896
Accrued vacation	475	329
Accrued payroll	15	247
Total accrued liabilities	$ 6,600	$ 6,377

(8) Contingent Earnout Liability

As described in Note 2 and Note 3, in connection with the execution of the Merger Agreement, MTAC entered into the Sponsor Support Agreement with the Sponsor Holders and Legacy TriSalus, pursuant to which, 3,125,000 of the shares of our Common Stock held by the Sponsor immediately after the Closing Date became unvested and subject to potential forfeiture if certain triggering events are not achieved during the Earnout Period. The earnout shares are classified as a liability and were initially measured at fair value at the Closing Date and will subsequently be remeasured at the end of each reporting period with the change in fair value of the earnout liability recorded in the Condensed Consolidated Statements of Operations.

The estimated fair value of the total contingent earnout liability at the closing on August 10, 2023, was $28,927 based on a Monte Carlo simulation valuation model. The liability was remeasured to its fair value of $9,023 as of September 30, 2023. This remeasurement resulted in the recording of $19,904 for the three and nine months ended September 30, 2023, classified as change in fair value of contingent earnout liability in the Condensed Consolidated Statements of Operations. Assumptions used in the valuation are described below:

	September 30, 2023	August 10, 2023
Current stock price	$ 5.12	$ 11.34
Expected share price volatility	65.0 %	65.0 %
Risk-free interest rate	4.6 %	4.2 %
Expected term (years)	4.9	5
Estimated dividend yield	— %	— %

The estimated fair value of the liability was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes. The inputs and assumptions utilized in the calculation require management to apply judgment and make estimates including:

(a) expected volatility, which is based on the historical equity volatility of publicly traded peer companies for a term equal to the expected term of the earnout period;

(b) expected term, which we based on the earnout period per the agreement;

(c) risk-free interest rate, which was determined by reference to the U.S. Treasury yield curve for time periods commensurate with the expected term of the earnout period; and

(d) expected dividend yield, which we estimate to be zero based on the fact that we have never paid or declared dividends.

These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with exact precision.

(9) Warrants

Warrants outstanding at September 30, 2023, and December 31, 2022, are as follows:

	September 30, 2023	December 31, 2022
Public Warrants	8,333,272	—
Private Placement Warrants	5,933,333	—
Series B-3 Warrants	—	15,819,000
Total warrants	14,266,605	15,819,000

Public and Private Placement Warrant Liabilities

In connection with consummation of the Business Combination, the Company assumed the warrant liabilities associated with 8,333,272 MTAC Public Warrants. Each Public Warrant is exercisable to purchase one share of common stock at a price of $11.50 per share, subject to adjustment. As of September 30, 2023, there were 8,333,272 Public Warrants outstanding.

The Public Warrants will become exercisable 30 days after the completion of the Business Combination. The Public Warrants expire 5 years after the completion of the Business Combination or earlier upon redemption or liquidation.

On August 31, 2023, the Company filed an amended registration statement on Form S-1 a(as may be amended from time to time) with the SEC registering the issuance of the shares of common stock issuable upon exercise of the warrants and will use its best efforts to cause such registration statement to become effective and to maintain a current prospectus relating to those shares of common stock until the warrants expire or are redeemed, as specified in the warrant agreement.

Once the warrants become exercisable, the Company may redeem for cash the outstanding Public Warrants:

a. in whole and not in part;

b. at a price of $0.01 per Public Warrant;

c. upon not less than 30 days' prior written notice of redemption to each warrant holder; and

d. if, and only if, the reported closing price of the Common Stock equals or exceeds $18.00 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 three business days before the Company sends the notice of redemption to the warrant holders.

If and when the warrants become redeemable by the Company, the Company may exercise its redemption right even if it is unable to register or qualify the underlying securities for sale under all applicable state securities laws.

If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis." The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, except as described below, the warrants will not be adjusted for issuances of common stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants. Accordingly, the warrants may expire worthless.

In addition to the Public Warrants, the Company assumed the warrant liabilities associated with 5,933,333 MTAC Private Placement Warrants. The Private Placement Warrants are identical to the Public Warrants, except that the Private Placement Warrants and the common stock issuable upon the exercise of the Private Placement Warrants will not be transferable, assignable or saleable until 30 days after the completion of the Business Combination, subject to certain limited exceptions. Additionally, the Private Placement Warrants will be exercisable on a cashless basis and be non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants. As of September 30, 2023, there were 5,933,333 Private Placement Warrants outstanding.

We determined that both the Public and Private placement Warrants do not meet the criteria to be equity classified and should be recorded as liabilities. Our analysis concluded liability classification under ASC 815, *Derivatives and*

Hedging, as these warrants include a provision that could allow cash settlement upon an event outside the control of the Company, and such event may not result in a change in control of the Company. As a result, the Private and Public Warrants do not meet the criteria for equity classification.

At the close of the Business Combination, the fair values of the Public Warrants and Private Placement Warrants were $1,500 and $1,068, respectively. As of September 30, 2023, the fair values of the Public Warrants and Private Placement Warrants were $3,166 and $2,255, respectively. The fair value of the Public Warrants has been measured based on the quoted price of such warrants on the Nasdaq Global Market. The transfer of Private Placement Warrants to anyone outside of a small group of individuals who are permitted transferees would result in the Private Placement Warrants having substantially the same terms as the Public Warrants. Therefore, we determined that the fair value of each Private Warrant is equivalent to that of each Public Warrant.

Series B-3 Warrants

The Series B-3 Warrants were issued in conjunction with shares of Series B-2 preferred stock in October 2022, March 2023 and May 2023. Each warrant allowed the holder to purchase one share of Series B-3 preferred stock for $0.05. The Series B-3 Warrants expired at the earlier of October 5, 2028, or the closing date of a change of control transaction. All in-the-money warrants that were outstanding at a change of control transaction would automatically net exercise.

In July 2023, Series B-3 Warrants to purchase 2,239,309 shares of Series B-3 preferred stock were exercised for $4,530. At the Closing Date of the Business Combination, all in-the-money outstanding warrants and Series B-3 Warrants were net-exercised and converted to shares of common stock of Legacy TriSalus, then exchanged for shares of TriSalus common stock. Out-of-the-money warrants for other classes of preferred stock expired. The Series B-2 tranche liabilities also expired at the Closing Date of the Business Combination.

Subsequent Event: Warrant Repurchase Program

In August 2023, our Board approved a warrant repurchase program, authorizing the repurchase of some or all of the Public Warrants (the “Warrant Repurchase Program”). The Board authorized an aggregate expenditure of up to $4,000 for such repurchases. The repurchases may be made from time to time in open market or privately negotiated transactions. We may adopt one or more purchase plans pursuant to Rule 10b5-1 under the Exchange Act, in order to implement the Warrant Repurchase Program. The Warrant Repurchase Program does not obligate us to purchase any Public Warrants and may be terminated, increased or decreased by the Board in its discretion at any time. We adopted a purchase plan in October 2023. Through October 31, 2023, we had repurchased 28,502 Public Warrants for $10.

(10) Income Taxes

At the end of each interim period, we make our best estimate of the effective tax rate expected to be applicable for the full calendar year and use that rate to provide for income taxes on a current year-to-date basis before discrete items. If a reliable estimate cannot be made, we may make a reasonable estimate of the annual effective tax rate, including use of the actual effective rate for the year-to-date. The impact of the discrete items is recorded in the quarter in which they occur.

We utilize the balance sheet method of accounting for income taxes and deferred taxes which are determined based on the differences between the financial statements and tax basis of assets and liabilities given the provisions of the enacted tax laws. In assessing the realizability of the deferred tax assets, we considered whether it is more likely than not that some portion or all of the deferred tax assets will not be realized through the generation of future taxable income. In making this determination, we assessed all of the evidence available at the time including recent earnings, forecasted income projections, and historical financial performance. We have fully reserved deferred tax assets as a result of this assessment.

Based on our full valuation allowance against the net deferred tax assets, our effective federal tax rate for the calendar year is zero, and we recorded an immaterial income tax expense in the nine months ended September 30, 2023 and 2022.

(11) Preferred Stock

Series A Convertible Preferred Stock

At the Closing Date, we issued 4,015,002 shares of Series A Convertible Preferred Stock for $40,150.

As of September 30, 2023, the Company is authorized to issue up to 10,000,000 shares of preferred stock with 5,984,998 shares available for issuance. The original issue price of the Series A Convertible Preferred Stock was

$10.00. The Series A Convertible Preferred Stock accrues cumulative dividends at the rate of 8.00% per annum on the original issue price. As of September 30, 2023, total undeclared cumulative dividends were $458. We have not recorded the undeclared dividends in our condensed consolidated financial statements.

All shares of Series A Convertible Preferred Stock had the following rights:

(i) Conversion

(a) Optional Conversion

The Series A Convertible Preferred Stock are convertible at any time at the option of the holder thereof into the number of shares of our Common Stock determined by the quotient of (i) the sum of $10.00 (as adjusted for any stock dividend, stock split, reverse stock split, combination or similar event affecting the Series A Convertible Preferred Stock) (the “Liquidation Preference”) and, if we have not elected to otherwise pay the accrued Annual Dividends (as defined below) in cash to the holder, the accrued Annual Dividends on such shares as of the date of conversion, divided by (ii) the Conversion Price (as defined in our Certificate of Designations, Preferences, and Rights of Series A Convertible Preferred Stock (the "Certificate of Designations")) of such shares in effect at the time of conversion.

(b) Automatic Conversion

On the four-year anniversary of the Closing, all then outstanding shares of Series A Convertible Preferred Stock shall automatically convert into the number of shares of our Common Stock equal to the quotient of (i) the sum of the Liquidation Preference and if we had not elected to otherwise pay the accrued Annual Dividends in cash to the holder, the accrued Annual Dividends on such shares as of the date of conversion, divided by (ii) the Conversion Price of such shares in effect at the time of conversion.

(ii) Voting Rights

Holders of the Series A Convertible Preferred Stock are entitled to vote with the holders of our Common Stock on all matters submitted to a vote of our stockholders, except as otherwise provided in the Certificate of Designations or as required by applicable law, voting together with the holders of our Common Stock as a single class. Each holder is entitled to a number of votes in respect of the shares of Series A Convertible Preferred Stock owned as of the record date by it, or if no such record date is established, as of the date such vote is taken or any written consent of stockholders is solicited, equal to the quotient of (i) $10.00 divided by (ii) the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of our Common Stock as determined at Closing.

As long as any shares of Series A Convertible Preferred Stock are outstanding, we shall not, without the affirmative vote of the Holders of a majority of the then-outstanding shares of the Series A Convertible Preferred Stock, (i) amend, alter, repeal or otherwise modify any provision of our certificate of incorporation or the Certificate of Designations in a manner that would alter or change the terms or the powers, preferences, rights or privileges of the Series A Convertible Preferred Stock as to affect them adversely; (ii) authorize, create, increase the authorized amount of, or issue any class or series of capital stock senior to the Series A Convertible Preferred Stock; (iii) increase the authorized number of shares of Series A Convertible Preferred Stock or enter into any agreement with respect to the foregoing.

(iii) Dividends

Holders of the Series A Convertible Preferred Stock are entitled to participate equally in any dividends declared to holders of Common Stock. In addition, each holder of the Series A Convertible Preferred Stock is entitled to receive cumulative annual dividends that accrue and accumulate on a daily basis at a rate per annum (calculated on the basis of an actual 365- or 366-day year, as applicable) equal to 8.00% of the original issue price of $10.00 per share (the "Annual Dividends”). The Annual Dividends will be either paid in cash, paid by issuing fully paid and nonassessable shares of Common Stock, or a combination thereof when, as and if authorized and declared by our Board. Upon conversion or a change of control, any unpaid Annual Dividends will be paid to the holders, either in the form of common stock upon a conversion, or in cash upon a change of control. So long as any shares of Series A Convertible Preferred Stock remain outstanding, unless all Annual Dividends on all outstanding shares of Series A Convertible Preferred Stock have been declared and paid in cash, we will be prohibited from declaring any dividends on, or making any distributions relating to, other classes of our capital stock ranking junior to the Series A Convertible Preferred Stock, subject to certain exceptions.

(iv) Anti-dilution Provisions

The initial Conversion Price of $10.00 is subject to customary adjustments in the case of certain distributions to holders of our Common Stock payable in shares of our Common Stock, subdivisions, splits or combinations of the shares of our Common Stock and distributions to all holders of shares of our Common Stock of any convertible securities or options or any other assets for which there is no corresponding distribution in respect of the Series A Convertible Preferred Stock.

The Conversion Price will automatically reset upon each of February 10, 2025, and July 10, 2027, the eighteen-month and forty-seven-month anniversaries of the Closing Date, to be equal to the lowest of:

(i) Initial Conversion Price, subject to adjustments for stock dividends and distributions or other distributions made to common stockholders for which there is no corresponding distribution for Preferred Stock,

(ii) the then-current Conversion Price, and

(iii) the higher of 1) the Floor Price ($2.10 per share) or 2) the trailing ten-Trading Day VWAP of the Common Stock determined as of the date of such reset.

(iv) Liquidation Preferences

The terms of the Series A Convertible Preferred Stock provide for liquidation preferences in the event of a change in control, liquidation, dissolution, or certain other fundamental transactions of the Company (a "Liquidation Event"), none of which were deemed probable as of September 30, 2023. The Liquidation Preferences of $10.00 per share, plus all unpaid dividends, are payable prior to payment to any class of capital stock that is junior to the Series A Convertible Preferred Stock.

If the assets of the Company or the consideration received in such Liquidation Event are insufficient to make payment of the full Liquidation Preferences to all holders of Series A Convertible Preferred Stock, then such assets will be distributed ratably to the holders of Series A Convertible Preferred Stock in proportion to the full amounts to which they would otherwise have been entitled. After payment of the aforementioned Liquidation Preferences, any remaining proceeds from a Liquidation Event will be distributed to all classes of capital stock that are junior to the Series A Convertible Preferred Stock pro rata on an as-if converted basis.

Legacy TriSalus Preferred Stock

Since inception, we have issued various series of preferred stock as described below. As described in Note 3, all of the Legacy TriSalus Preferred Stock was converted to Legacy TriSalus Common Stock immediately prior to the Merger and, upon consummation of the Merger, were exchanged for shares of our Common Stock. In accordance with the terms of the Legacy TriSalus Preferred Stock, upon an acquisition of the Company, the proceeds would be used to first pay the liquidation preferences on the preferred stock prior to payment to common stockholders. We have determined this is an in-substance redemption feature since holders of preferred stock represent a majority of our Board and control a majority of the stockholder vote on an as-if-converted basis. Thus, a decision to pursue an acquisition or accept the terms of an acquisition — and thereby redeem the convertible preferred stock — was deemed to be outside of our control. As a result, the Legacy TriSalus Preferred Stock has been classified as temporary equity in the accompanying Condensed Consolidated Balance Sheets. We have not adjusted the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as the instruments were not currently redeemable and we believed it was not probable that the instruments would become redeemable.

Convertible preferred stock at September 30, 2023, August 10, 2023, and December 31, 2022, is as follows:

Series	September 30, 2023	August 10, 2023	December 31, 2022
Series A-1 preferred stock, $0.001 par value per share. Issued, and outstanding 0 and 131,797 shares at September 30, 2023, and December 31, 2022, respectively	$ —	$ 6,065	$ 6,065
Series A-2 preferred stock, $0.001 par value per share. Issued, and outstanding 0 and 576,126 shares at September 30, 2023, and December 31, 2022, respectively	—	8,976	8,976
Series A-3 preferred stock, $0.001 par value per share. Issued, and outstanding 0 and 612,822 shares at September 30, 2023, and December 31, 2022, respectively	—	10,611	10,611
Series A-4 preferred stock, $0.001 par value per share. Issued, and outstanding 0 and 127,787 shares at September 30, 2023, and December 31, 2022, respectively	—	1,993	1,993
Series A-5 preferred stock, $0.001 par value per share. Issued and outstanding 0 shares at September 30, 2023;authorized 734,533, issued and outstanding 730,320 and December 31, 2022	—	12,858	12,858
Series A-6 preferred stock, $0.001 par value per share. Issued and outstanding 0 shares at September 30, 2023; authorized 805,848, issued and outstanding 800,657 at December 31, 2022	—	15,476	15,476
Series B preferred stock, $0.001 par value per share. Issued and outstanding 0 shares at September 30, 2023; authorized 7,021,678, issued and outstanding 6,984,971 at December 31, 2022, respectively	—	84,637	84,528
Series B-1 preferred stock, $0.001 par value per share. Issued, and outstanding 0 shares at September 30, 2023, authorized, issued and outstanding 1,659,672 at and December 31, 2022	—	23,500	23,499
Series B-2 preferred stock, $0.001 par value per share. Issued and outstanding 0 and 706,243 shares at September 30, 2023, and December 31, 2022, respectively	—	—	—
Series B-3 preferred stock, $0.001 par value per share. Issued and outstanding 0 and 0 shares at September 30, 2023, and December 31, 2022, respectively	—	39,858	—
Total convertible preferred stock	$ —	$ 203,974	$ 164,006

The following table summarizes activity in convertible preferred stock in the nine months ended September 30, 2023, and 2022.

Series	Balance at December 31, 2022	Issuances	Retirements / Conversions	Balance at September 30, 2023
Series A-1	$ 6,065	$ —	$ (6,065)	$ —
Series A-2	8,976	—	(8,976)	—
Series A-3	10,611	—	(10,611)	—
Series A-4	1,993	—	(1,993)	—
Series A-5	12,858	—	(12,858)	—
Series A-6	15,476	—	(15,476)	—
Series B	84,528	109	(84,637)	—
Series B-1	23,499	1	(23,500)	—
Series B-2	—	—	—	—
Series B-3	—	39,858	(39,858)	—
Total convertible preferred stock	$ 164,006	$ 39,968	$ (203,974)	$ —

Series	Balance at December 31, 2021	Issuances	Balance at September 30, 2022
Series A-1	$ 6,065	$ —	$ 6,065
Series A-2	8,976	—	8,976
Series A-3	10,611	—	10,611
Series A-4	1,993	—	1,993
Series A-5	12,858	—	12,858
Series A-6	15,476	—	15,476
Series B	84,528	—	84,528
Series B-1	20,000	3,499	23,499
Total convertible preferred stock	$ 160,507	$ 3,499	$ 164,006

Warrants to purchase convertible preferred stock at September 30, 2023, and December 31, 2022, are as follows:

Series	September 30, 2023	December 31, 2022
Series A-5 preferred stock, $17.81 exercise price	—	4,213
Series A-6 preferred stock, $20.23 exercise price	—	5,190
Series B preferred stock, $0.41 exercise price	—	36,707
Series B-3 preferred stock, $2.03 exercise price	—	2,824,974
Total warrants	—	2,871,084

The following table summarizes activity in warrants to purchase preferred stock in the nine months ended September 30, 2023. There was no activity in the nine months ended September 30, 2022.

Series	Balance at December 31, 2022	Exercises	Issuances	Retirements / Conversions	Balance at September 30, 2023
Series A-5	4,213	—	—	(4,213)	—
Series A-6	5,190	—	—	(5,190)	—
Series B	36,707	(11,123)	—	(25,584)	—
Series B-3	2,824,974	(4,771,642)	2,595,777	(649,109)	—

The Series A-5 and A-6 warrants were retired at the Closing Date as they were out-of-the money. The Series B and B-3 warrants were net-converted to shares of Legacy TriSalus Common Stock, then exchanged for shares of our Common Stock at the Closing Date.

The rights associated with the Legacy TriSalus Preferred Stock are described in our December 31, 2022, financial statements included in MTAC's definitive proxy statement filed with the SEC on July 18, 2023.

October 2022 Financing

In early October 2022, we sold 706,243 shares of Series B-2 preferred stock in a private financing, primarily to existing stockholders, at a price of $14.16 per share, raising approximately $9,755 in net proceeds (the "B-2 Preferred Stock Financing"). For each share sold, we also issued a warrant to purchase four shares of Series B-3 preferred stock (with total warrants issued being for 2,824,974 shares of Series B-3 preferred stock) with a strike price of $2.03 per share. The B-2 Preferred Stock Financing included, at our audit committee's option, a second tranche for the sale of up to 518,854 shares of Series B-2 preferred stock for $7,347 (which could be increased up to $10,000 through the sale of additional shares), with each such share of Series B-2 preferred stock accompanied by a warrant to purchase four shares of Series B-3 preferred stock at a strike price of $2.03 per share, for a total of 2,075,417 shares of Series B-3 preferred stock, and a third tranche, at the election of investors who participated in the second tranche, for the sale of up to 306,053 shares of Series B-2 preferred stock for $4,334 (which could be increased up to an aggregate of 353,121 shares of Series B-2 preferred stock for approximately $5,000 through the sale of additional shares of Series B-2 preferred stock), with each such share of Series B-2 preferred stock accompanied by a warrant to purchase eight shares of Series B-3 preferred stock at a strike price of $2.03 per share, for a total of 2,448,428 shares of Series B-3 preferred stock. Investors can elect to not participate in the second tranche, and thereby give up their rights to participate in the third tranche, but such election would cause all of their shares of Series B-2 preferred stock and Series B-3 preferred stock to immediately convert to common stock and any warrants to purchase Series B-3 preferred stock to convert to warrants to purchase common stock.

As a result of the issuance of the Series B-2 preferred stock, accompanying warrants to purchase Series B-3 preferred stock, and the second and third tranche rights and obligations, the anti-dilution feature of all prior issued preferred stock series was triggered. In accordance with the anti-dilution rights in the Company's certificate of incorporation, and in connection with the initial closing of the B-2 Preferred Stock Financing, the conversion prices of the Company's preferred stock (i) were adjusted to $1.06 for Series A-1 preferred stock, $0.33 for Series A-2 preferred stock, $0.37 for Series A-3 preferred stock, $0.34 for Series A-4 preferred stock, $0.37 for Series A-5 preferred stock, $0.42 for Series A-6 preferred stock, $0.26 for Series B preferred stock, and $0.30 for Series B-1 preferred stock and (ii) set to $0.35 for Series B-2 preferred stock and $0.05 for Series B-3 preferred stock, which correlate to approximate (in each case rounded to three decimals) exchange ratios of 1.155 to 1 for Series A-1 preferred stock, 1.173 to 1 for Series A-2 preferred stock, 1.162 to 1 for Series A-3 preferred stock, 1.165 to 1 for Series A-4 preferred stock, 1.189 to 1 for Series A-5 preferred stock, 1.190 to 1 for Series A-6 preferred stock, 1.154 to 1 for Series B preferred stock, 1.167 to 1 for Series B-1 preferred stock, 1 to 1 for Series B-2 preferred stock and 1 to 1 for Series B-3 preferred stock.

We offered the Series B-2 preferred stock to all of our existing preferred stockholders (representing approximately 99.2% of our then-outstanding shares on an as-converted to common stock basis) to continue to fund our operations through the expected period for completing the Business Combination (see Note 11), including expenses expected to be incurred in connection with the Business Combination and readying ourselves to be a public company. Board members, executives and other employees who participated in the B-2 Preferred Stock Financing did so under the same terms as other holders who do not provide services. As such, the Company concluded the B-2 Preferred Stock Financing was not compensatory and is not within the scope of ASC Topic 718, *Compensation — Stock Compensation*.

The warrants to purchase Series B-3 preferred stock ("Series B-3 Warrants") represent freestanding financial instruments that should be recognized as a liability as we are required to deliver puttable shares upon exercise of the warrants, which may be ultimately settled for cash due to the in-substance redemption feature, as described above. Similarly, the combined rights and obligations for the second and third tranches for Series B-2 preferred stock ("Series B-2 Tranche Liability") represents a freestanding financial instrument that should be classified as a liability under ASC 480 as, (i) the decision to exercise the tranche is outside of our control, as holders of Series B-2 preferred stock represent a majority of our Audit Committee (which, pursuant to the financing agreements for the B-2 Preferred Stock Financing determines whether to call the second tranche), and (ii) the Company is required to deliver puttable shares upon execution of the tranches rights and obligations, which may be ultimately settled in cash. Both the Series B-3 Warrants and the Series B-2 Tranche Liability are classified as liabilities and are presented on the accompanying Condensed Consolidated Balance Sheets at their estimated fair values at each reporting date and immediately prior to settlement with the resulting change in fair value recognized in earnings.

2023 Financing

In January through September 2023, holders of warrants to purchase 4,771,642 shares of Series B-3 preferred stock exercised their purchase rights, for proceeds of approximately $9,630. In addition, $25,409 of warrant liabilities was transferred to Series B-3 preferred stock. Also, holders of warrants to purchase 11,123 shares of Series B preferred stock exercised their purchase rights, for proceeds of $4, plus the transfer of warrant liabilities of $106 to Series B preferred stock.

In March 2023, we effectuated closings ("Second Tranche Closings") of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 207,541 shares of Series B-2 preferred stock and accompanying warrants to purchase 830,167 shares of Series B-3 preferred stock, representing 40% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $2,932, net of execution costs, and (ii) 17,656 shares of Series B-2 preferred stock and accompanying warrants to purchase 70,624 shares of Series B-3 preferred stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $250. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution rights in the Company's certificate of incorporation, the conversion prices of the Company's preferred stock were adjusted. The conversion prices were further adjusted as a result of the June 2023 exercise of a portion of the second tranche of the B-2 Preferred Stock Financing described below, which represent the conversion prices in effect on the Closing Date.

In May 2023, we amended the Series B-2 preferred stock agreement and warrant agreement to purchase Series B-3 preferred stock to extend the expiration date for the second tranche from February 28, 2023, to May 31, 2023.

In June 2023, we effectuated closings of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 257,779 shares of Series B-2 preferred stock and accompanying warrants to purchase 1,031,116 shares of Series B-3 preferred stock, representing approximately 49.7% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $3,650, and (ii) 165,967 shares of Series B-2 preferred stock and accompanying warrants to purchase 663,868 shares of Series B-3 preferred stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $2,350. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution rights in the Company's certificate of incorporation, the conversion prices of the Company's preferred stock (i) were adjusted to $38.84 for Series A-1 preferred stock, $12.14 for Series A-2 preferred stock, $13.36 for Series A-3 preferred stock, $12.55 for Series A-4 preferred stock, $13.36 for Series A-5 preferred stock, $14.97 for Series A-6 preferred stock, $9.71 for Series B preferred stock, and $10.93 for Series B-1 preferred stock and (ii) remained the same for Series B-2 preferred stock $14.16 and Series B-3 preferred stock $2.03, which correlate to approximate (in each case rounded to three decimals) exchange ratios of 1.275 to 1 for Series A-1 preferred stock, 1.290 to 1 for Series A-2 preferred stock, 1.303 to 1 for Series A-3 preferred stock, 1.277 to 1 for Series A-4 preferred stock, 1.333 to 1 for Series A-5 preferred stock, 1.351 to 1 for Series A-6 preferred stock, 1.250 to 1 for Series B preferred stock, 1.296 to 1 for Series B-1 preferred stock, 1 to 1 for Series B-2 preferred stock and 1 to 1 for Series B-3 preferred stock. These conversion prices remained in effect at the Closing Date. Any portion of the Series B-3 Warrants that remained unexercised at the time the Business Combination is consummated were automatically net settled for shares of Legacy TriSalus Common Stock immediately prior to the closing of the Business Combination (see Note 3) and exchanged into shares of our Common Stock at the Closing Date.

The fair value of the Series B-3 Warrants as of December 31, 2022, was determined using a probability-weighted expected outcome model whereby the following two scenarios were probability-weighted based on the Company's expectation of each occurring: (1) a status quo scenario whereby the Company would continue as a private company and (2) a scenario where the Business Combination would close. The fair value of the Series B-3 Warrants as of August 10, 2023, was determined solely using the scenario where the Business Combination would close. Under the status quo scenario, the Series B-3 Warrants, including warrants to be issued under the second and third tranches, were valued using the Black-Scholes model. The fair value of the Series B-2 Tranche Liability was determined using a Binomial Tranche Model. Both models incorporated the following significant assumptions for the respective valuation dates:

	December 31, 2022
Series B-2 preferred stock fair value per share	$14.97
Series B-2 preferred stock exercise price per share	$14.16
Series B-3 preferred stock fair value per share	$3.24
Series B-3 Warrants exercise price per share	$2.03
Volatility	50.0% – 65.0%
Risk free rate	4.0% – 4.7%
Series B-2 Tranche Liability expected term	0.2 – 0.4 years
Series B-3 Warrants expected term	5.8 – 6.0 years
Expected dividends	—

The fair value of the underlying shares of Series B-2 preferred stock and the Series B-3 Warrants used in these models were derived from estimates of the Company's equity fair value using the Guideline Public Company Method, specifically revenue multiples of comparable public companies were multiplied by the Company's forecasted 2023 and

2024 revenue. The valuation of Series B-3 Warrants under the Business Combination scenario incorporates an estimate of the fair value of the underlying Series B-3 preferred stock upon the close of the Business Combination of $9.31 and $10.93 per share, as of August 10, 2023, and December 31, 2022, respectively, which is based upon the enterprise value stated in the Merger Agreement of $220,000 allocated to all outstanding shares of preferred stock, warrants to purchase preferred stock, and common stock on an as-if converted basis, and for the December 31, 2022 valuation, discounted at 30% from the expected Business Combination Closing Date. The Business Combination scenario as of August 10, 2023, and December 31, 2022, assumed there would be no additional exercises of the second and third tranches, and thus no value was assigned to the outstanding tranche rights and obligations, as the Company would not exercise its right to call the remaining second tranche.

The fair value of the Series B-3 Warrant Liabilities at issuance resulting from the completion of the Second Tranche Closings was estimated at $14,701. The excess of the warrant liability's fair value compared to the proceeds received in the Second Tranche Closings resulted in a charge to loss on equity issuance in the Condensed Consolidated statements of operations of $4,171 for the nine months ended September 30, 2023.

(12) Net Loss per Share

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. During periods where we might earn net income, we would allocate to participating securities a proportional share of net income determined by dividing total weighted-average participating securities by the sum of the total weighted-average common shares and participating securities (the "two-class method"). Our preferred stock participates in any dividends declared by us and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods where we incurred net losses, we allocate no loss to participating securities because they have no contractual obligation to share in our losses. We computed diluted loss per common share after giving consideration to the dilutive effect of stock options and warrants that are outstanding during the period, except where such nonparticipating securities would be antidilutive. Because we have reported net losses for the nine-month periods ended September 30, 2023 and 2022, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following potentially dilutive securities (in common stock equivalent shares) have been excluded from the computation of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported:

	September 30,	
	2023	2022
Preferred stock	4,015,002	11,624,155
Preferred stock warrants	—	46,111
Common stock warrants	14,266,605	—
Restricted stock units	184,018	—
Options to purchase common stock	2,632,206	1,710,860
	21,097,831	13,381,126

As described in Note 9, the triggering of the anti-dilution feature resulting from the closing of the second tranche of the Initial Preferred Stock Financing decreased the conversion prices applicable to all outstanding shares for previously issued preferred stock. As a result, a deemed dividend to the preferred stockholders of $2,981 was recorded as an increase in the net loss attributable to common stockholders reflected in our unaudited Condensed Consolidated Statements of Operations for the nine months ended September 30, 2023. The deemed dividend increased the net loss per common share by $0.72 for the nine months ended September 30, 2023.

(13) Share-Based Compensation

We currently maintain the 2023 Equity Incentive Plan (the "2023 Plan"), which our Board of Directors and stockholders approved in connection with the Business Combination for purposes of granting equity-based incentive awards to our employees and consultants, including our executive officers and directors. Prior to the Business Combination, TriSalus granted equity incentive awards under the 2009 Amended and Restated Equity Incentive Plan (the "2009 Plan"). The 2009 Plan will not be used following the Business Combination. However, any awards granted under the 2009 Plan remain subject to the terms of the 2009 Plan and the applicable award agreement. Historically, we have used options as an incentive for long-term compensation to our executive officers because options allow our executive officers to realize value from this form of equity compensation only if the value of the underlying equity securities increase relative to the option's exercise price, which exercise price is set at the fair market value of the underlying equity securities on the grant date.

Under the 2023 Plan, the Company's Board may grant equity-based incentive awards to employees, consultants and other service providers of the Company and its affiliates within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended. Initially, 5,585,008 shares were authorized under the 2023 Plan. In addition, the share reserve will automatically increase on January 1 of each year for a period of 10 years, commencing on January 1, 2024, and ending on January 1, 2033, in an amount equal to (1) five percent of the total number of shares of the fully diluted Common Stock determined on December 31 of the preceding year, or (2) a lesser number of shares of Common Stock determined by our Board prior to January 1 of a given year. During the nine months ended September 30, 2023, we granted 1,179,480 options with a weighted average fair value of $2.66, and 184,018 restricted stock units with a weighted average fair value of $2.43. As of September 30, 2023, the balances under the two plans are below.

	September 30, 2023		
	Authorized	**Outstanding**	**Available for Issue**
2009 Plan	1,915,724	1,915,724	—
2023 Plan	5,585,008	900,500	4,684,508
Total	7,500,732	2,816,224	4,684,508

As of September 30, 2023, we had unrecognized compensation expense of $250 and $337, respectively, for options and RSUs granted under the 2009 Plan, and $3,002 for options granted under the 2023 Plan.

Our Board, or a duly authorized committee thereof, administers the 2023 Plan. Our Board may also delegate to one or more of our officers the authority to, among other things, (1) designate employees (other than officers) to receive specified stock awards and (2) determine the number of shares subject to such stock awards. Under the 2023 Plan, the Board has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value and exercise price, and the provisions of each stock award, including the exercise period and the vesting schedule applicable to a stock award, subject to the limitations of the 2023 Plan.

Stock options are granted with an exercise price no less than 100% of the estimated fair value of a share of Common Stock at the date of grant.

(14) Dynavax Purchase

In July 2020, we purchased all of the intellectual property and trial drug substance for SD-101 from Dynavax Technologies ("Dynavax"). We did not acquire any equity in Dynavax, nor any production facilities or personnel; this was a purchase of in-process research and development ("IPR&D"). SD-101, an investigational agent in development, is a toll-like receptor 9 ("TLR9") agonist which is believed to bind to the TLR9 receptors found on suppressive immune cells including myeloid-derived suppressor cells ("MDSCs") and antigen-presenting immune cells. Toll-like receptors play a key role in the innate immune system and create a bridge to adaptive immunity. It is believed that activating TLR9 primes immune cells to promote anti-tumor T cell function. We believe that SD-101, when delivered using our PEDD devices, can improve therapeutic distribution to solid tumors and improve outcomes for liver metastases and pancreatic cancer. We initiated a clinical study to evaluate SD-101 for the treatment of uveal melanoma liver metastases in September 2021, and initiated an additional study, for primary liver tumors, in March 2022.

Payments under the Dynavax purchase agreement consist of: (a) one upfront payment of $9,000 that was split into two payments ($5,000 and $4,000, paid in July and December 2020, respectively), (b) milestone payments upon the achievement of certain development and commercial milestones, and (c) royalty payments based on aggregate annual net sales after SD-101 receives FDA approval to be sold.

The milestone payments range from $1,000 to $10,000, triggered by development achievements for each of up to four indications. The development milestone payments cannot exceed $170,000. We have made milestone payments of $1,000 in September 2021, after initiating our clinical study of uveal melanoma liver metastases, June 2022, after initiating our clinical study for primary liver tumors, and August 2023, after initiating our clinical study for pancreatic cancer.

In addition, we will have to pay up to four commercial milestones, $10,000 upon first commercial sale of the product; $20,000 upon the first occurrence of $250,000 in annual net sales; $20,000 upon the first occurrence of $500,000 in annual net sales; and $30,000 upon the first occurrence of $1,000,000 in annual net sales. In aggregate, the commercial milestones shall not exceed $80,000.

We will also pay annual royalties at the rate of 10% for aggregate annual net sales less than or equal to $1,000,000 and 12% for aggregate annual net sales above that amount.

We record the milestone payments in R&D expense when they are incurred. We have reflected these milestone payments in the Consolidated Statements of Cash Flows as investing activities to reflect the contractual investment in the IPR&D. The milestone payments and royalty payments are contingent upon future events and therefore will also be recorded as expense when it is probable that a milestone has been achieved or when royalties are due.

(15) Commitments and Contingencies

From time to time, we may have certain contingent liabilities, including litigation, which arise in the ordinary course of its business activities. We accrue contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. In the opinion of management, there are no pending claims for which the outcome is expected to result in a material adverse effect on our consolidated financial position, results of operations, or cash flows.

Pursuant to the Amended and Restated Registration Rights Agreement, subject to certain requirements and customary conditions, the Company also grants piggyback registration rights and demand registration rights to the parties thereto, will pay certain expenses related to such registrations and will indemnify the parties thereto against certain liabilities related to such registrations. The Company’s registration obligations under the Amended and Restated Registration Rights Agreement will terminate with respect to any party thereto on the date that such party no longer holds any Registrable Securities (as defined in the Amended and Restated Registration Rights Agreement). The Amended and Restated Registration Rights Agreement does not contain liquidated damages or other cash settlement provisions resulting from delays in registering the Company’s securities.

We are not a party to any legal proceedings and we are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited interim consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. Information included in this Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). This information may involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of TriSalus Life Sciences, Inc., (the "Company"), to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. Forward-looking statements, which involve assumptions and describe future plans, strategies and expectations of the Company, are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. These forward-looking statements are based on assumptions that may be incorrect, and there can be no assurance that these projections included in these forward-looking statements will come to pass. Actual results of the Company could differ materially from those expressed or implied by the forward-looking statements as a result of various factors. Except as required by applicable laws, the Company has no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

For purposes of this discussion, "TriSalus," "the Company," "we," "us" or "our" refer to TriSalus Life Sciences, Inc. (which changed its name to TriSalus Operating Life Sciences, Inc. in connection with the Business Combination) and its subsidiaries prior to the consummation of the Business Combination and TriSalus Life Sciences, Inc. (formerly known as MedTech Acquisition Corporation) after the consummation of the Business Combination, unless the context otherwise requires.

Overview

We are engaged in the research, development, and sales of innovative drug delivery technology and immune-oncology therapeutics to improve outcomes in difficult to treat liver and pancreatic cancer. Our technology is utilized in the delivery of our therapeutics and administered by interventional radiologists. We are developing and marketing two product lines: Pressure Enabled Drug Delivery ("PEDD") infusion systems, in use today, and an investigational agent, called SD-101, which shows potential to enhance immune system response in the treatment of hepatocellular cancer, pancreatic cancer and other solid tumors in the liver. The combination of our PEDD technology with SD-101, is focused on solving the two main barriers in the tumor micro environment that inhibits the success of immunotherapy. The first barrier (mechanical) is comprised of high intratumoral pressure within tumors that limits drug uptake and the second barrier (biological) is the reversal of intratumoral immunosuppression.

In 2020, we also launched TriNav™, which is the newest delivery device with SmartValve technology for our proprietary PEDD approach. Current sales consist of the TriNav Infusion System, introduced in 2020, and a family of related guiding catheters. In 2020, we gained transitional pass-through payments ("TPT") approval from the Centers for Medicare & Medicaid Services ("CMS"), which allows hospitals to cover the cost of using TriNav. The approval began in January 2020 and is scheduled to expire at the end of 2023. On June 1, 2023, TriSalus applied for a new technology Ambulatory Payment Classifications ("APC") code with CMS and met with CMS on June 26, 2023, to review the application. If granted, the new technology APC code would allow for continuing reimbursement for the TriNav device at similar reimbursement rates for the period beginning January 1, 2024, but there can be no assurance that such code will be granted or that continuing reimbursement will be available at similar reimbursement rates or at all. SD-101 has a dual mechanism of action in solid tumors which includes the alteration of the tumor microenvironment by reducing immunosuppressive myeloid derived suppressor cells while simultaneously activating immune response and recruiting T-cells to the tumor, allowing checkpoint inhibitors to work more effectively.

We are currently in our early stage of development and have yet to generate revenues sufficient to drive positive cash flows from operations. Beginning in 2020, we began a strategic transformation from a company focused solely on the sale of our infusion systems to a therapeutic company whereby our medical devices are marketed in combination with the pharmaceutical drugs and other treatments that the devices deliver to patients. This transformation led us to acquire our first immune-oncology drug, SD-101, in July 2020, and to begin clinical development of SD-101 for the treatment of liver and pancreatic cancers.

The Business Combination

On November 11, 2022, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with MedTech Acquisition Corporation ("MTAC") and MTAC Merger Sub, Inc., a wholly owned subsidiary of MTAC ("Merger Sub"), pursuant to which, TriSalus would merge with and into Merger Sub, with TriSalus surviving the merger and becoming a wholly owned subsidiary of MTAC (the "Business Combination"). The aggregate

consideration payable to the stockholders of TriSalus was $220.0 million, payable in 22,000,000 shares of Combined Company Common Stock.

On August 8, 2023, the stockholders of MTAC approved the Business Combination, and the Business Combination closed on August 10, 2023. Pursuant to the Merger Agreement, 890,020,482 shares of TriSalus common stock (after conversion of all outstanding shares of preferred stock and all in-the-money warrants) were exchanged for approximately 22,000,000 shares of MTAC common stock, reflecting an exchange ratio of approximately 0.02471853. All share and per share amounts of our common and preferred stock have been retrospectively adjusted for the exchange ratio in the following discussion.

Following the consummation of the Business Combination, we were deemed the accounting acquirer and is accounting for the Business Combination as a reverse recapitalization.

Factors Affecting Our Performance

We believe that our performance and future success depend on several factors that present significant opportunities for us but also pose risks and challenges, including liquidity and those discussed below:

1) *The continued acceptance and growth of TriNav in the marketplace*. While we believe TriNav to be a superior technology for the delivery of therapies to tumors, particularly high-density tumors, there are other technologies with which we compete. Our ability to grow TriNav sales depends on the skills of our sales force and the willingness of the marketplace to use TriNav.

2) *Our ability to maintain our current TriNav pricing and gross margins to help fund the rest of our activities.* Our current pricing allows us to generate a substantial gross margin, which provides funds to support our growth and our research and development ("R&D") for both TriNav and SD-101. TriNav sells at a significant premium to competitive products. Our higher price is currently supported by the TPT payment program from CMS; however, the current TPT authorization expires on December 31, 2023. On June 1, 2023, TriSalus applied for a new technology Ambulatory Payment Classifications ("APC") code with CMS and met with them on June 26, 2023, to review the application. If granted, the new technology APC code would allow for continuing reimbursement for the TriNav device at similar reimbursement rates for the period beginning January 1, 2024, but there can be no assurance that such code will be granted or that continuing reimbursement will be available at similar reimbursement rates or at all. If we are unable to obtain such permanent reimbursement or continuing reimbursement is not available at similar reimbursement rates, we may be forced to reduce our price to compete, which would impact our margins.

3) *The success and cost of our clinical trials of SD-101*. SD-101 is in Phase 1 human trials to determine if, when delivered via TriNav, it is safe and effective in treating certain cancers. As with all drug candidates, the cost of operating clinical trials can be substantial, with no guarantee that the trials will result in favorable data.

4) *Obtaining FDA approval of SD-101 for sale*. Our clinical trials are still in early stages, and there is no certainty that we will generate favorable data or that, upon review, the FDA will approve SD-101 for sale.

Recent Developments

Preferred Stock Financing

In October 2022, we sold 706,243 shares of Series B-2 preferred stock in a private financing, primarily to existing stockholders, at a price of $14.16 per share (raising approximately $9.8 million, net of issuance costs) (the "Initial Preferred Stock Financing"). For each share sold, we also issued a warrant to purchase four shares of Series B-3 preferred stock for no additional consideration (warrants to purchase an aggregate of 2,824,974 shares of Series B-3 preferred stock were issued in the Initial Preferred Stock Financing). The strike price of the warrants issued was $2.03 per share. The Initial Preferred Stock Financing included, at the unilateral option of the Company's Audit Committee, a second tranche for to the sale of up to 518,854 shares of Series B-2 preferred stock for approximately $7.3 million (which could be increased up to an aggregate of 706,243 shares of Series B-2 preferred stock for approximately $10.0 million), with each such share of Series B-2 preferred stock accompanied by a warrant to purchase four shares of Series B-3 preferred stock at a strike price of $2.03 per share (warrants to purchase up to an aggregate of 2,075,417 shares of Series B-3 preferred stock may be issued in closings of the second tranche of the Initial Preferred Stock Financing assuming the full $10.0 million is sold); and a third tranche, at the unilateral election of investors who participated in the second tranche, for the sale of up to 306,053 shares of Series B-2 preferred stock, for approximately $4.3 million (which could be increased up to an aggregate of 353,121 shares of Series B-2 preferred stock for approximately $5.0 million), with each such share of Series B-2 preferred stock accompanied by a warrant to purchase eight shares of Series B-3 preferred stock at a strike price of $2.03 per share (warrants to purchase up to an aggregate of 2,824,974 shares of Series B-3 preferred stock may be issued in the third tranche closing assuming the full $5.0 million is sold). We made offers to participate in the Series B-2 preferred stock financing to all of our existing preferred stockholders (representing approximately 99.2% of our then outstanding shares on an as converted to

common stock basis) to continue to fund our operations through the Closing of our Business Combination, including our expenses in connection with the Business Combination and readying ourselves to be a public company.

In March 2023, we effectuated closings ("Second Tranche Closings") of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 207,541 shares of Series B-2 preferred stock and accompanying warrants to purchase 830,167 shares of Series B-3 preferred stock, representing 40% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $2.9 million, net of execution costs, and (ii) 17,656 shares of Series B-2 preferred stock and accompanying warrants to purchase 70,624 shares of Series B-3 preferred stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $250. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution rights in the Company's certificate of incorporation, the conversion prices of the Company's preferred stock were adjusted. The conversion prices were further adjusted as a result of the June 2023 exercise of a portion of the second tranche of the B-2 Preferred Stock Financing described below, which represent the conversion prices in effect on the Closing Date.

In May 2023, we amended the Series B-2 preferred stock agreement and warrant agreement to purchase Series B-3 preferred stock to extend the expiration date for the second tranche from February 28, 2023, to May 31, 2023.

In June 2023, we effectuated closings of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 257,779 shares of Series B-2 preferred stock and accompanying warrants to purchase 1,031,116 shares of Series B-3 preferred stock, representing approximately 49.7% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $3.7 million, and (ii) 165,967 shares of Series B-2 preferred stock and accompanying warrants to purchase 663,868 shares of Series B-3 preferred stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $2,350. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution rights in the Company's certificate of incorporation, the conversion prices of the Company's preferred stock (i) were adjusted to $38.84 for Series A-1 preferred stock, $12.14 for Series A-2 preferred stock, $13.36 for Series A-3 preferred stock, $12.55 for Series A-4 preferred stock, $13.36 for Series A-5 preferred stock, $14.97 for Series A-6 preferred stock, $9.71 for Series B preferred stock, and $10.93 for Series B-1 preferred stock and (ii) remained the same for Series B-2 preferred stock $14.16 and Series B-3 preferred stock $2.03, which correlate to approximate (in each case rounded to three decimals) exchange ratios of 1.275 to 1 for Series A-1 preferred stock, 1.290 to 1 for Series A-2 preferred stock, 1.303 to 1 for Series A-3 preferred stock, 1.277 to 1 for Series A-4 preferred stock, 1.333 to 1 for Series A-5 preferred stock, 1.351 to 1 for Series A-6 preferred stock, 1.250 to 1 for Series B preferred stock, 1.296 to 1 for Series B-1 preferred stock, 1 to 1 for Series B-2 preferred stock and 1 to 1 for Series B-3 preferred stock. These conversion prices remained in effect at the Closing Date. Any portion of the Series B-3 Warrants that remained unexercised at the time the Business Combination is consummated were automatically net settled for shares of Legacy TriSalus Common Stock immediately prior to the closing of the Business Combination (see Note 3) and exchanged into shares of our Common Stock at the Closing Date.

In July 2023, holders of warrants to purchase 2,239,977 shares of Series B-3 preferred stock exercised their purchase rights for proceeds of approximately $4.5 million.

Subsequent Events

Warrant Repurchase Program

In August 2023, our Board approved a warrant repurchase program, authorizing the repurchase of some or all of the Public Warrants (the "Warrant Repurchase Program"). The Board authorized an aggregate expenditure of up to $4.0 million for such repurchases. The repurchases may be made from time to time in open market or privately negotiated transactions. We may adopt one or more purchase plans pursuant to Rule 10b5-1 under the Exchange Act, in order to implement the Warrant Repurchase Program. The Warrant Repurchase Program does not obligate us to purchase any Public Warrants and may be terminated, increased or decreased by the Board in its discretion at any time. We adopted a purchase plan in October 2023. Through October 31, 2023, we had repurchased 28,502 Public Warrants for $9.9 thousand.

Standby Equity Purchase Agreement

On October 2, 2023, we entered into a Standby Equity Purchase Agreement (the "Yorkville Purchase Agreement") with YA II PN, Ltd. ("Yorkville"). Yorkville is a fund managed by Yorkville Advisors Global, LP, headquartered in Mountainside, New Jersey.

Pursuant to the Yorkville Purchase Agreement, we shall have the right, but not the obligation, to sell to Yorkville up to $30.0 million of our Common Stock at our request any time during the commitment period commencing on October 2, 2023 (the "Effective Date"), and terminating on the first day of the month following the 24-month

anniversary of the Effective Date. Each issuance and sale by us to Yorkville under the Yorkville Purchase Agreement (an "Advance") is subject to a maximum limit equal to the greater of: (i) an amount equal to 100% of the average of the daily volume traded of our Common Stock on the Nasdaq Stock Market ("Nasdaq") for the 10 trading days immediately preceding an Advance notice, or (ii) 1,000,000 shares of Common Stock. The shares will be issued and sold to Yorkville at a per share price equal to, at our election as specified in the relevant Advance notice: (i) 96% of the Market Price (as defined below) for any period commencing on the receipt of the Advance notice by Yorkville and ending on 4:00 p.m. New York City time on the applicable Advance notice date (the "Option 1 Pricing Period"), and (ii) 97% of the Market Price for any three consecutive trading days commencing on the Advance notice date (the "Option 2 Pricing Period," and each of the Option 1 Pricing Period and the Option 2 Pricing Period, a "Pricing Period"). "Market Price" is defined as, for any Option 1 Pricing Period, the daily volume weighted average price ("VWAP") of the Common Stock on Nasdaq, and for any Option 2 Pricing Period, the lowest VWAP of the Common Stock on the Nasdaq during the Option 2 Pricing Period. The Advances are subject to certain limitations, including that Yorkville cannot purchase any shares that would result in it beneficially owning more than 4.99% of our outstanding Common Stock at the time of an Advance (the "Ownership Limitation") or acquiring since the Effective Date under the Yorkville Purchase Agreement more than 19.99% of our outstanding Common Stock, as of the date of the Yorkville Purchase Agreement.

Components of Results of Operations

The following discussion sets forth certain components of our consolidated statements of operations as well as factors that impact those items.

Revenue

We currently operate in one reportable segment and revenue is generated from sales of PEDD infusion systems to our customers, principally related to TriNav. Revenue is recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration to which we expect to be entitled in exchange for those products or services.

The primary end-user customers for our products are hospitals, clinics and physicians. We had certain arrangements with our distributors under which they purchase our products and then resell them in geographic markets where we do not have a sales presence. These arrangements provided for a discount on the invoice when the distributor resold our units at our normal sales price. Such sales are recorded net of the discounts. All such arrangements were terminated on or before December 31, 2022.

Cost of Goods Sold

Cost of goods sold primarily consists of raw materials, direct labor and manufacturing overhead costs related to sales of TriNav.

Gross Profit and Gross Margin

Gross profit represents revenue less cost of goods sold. Gross margin is gross profit expressed as a percentage of revenue. Our gross margin and overall profitability may in the future fluctuate from period to period based on a number of factors, such as the innovation initiatives we undertake, manufacturing costs and efficiencies, and obtaining a permanent reimbursement code for our product.

Operating Expenses

Our operating expenses consist of R&D, sales and marketing and general and administrative expenses.

Research and Development

R&D expenses include engineering, drug supply, regulatory, pre-clinical and clinical activities. We expense R&D costs as incurred. We recognize expenses for certain development activities, such as preclinical studies and manufacturing, based on an evaluation of the progress to completion of specific tasks using data or other information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of expenses incurred. Non-refundable advance payments for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses. These amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

R&D activities account for a significant portion of our operating expenses. We expect our R&D expenses to increase significantly in future periods as we continue to implement our business strategy, which includes advancing our manufacturing technologies into and through clinical development of SD-101, expanding our R&D efforts,

including hiring additional personnel to support our R&D efforts, and seeking regulatory approvals for our drug candidates that successfully complete clinical trials. In addition, drug candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, although we expect our R&D expenses to increase as SD-101 advances into later stages of clinical development, we do not believe that it is possible at this time to accurately project total program-specific expenses through to commercialization.

Sales and Marketing

Sales and marketing expense consists primarily of salaries, commissions, travel and related business expenses, attendance at medical society meetings, product promotions and marketing activities.

General and Administrative

General and administrative expense includes executive management, finance, information technology, human resources, business development, legal, and the administrative and professional costs associated with those activities. General and administrative costs also include corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in production or R&D expenses, as well as regulatory and professional fees for legal, patent, accounting and other consulting services.

Loss on Equity Issuance

Loss on equity issuance represents the excess of the fair value of the warrants to purchase Series B-3 preferred stock and the Series B-2 tranche liabilities over the proceeds received from the Initial Preferred Stock Financing and subsequent tranche closings.

Change in Fair Value of Tranche and Warrant Liabilities

Change in fair value of warrant and tranche liabilities represents the change in fair value of the warrants to purchase Series B-3 preferred stock and the Series B-2 tranche liabilities at each reporting period that were issued as part of the Initial Preferred Stock Financing, and changes in the fair value of the Public and Private Warrants in this line.

Change in Fair Value of Contingent Earnout Liability

Change in fair value of contingent earnout liability represents the change recorded as a result of remeasurement of the fair value.

Deemed dividend related to Series B-2 preferred stock down round provision

The deemed dividend represents the value attributed to the increase in shares of common stock that preferred stockholders would receive upon conversion to common stock as a result of the Series B-2 preferred stock financing rounds in October 2022 and March 2023, which was deemed to be a down round and triggered the anti-dilution provisions associated with our preferred stock. The resulting increase in value of the preferred stock was deemed to be a dividend to the preferred stockholders and was recognized as a non-cash adjustment to additional paid-in-capital.

Income Tax Benefit (Expense)

Our income tax provision consists primarily of U.S. federal and state income taxes. We maintain a full valuation allowance for our federal and state deferred tax assets, including net operating loss carryforwards, as we have concluded that it is not more likely than not that the deferred tax assets will be realized.

Results of Operations:

The following table sets forth our consolidated statements of operations data for each of the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	$ 5,193	$ 3,923	$ 12,790	$ 9,172
Cost of goods sold	589	701	2,023	1,442
Gross profit	4,604	3,222	10,767	7,730
Operating expenses:				
Research and development	9,367	4,808	21,871	15,091
Sales and marketing	4,689	3,030	11,430	8,881
General and administrative	9,025	3,495	17,498	8,425
Loss from operations	(18,477)	(8,111)	(40,032)	(24,667)
Interest income	116	49	187	75
Interest expense	(4)	—	(13)	—
Loss on equity issuance	—	—	(4,171)	—
Change in fair value of tranche and warrant liabilities	(2,812)	—	660	21
Change in fair value of contingent earnout liability	19,904	—	19,904	—
Other expense, net	(13)	(31)	(56)	(71)
Loss before income taxes	(1,286)	(8,093)	(23,521)	(24,642)
Income tax expense	—	—	8	3
Net loss available to common stockholders	$ (1,286)	$ (8,093)	$ (23,529)	$ (24,645)
Deemed dividend related to Series B-2 preferred stock down round provision	$ —	$ —	$ (2,981)	$ —
Undeclared dividends on Series A preferred stock	$ (458)	$ —	$ (458)	$ —
Net loss attributable to common stockholders	$ (1,744)	$ (8,093)	$ (26,968)	$ (24,645)

The following table sets forth our consolidated statements of operations data expressed as a percentage of revenue:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	100.0 %	100.0 %	100.0 %	100.0 %
Cost of goods sold	11.3	17.9	15.8	15.7
Gross profit	88.7	82.1	84.2	84.3
Operating expenses:				
Research and development	180.4	122.6	171.0	164.5
Sales and marketing	90.3	77.2	89.4	96.8
General and administrative	173.8	89.1	136.8	91.9
Loss from operations	(355.8)	(206.8)	(313.0)	(268.9)
Interest income	2.2	1.2	1.5	0.8
Interest expense	(0.1)	—	(0.1)	—
Loss on equity issuance	—	—	(32.6)	—
Change in fair value of tranche and warrant liabilities	(54.1)	—	5.2	0.2
Change in fair value of earnout liabilities	383.3	—	155.6	—
Other expense, net	(0.3)	(0.8)	(0.4)	(0.8)
Loss before income taxes	(24.8)	(206.3)	(183.9)	(268.7)
Income tax benefit (expense)	—	0.0	0.1	0.0
Net loss available to common stockholders	(24.8)%	(206.3)%	(184.0)%	(268.7)%
Deemed dividend related to Series B-2 preferred stock down round provision	— %	— %	(23.3)%	0.0 %
Undeclared dividends on Series A preferred stock	(8.8)%	— %	(3.6)%	— %
Net loss attributable to common stockholders	(33.6)%	(206.3)%	(210.8)%	(268.7)%

Comparison of the Three Months Ended September 30, 2023, and 2022

Revenue

Revenue increased by $1.3 million or 32.4% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase in revenue was primarily due to an increase of $1.1 million in units of TriNav sold as our launch of the product, begun in 2020, recovered from the impact of the Covid-19 pandemic. In addition, we realized a reduction in sales discounts of $0.2 million as we terminated the distributor agreements that required the discounts.

Cost of Goods Sold and Gross Profit

Cost of goods sold decreased by $0.1 million, or 16.0%, for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The decrease in cost of goods sold was primarily due to increased manufacturing efficiencies driven by additional production of TriNav to support our sales growth.

Gross profit increased by $1.4 million or 42.9%, and gross margin increased to 88.7% from 82.1% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase in gross profit was due primarily to the increase in revenue. The increase in gross margin percentage was driven principally by increased manufacturing efficiencies.

Operating Expenses

Research and Development

R&D expenses increased by $4.6 million, or 94.8%, for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase was primarily driven by a $3.4 million increase in expense for our three clinical trials of our drug candidate, SD-101, and a $0.5 million increase in expense for development of manufacturing for SD-101, along with increases in headcount related expenses and travel of $0.7 million.

Sales and Marketing

Sales and marketing expenses increased by $1.7 million or 54.8%, for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase was primarily driven by a $1.9 million increase for payroll and travel expenses due to increased headcount of sales and marketing personnel to support our sales of TriNav. The increase was partially offset by a reduction in professional services of $0.2 million, reflecting lower expenditures after completing development of our web site and social media platforms.

General and Administrative

General and administrative expenses increased by $5.5 million, or 158.2%, for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase was primarily due to a $4.8 million increase for professional services, principally for legal, consulting and auditing work in connection with the Business Combination, and a $0.7 increase in payroll and travel expenses related to additional personnel.

Interest Income

Interest income increased by $67 thousand for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase was due to higher interest received from the investment of our excess cash in short-term money market funds in three months ended September 30, 2023.

Change in Fair Value of Tranche and Warrant Liabilities

The change in fair value of tranche and warrant liabilities resulted in a loss of $2.8 million in the three months ended September 30, 2023, due to the increase in the trading price of the Publicly Traded Warrants.

Change in Fair Value of Earnout Liabilities

The change in fair value of earnout liability resulted in a gain of $19.9 million in the three months ended September 30, 2023, due to the decrease in the market price of the underlying common stock.

Comparison of the Nine Months Ended September 30, 2023, and 2022

Revenue

Revenue increased $3.6 million, or 39.4%, for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase was primarily due to higher sales volume of TriNav, amounting to $3.1 million, and a reduction in discounts of $0.5 million as a result of the shift away from sales to distributors.

Cost of Goods Sold and Gross Profit

Cost of goods sold increased by $0.6 million, or 40.3%, for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase in cost of goods sold was primarily due to the higher volume of TriNav produced in the period to support the higher sales volume.

Gross profit increased by $3.0 million, or 39.3%, for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, and gross margin decreased from 84.3% to 84.2%. The increase in gross profit was driven primarily by higher sales volume. The decrease in gross margin was driven primarily by higher overhead costs, principally labor.

Operating Expenses

Research and Development

R&D expenses increased by $6.8 million, or 44.9%, for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase was primarily due to a $5.2 million increase in spending on our clinical trials, an increase of $1.0 million for development of manufacturing of SD-101, and an increase of $0.6 million in payroll expense as we increased our headcount.

Sales and Marketing

Sales and marketing expenses increased by $2.5 million, or 28.7%, for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase was primarily driven by a $2.6 million increase for additional payroll expenses due to an increase in headcount of sales and marketing personnel, and

$0.7 million of additional travel expense, partially offset by a $0.8 million decrease in marketing expense, reflecting lower expenditures after completing development of our web site and social media platforms.

General and Administrative Expenses

General and administrative expenses increased by $9.1 million, or 107.7%, for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase was primarily due to a $7.7 million increase in professional service fee due to additional legal, consulting, and audit-related expenditures incurred leading up to the Business Combination, and a $1.4 million increase for payroll, personnel, and travel expenses due to increased headcount of general and administrative personnel.

Interest Income

Interest income increased by $112.0 thousand, or 149.3%, for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase was primarily due to a combination of higher surplus cash balances invested in money market funds and higher interest rates during the nine months ended September 30, 2023.

Loss on Equity Issuance

A loss on equity issuance of $4.2 million was recorded in the nine months ended September 30, 2023, attributable to the issuance of Series B-2 preferred stock and the accompanying warrants to purchase Series B-3 preferred stock and related tranche obligations, which were valued in excess of the proceeds received as part of the transaction. The fair value exceeded proceeds primarily due to the issuance of warrants to purchase four shares of Series B-3 preferred stock for every one share of Series B-2 preferred stock purchased in the Initial Preferred Stock Financing.

Change in Fair Value of Tranche and Warrant Liabilities

The change in fair value of tranche and warrant liabilities resulted in a gain of $0.7 million in the nine months ended September 30, 2023, due to reductions in the measured fair value of the tranche and warrant liabilities. There were no tranche or warrant liabilities in the nine months ended September 30, 2022.

Change in Fair Value of Earnout Liabilities

The change in fair value of earnout liability resulted in a gain of $19.9 million in the nine months ended September 30, 2023, due to a decrease in the market price of the underlying common stock. There was no earnout liability in the nine months ended September 30, 2022.

Deemed dividend related to Series B-2 preferred stock down round provision

The deemed dividend is related to the Initial Preferred Stock Financing, which was deemed to be a down round and triggered the anti-dilution provisions associated with our preferred stock. As a result, the conversion prices of all prior series of preferred stock were adjusted such that the holders would receive more shares of common stock upon conversion than previously. The resulting increase in value of the preferred stock was deemed to be a dividend to the preferred stockholders and we recognized a $3.0 million, non-cash adjustment to additional paid-in-capital for the nine months ended September 30, 2023. There was no such adjustment recorded in the nine months ended September 30, 2022.

Liquidity and Capital Resources

Overview

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future due to the investments we will continue to make in R&D and sales and marketing, and due to additional general and administrative costs we expect to incur as a public company. We incurred net losses of $23.5 million for the nine months ended September 30, 2023. We had cash and cash equivalents of approximately $21.4 million at September 30, 2023. Since inception, we have financed operations primarily through the issuance of preferred stock, convertible notes, and term loans. We are still in our early stages of development and have yet to generate revenues sufficient to fund cash flows from operations. Our ability to fund future operations and execute our long-term business plan and strategy, including our transformation into a therapeutics company, will require that we raise additional capital through a combination of collaborations, strategic alliances and licensing arrangements, and issuance of additional equity and/or debt. There can be no assurance that we will be able to raise such additional financing on satisfactory terms. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. If we cannot expand our operations or otherwise capitalize on our business

opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected. As a result, we have concluded that there is substantial doubt of our ability to continue as a going concern for a reasonable period of time, which is considered to be one year from the issuance date of the financial statements.

Our ability to continue as a going concern is dependent upon obtaining additional capital and financing. Our financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should we be unable to continue as a going concern. In connection with the consummation of the Business Combination on August 10, 2023, we raised an additional $36.9 million of cash (net of expenses related to closing the Business Combination). In addition, as described below, we received $4.5 million in cash proceeds from the exercise of warrants to purchase Series B-3 preferred stock in July 2023.As of September 30, 2023, we had approximately $21.4 million in cash and cash equivalents. Based on our sales, operations and research and development plans, we do not currently expect that our cash and cash equivalents as of September 30, 2023, will be sufficient to fund our projected liquidity requirements for the next 12 months, creating substantial doubt about our ability to continue as a going concern. We have based these estimates on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect, and future capital requirements and the adequacy of available funds will depend on many factors, including those described in the section titled “Risk Factors” in this Quarterly Report on Form 10-Q. See also “Funding Requirements” below.

In October 2022, we raised $9.8 million, net of issuance costs, through the issuance of Series B-2 preferred stock and warrants to purchase Series B-3 preferred stock. This issuance also included, at our option, a second tranche of Series B-2 preferred stock and warrants to purchase Series B-3 preferred stock (“Series B-3 Warrants”) for up to approximately $7.4 million (which could be increased to $10 million) and a third tranche, at the election of investors in the second tranche, of up to $4.3 million (which could be increased to $5 million) of Series B-2 preferred stock and warrants to purchase Series B-3 preferred stock, subject, in all respects, to the covenants in the Merger Agreement prohibiting us from issuing additional securities during the Interim Period without MTAC’s prior consent. We offered the Series B-2 preferred stock to all of our preferred stockholders at the time of the Initial Preferred Stock Financing (representing approximately 99.2% of our then outstanding shares on an as-converted to common stock basis).

In January through July 2023, holders of warrants to purchase 4,771,642 shares of Series B-3 preferred stock exercised their purchase right, for proceeds of approximately $9.6 million. In March 2023, we effectuated (i) a closing of a portion of the second tranche of the Initial Preferred Stock Financing whereby 207,541 shares of Series B-2 preferred stock and accompanying warrants to purchase 830,167 shares of Series B-3 preferred stock, representing 40% of the shares committed in the second tranche, were sold for an aggregate purchase price of $2.9 million, and (ii) an additional closing under the purchase agreement for the Initial Preferred Stock Financing whereby 17,656 shares of Series B-2 preferred stock and accompanying warrants to purchase 70,624 shares of Series B-3 preferred stock were sold for an aggregate purchase price of $0.2 million.

In June 2023, we effectuated (i) a closing of a portion of the second tranche of the Initial Preferred Stock Financing whereby 257,779 shares of Series B-2 preferred stock and accompanying warrants to purchase 1,031,116 shares of Series B-3 preferred stock, representing approximately 49.7% of the shares committed in the second tranche, were sold for an aggregate purchase price of $3.7 million, and (ii) an additional closing under the purchase agreement for the Initial Preferred Stock Financing whereby 165,967 shares of Series B-2 preferred stock and accompanying warrants to purchase 663,868 shares of Series B-3 preferred stock were sold for an aggregate purchase price of $2.3 million.

Cash Flows

Comparison of the Nine Months Ended September 30, 2023, and September 30, 2022

The following table presents net cash from operating, investing, and financing activities (in thousands):

	Nine Months Ended September 30,	
	2023	**2022**
Net cash used in operating activities	$ (41,196)	$ (24,003)
Net cash used in investing activities	(1,421)	(1,514)
Net cash provided by financing activities	54,586	7,554
Net increase / (decrease) in cash, cash equivalents and restricted cash	$ 11,969	$ (17,963)

Cash Used in Operating Activities

For the nine months ended September 30, 2023, net cash used in operating activities was $41.2 million. The net cash used in operating activities consisted of net loss of $23.5 million, adjusted for non-cash charges totaling

$15.4 million, primarily related to a gain on the adjustment of the fair value of the contingent earnout liability of $19.9 million, and a gain on the adjustment of the fair value of warrants to purchase preferred stock of $0.7 million, partially offset by a loss on equity issuance of $4.2 million, depreciation of $0.5 million and share-based compensation of $0.4 million. Net operating assets and liabilities decreased $3.2 million, due primarily to an increase in accounts receivable and a decrease in accounts payable.

For the nine months ended September 30, 2022, net cash used in operating activities was $24.0 million. The net cash used in operating activities consisted of net loss of $24.6 million, adjusted for non-cash charges totaling $0.7 million, primarily related to depreciation and amortization of $0.5 million and stock-based compensation expense of $0.3 million. In addition, there was a net increase of $1.1 million in our net operating assets and liabilities. The increase in our net operating assets and liabilities was driven by an increase in prepaid expenses of $1.3 million and accounts receivable of $0.9 million, and a decrease in trade payable, accrued expenses and other current liabilities of $1.1 million.

Cash Used in Investing Activities

Net cash used in investing activities of $1.4 million for the nine months ended September 30, 2023, was due to purchases of property and equipment of $0.2 million ,payments of $0.2 million to acquire or maintain intellectual property, and a milestone payment of $1.0 million to Dynavax.

Net cash used in investing activities of $1.5 million for the nine months ended September 30, 2022, was primarily due to purchases of property and equipment of $0.4 million, payments of $0.1 million to acquire or maintain intellectual property, and a milestone payment of $1.0 million to Dynavax.

Cash Used in Financing Activities

Net cash provided by financing activities of $54.6 million for the nine months ended September 30, 2023, consisted principally of proceeds from the merger of $36.9 million, proceeds from the issuance of Series B-2 preferred stock of $9.2 million, and proceeds from the exercise of warrants to purchase Series B-3 preferred stock of $9.6 million, partially offset by expenses incurred related to the Business Combination of $1.1 million.

Net cash provided by financing activities of $7.6 million for the nine months ended September 30, 2022, consisted of prepayments of $4.0 million for Series B-2 preferred stock that was issued in the fourth quarter of 2022 and proceeds from the sale of Series B-1 preferred stock of $3.5 million.

Funding Requirements

Our primary use of cash is to fund operating expenses, which consist of research, development and clinical expenses related to our lead product candidate SD-101, and preclinical programs, sales and marketing expenses related to the growth of TriNav, as well as general and administrative expenses. We plan to advance the development of SD-101, initiate new research and pre-clinical development efforts and seek marketing approval for product candidates that we successfully develop. If we obtain approval for our product candidates, we expect to incur commercialization expenses, which may be significant, related to establishing sales, marketing, manufacturing capabilities, distribution and other commercial infrastructure to commercialize such products. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Inflation and rising interest rates may result in an economic recession globally or in the U.S., which could lead to a reduction in product demand, a decrease in corporate capital expenditures, prolonged unemployment, labor shortages, reduction in consumer confidence, adverse geopolitical and macroeconomic events, or any similar negative economic condition. Economic conditions in some parts of the world have been worsening, with disruptions to, and volatility and uncertainty in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflation and rising interest rates. These conditions have been further exacerbated by recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, the wars in Ukraine and Israel and the lingering effects of the COVID-19 pandemic. It is not possible at this time to estimate the long-term impact that these and related events could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. If these conditions persist and deepen, we could experience an inability to access additional capital, or our liquidity could otherwise be impacted. If we are unable to raise capital when needed and on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs and/or other efforts. A recession or additional market corrections resulting from the impact of difficult macroeconomic conditions, disruptions in the banking system, and the lingering effects of the COVID-19 pandemic could materially affect our business and the value of our securities.

We also expect to continue to incur significant expenses in connection with our ongoing activities related to TriNav, including sales and marketing expenses and expenditures to support expansion of our production capacity to support our expected sales growth. Our future capital requirements, both near and long-term, will depend on many

factors, including but not limited to: the success of our commercialization of TriNav including, among other things, continued patient and physician adoption of TriNav and our ability to maintain adequate reimbursement for TriNav; the cost of commercialization activities for TriNav, including manufacturing, distribution, marketing and sales; net product revenues received from sales of TriNav; the outcome, timing and cost of the regulatory approval process for SD-101 by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect; the costs involved in preparing, filing and prosecuting patent applications and annuity fees relating to issued patents; the cost of maintaining and enforcing our intellectual property rights, as well as the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us; the initiation, progress, timing, costs and results of clinical trials and other research and development related to our product candidates; and the extent to which we in-license, acquire or otherwise partner in development or commercialization of other products, product candidates or technologies; the achievement of milestones or occurrence of other developments that trigger payments under the Dynavax Agreement or any other collaboration or other agreements; the number of future product candidates that we may pursue and their development requirements; the costs of commercialization activities for any of our product candidates that may receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities; the amount and timing of future revenue, if any, received from commercial sales of our current and future product candidates upon any marketing approvals; and the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of securities offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interest in our company may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the price of our common shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As of September 30, 2023, we had approximately $21.4 million in cash and cash equivalents. Based on our sales, operations, and research and development plans, we do not currently expect that our cash and cash equivalents as of September 30, 2023, will be sufficient to fund our projected liquidity requirements for the next 12 months, creating substantial doubt about our ability to continue as a going concern. We will likely require additional capital in the near term in order to continue to fund our operations through equity or debt financings, partnerships, collaborations, or other sources which may not be available on a timely basis, on favorable terms, or at all, and such capital, if obtained, may not be sufficient to enable us to continue to implement our long-term business strategy. See factors in the section titled "Risk Factors" and also "Funding Requirements" above. As further discussed above in the section titled "Recent Developments," in October 2023, we entered into the Yorkville Purchase Agreement, whereby we have the right, but not the obligation, to sell to Yorkville up to $30.0 million of shares of Common Stock.

Additionally, we may never become profitable, or if we do, may not be able to sustain profitability on a recurring basis. If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected and we may need to delay or curtail our operations until such funding is received.

Our continuation as a going concern is dependent on our ability to generate sufficient cash flows from operations and/or obtain additional capital through equity or debt financings, partnerships, collaborations, or other sources to carry out our long-term business strategy. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than fair value for such assets and less than the value at which such assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. As discussed in Note 1 to our unaudited consolidated financial statements accompanying this Quarterly Report on Form 10-Q, there is substantial doubt regarding our ability to continue as a going concern as of September 30, 2023.

Contractual Obligations and Commitments

Our contractual obligations as of September 30, 2023, include lease obligations of $1.7 million, reflecting the minimum commitments for our principal administrative and production facility and other office spaces.

Pursuant to the Asset Purchase Agreement, dated July 31, 2020, between TriSalus and Dynavax, we have paid Dynavax $12 million as of September 30, 2023, and may be required to pay Dynavax up to an additional $158 million upon the achievement of certain development and regulatory milestones with respect to SD-101. We will also be required to pay up to $80 million upon achieving certain commercial milestones once sales of SD-101 have begun. The Dynavax Agreement also obligates us to pay low double-digit royalties based on potential future net sales of product containing SD-101 compound on a product-by-product and country-by-country basis during the applicable royalty term. Such royalties are subject to reduction by up to 50% in certain circumstances.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet financing arrangements or any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities, which were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Estimates:

Our significant accounting policies are summarized in Note 2 “Summary of Significant Accounting Policies” in the unaudited condensed consolidated financial statements accompanying this Quarterly Report on Form 10-Q. While all of these significant accounting policies affect the reporting of our financial condition and results of operations, we view certain of these policies as critical. Policies determined to be critical are those policies that have the most significant impact on our financial statements and require us to use a greater degree of judgment and/or estimates. Actual results may differ from those estimates. Additionally, changes in accounting estimates could occur in the future from period to period.

Revenue Recognition

Our revenue is derived from shipments of our TriNav infusion devices to our customers which are generally comprised of hospitals, clinics and physicians, and is recognized in accordance with the provisions of the Financial Accounting Standards Board, ASC 606, *Revenue from Contracts with Customers*, and all related applicable guidance.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps: (i) identify the contract; (ii) identify the performance obligation; (iii) determine the transaction price; (iv) allocate the transaction price; and (v) recognize revenue.

We contract with our customers based on customer purchase orders. For each contract, we consider the promise to transfer products, each of which is distinct, to be the identified performance obligation. As part of our performance obligation, products are delivered in accordance with the terms of the purchase order and we do not have any on-going service obligation after delivery.

We maintain a single, discrete transaction price for each of the products, with no adjustments since the price is approved by CMS. We do not have multiple performance obligations to complete when a purchase order is fulfilled, hence the transaction price is always allocated fully to the units being sold.

Revenue is recognized when the units for a purchase order have been shipped and control of the units has been transferred to the customer. Ex-works shipment is followed, wherein we recognize revenue when the shipment leaves our premises. In certain cases where purchase orders specify alternate shipping terms, usually delivery at place, revenue recognition is deferred until we are assured the units are delivered.

Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established for discounts, returns, rebates and allowances. We do not have a history of any refunds, allowances or other concessions provided to our customers from the agreed-upon sales price after delivery of the product. We do not offer discounts, except to distributors as discussed below. We had certain arrangements with distributors under which the distributors purchased and then resold our products in geographic markets where we did not have sales presence. These arrangements provided for a discount on the invoice. When the distributor resold our units at our normal sales price, the discount served to compensate the distributor for their efforts. We recorded these sales net of the discounts. One of our distributors, ACD, accounted for approximately 20% of our sales for the year ended December 31, 2022. We discontinued the distributor agreement with ACD in December 2022.

We provide certain customers with rebates that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the conditions for the rebates are achieved. The rebates result from performance-based offers that are primarily based on attaining contractually specified sales volumes.

Contingent Earnout Liability

In connection with the Business Combination, the Sponsor received shares that will vest upon the achievement of certain share price targets and change in control events. In accordance with ASC 815-40, *Derivatives and Hedging*, the earnout shares were classified as a liability as they do not qualify as being indexed to the Company's own stock and therefore are measured at fair value at each reporting date with changes in fair value recorded in the Condensed Consolidated Statements of Operations.

The estimated fair value of the earnout liability was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes. The inputs and assumptions utilized in the calculation require management to apply judgment and make estimates including:

- expected volatility, which is based on the historical equity volatility of publicly traded peer companies for a term equal to the expected term of the earnout period;
- expected term, which we based on the earnout period per the agreement;
- risk-free interest rate, which was determined by reference to the U.S. Treasury yield curve for time periods commensurate with the expected term of the earnout period; and
- expected dividend yield, which we estimate to be zero based on the fact that we have never paid or declared dividends.

These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with exact precision.

Research and Development

R&D costs include our engineering, drug supply, regulatory, pre-clinical and clinical activities. R&D costs are expensed as incurred. Approximately 12% of our R&D costs are headcount-related; the balance is external services we purchase, such as pre-clinical supplies and materials, clinical study management and supplies, and consulting related to our R&D.

We are required to estimate our expenses resulting from our obligations under agreements with vendors, consultants, and contract research organizations, in connection with conducting R&D activities. The financial terms of these contracts are subject to negotiations, which vary from agreement to agreement and may result in payment flows that do not match the periods over which goods or services are provided. We reflect R&D expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the agreements, along with preparation of financial models, taking into account discussions with research and other key personnel as to the progress of studies or other services being performed. To date, we have had no material differences between our estimates of such expenses and the amounts actually incurred. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Warrant and Tranche Rights and Obligation Liabilities

We classified the Public and Private Placement Warrants as liabilities on the Condensed Consolidated Balance Sheets. We measured the warrants at fair value at August 10, 2023, when we assumed them in the Business Combination, and at September 30, 2023. The fair value of the public warrants is based on their trading price; we used the price of the public warrants as the fair value of the private placement warrants, as the rights and characteristics of the warrants are the same.

We classified the Series B-2 tranche rights and obligations and Series B-3 Warrants as liabilities on the Condensed Consolidated Balance Sheets. We measured the Series B-2 Tranche Rights and Series B-3 Warrants at fair value upon issuance in October 2022, March 2023, and June 2023, and remeasured the liabilities to fair value at December 31, 2022, March 31, 2023, June 30, 2023, and August 10, 2023, with changes in the fair value at each measurement date recognized in Change in fair value of tranche and warrant liabilities in the consolidated statements of operations. The Series B-2 Tranche Rights and series B-3 Warrants were extinguished in the Business Combination.

The fair value of the Series B-2 tranche liabilities was determined using a Binomial Tranche Model. The fair value of the Series B-3 Warrants was determined using a probability-weighted expected outcome model whereby the following two scenarios were probability-weighted based on the Company's expectation of each occurring: (1) a status

quo scenario whereby the Company would continue as a private company and (2) a scenario where the Business Combination would close. Under the status quo scenario, the Series B-3 Warrants, including warrants to be issued under the second and third tranches, were valued using the Black-Scholes model.

The fair value of the Series B-2 tranche liabilities and Series B-3 Warrants used various inputs and assumptions that required management to apply judgment and make estimates, including:

- the equity value under the status quo scenario, which was determined using the Guideline Public Company method within the market approach to estimate the fair value of equity on a minority, marketable basis using selected publicly traded peer companies and valuation multiples based on size, growth, profitability, and other relevant factors;
- the fair value of underlying Series B-2 preferred stock, which was determined using the Option Pricing Model to allocate the Company's equity value among its various classes of equity securities under the status quo scenario;
- issuance and exercise price, which was based on the terms of the purchase agreement;
- expected term, which we based on the expiry periods as defined in the purchase agreement;
- expected volatility, which was based on the historical equity volatility of publicly traded peer companies for a term equal to the expected term of the warrants and tranche liabilities;
- risk-free interest rate, which was determined by reference to the U.S. Treasury yield curve for time periods commensurate with the expected terms of the warrants and tranche liabilities; and
- expected dividend yield, which we estimate to be zero based on the fact that we have never paid or declared dividends.

These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with exact precision. The scenario probability is the most sensitive estimated input into the calculation of the fair value of the Series B-3 Warrants. The risk of exposure is estimated using a sensitivity analysis of potential changes in the significant unobservable inputs, primarily the scenario probability input that is the most susceptible to valuation risk.

Emerging Growth Company Status

Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards. The JOBS Act provides that a company can choose not to take advantage of the extended transition period and comply with the requirements that apply to non-emerging growth companies, and any such election to not take advantage of the extended transition period is irrevocable. MTAC previously elected to avail itself of the extended transition period, and following the consummation of the Business Combination, we will be an emerging growth company and will take advantage of the benefits of the extended transition period that the emerging growth company status permits. During the extended transition period, it may be difficult or impossible to compare our financial results with the financial results of another public company that complies with public company effective dates for accounting standard updates because of the potential differences in accounting standards used.

We will remain an emerging growth company under the JOBS Act until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of MTAC's initial public offering (i.e., December 31, 2025), (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common equity that is held by non-affiliates exceeds $700.0 million as of the end of the prior fiscal year's second fiscal quarter; and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

Note 2(q) to our unaudited condensed consolidated financial statements accompanying this Quarterly Report on Form 10-Q includes more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one, of their potential impact on our financial condition and our results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act") Rule 13a15 that are designed to provide reasonable assurance that the information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Because of the inherent limitations to the effectiveness of any system of disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, with a company have been prevented or detected on a timely basis. Even disclosure controls and procedures determined to be effective can only provide reasonable assurance that their objectives are achieved.

As of September 30, 2023, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) pursuant to Rule 13a-15 of the Exchange Act. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are not effective at the reasonable assurance level.

Material Weaknesses

Our management has identified material weaknesses in our internal control over financial reporting and we may identify additional material weaknesses in the future. If we fail to remediate the material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the financial statements would not be prevented or detected on a timely basis.

We have the following material weaknesses in our internal controls over financial reporting:

- In connection with our audited consolidated financial statements for the year ended December 31, 2021, and for the year ended December 31, 2022, management identified a material weakness in its internal control over financial reporting due to a lack of sufficient number of trained resources with the appropriate skills and knowledge and with assigned responsibilities and accountability for the design and operation of internal controls over financial reporting. At December 31, 2022, we had five trained resources, which management determined to be insufficient to provide adequate internal controls over financial reporting.
- In connection with our audited consolidated financial statements for the year ended December 31, 2022, management identified a material weakness in our internal control over financial reporting with respect to inadequate internal controls over the valuation of the warrant and tranche rights and obligations liabilities resulting from the Series B-2 preferred stock financing. Specifically, we did not design and implement controls over the completeness and accuracy of the data and assumptions used by our external valuation specialist. In addition, our communication and review process did not detect inconsistent information used in the valuation.

This leads management to conclude that our disclosure controls and procedures are not effective to give reasonable assurance that the information required to be disclosed in reports that we file under the Exchange Act is recorded, processed, summarized, and reported as and when required.

Remediation Activities

To the extent reasonably possible given our limited resources, we intend to take measures to cure the aforementioned weaknesses, including, but not limited to, increasing the capacity and quantity of our qualified financial personnel to ensure that accounting policies and procedures are consistent across the organization and that we have adequate control over our Exchange Act reporting disclosures. Our management developed a remediation plan, and we are taking steps to remediate each of the material weaknesses described above. The remediation plan included hiring four additional trained resources with requisite experience with complicated accounting issues, designing and enforcing processes that ensure adequate segregation of duties within the finance function and adequately reviewing the assumptions and inputs to accounting estimates and engaging outside expert consultants as needed. As of September 30, 2023, we have hired two of the four additional trained resources with such requisite experience. The material weaknesses will be considered remediated when our management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. Our management will continue to monitor the effectiveness of the remediation plan and will make the

changes it determines to be appropriate. Although our management intends to complete this remediation process as quickly as practicable, it cannot at this time estimate how long it will take, and initiatives may not prove to be successful in remediating the material weaknesses.

The material weaknesses discussed above will not be considered remediated until the applicable new or enhanced controls operate for a sufficient period of time and management has concluded, through testing that these controls are designed and operating effectively.

Changes in Internal Control over Financial Reporting

Other than the material weaknesses and remediation efforts described above, there have been no changes in our internal control procedures over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the nine months ended September 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial position.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Special 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 Quarterly Report on Form 10-Q, including the accompanying financial statements and related notes, and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following events or developments described as risks were to occur, either alone or taken together, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market 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 also adversely affect our business.

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Financial Condition

We have a limited operating history, have incurred significant losses since our inception and anticipate incurring increasing expenses and continuing losses for the foreseeable future. Our independent registered public accountants and management have expressed substantial doubt as to our ability to continue as a going concern.

We are a commercial-stage medical device and Phase I clinical-stage pharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have incurred significant losses since inception, including net losses of $23.5 million and $47.2 million for the nine months ended September 30, 2023, and the year ended December 31, 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $212.9 million. We anticipate incurring increasing research and development and general and administrative expenses related to our operations and transition into a public company for the foreseeable future. Losses will likely continue and may increase in the future as we continue to incur significant expenses related to drug development. We may find that these efforts are more expensive than we currently anticipate or that these efforts may not result in revenues, which would further increase our losses. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by clinical-stage pharmaceutical companies. If we are unable to achieve and/or sustain profitability, or if we are unable to achieve the growth that we expect from these efforts, it could have a material adverse effect on our business, financial condition or results of operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

In addition, the Report of Independent Registered Public Accounting Firm to our December 31, 2022, financial statements includes an explanatory paragraph that expressed substantial doubt about our ability to continue as a going concern. Additionally, our management has independently determined that there is substantial doubt about our ability to continue as a going concern because we have incurred significant operating losses and expect to continue incurring losses for the foreseeable future. Our financial statements were prepared assuming that we will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty. Although we have raised additional cash in connection with the Closing of the Business Combination and received cash proceeds from the exercise of warrants to purchase Series B-3 preferred stock in July 2023, without additional financing and based on our sales, operations and research and development plans, our management estimates that our existing cash and cash equivalents as of September 30, 2023, will be insufficient to fund our projected liquidity requirements for the next 12 months, creating substantial doubt about our ability to continue as a going concern, and we may be unable to realize assets and discharge liabilities in the ordinary course of operations. If we are unable to obtain sufficient funding, we may be forced to delay, scale back, or eliminate some or all of our research and development activities, our financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern.

Future financial statements may include similar qualifications about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our

ability to continue as a going concern; investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

The Dynavax Agreement entered into by Legacy TriSalus in connection with its purchase of SD-101 requires us to make potentially significant payments to Dynavax before we will have regulatory approval of SD-101 and be able to generate revenue from sales of SD-101.

Pursuant to the Dynavax Agreement, we and Legacy TriSalus have paid Dynavax $12 million to date and we may be required to pay Dynavax up to an additional $158 million upon the achievement of certain development and regulatory milestones with respect to SD-101. We will also be required to pay up to $80 million upon achieving certain commercial milestones once sales of SD-101 have begun. The Dynavax Agreement also obligates us to pay royalties based on potential future net sales of products containing SD-101 compound on a product-by-product and country-by-country basis during the applicable royalty term. Such royalties are subject to reduction by up to 50% in certain circumstances. Our failure to satisfy these payment obligations or other obligations under the Dynavax Agreement could result in penalties or litigation, which could have a material adverse effect on our business, financial condition, and results of operations.

Until we are able to generate significant revenues or achieve profitability through product sales, we will require substantial additional capital to finance our operations and continue development of our product candidates. We cannot be certain that such additional financing will be available on terms favorable to us, or at all, which could limit our ability to grow and jeopardize our ability to continue our business operations.

Based on our sales, operations, and research and development plans, we expect that our existing cash and cash equivalents as of September 30, 2023, will be sufficient to fund operations into early 2024. However, we expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in the commercialization of SD-101, clinical trials and other development, manufacturing and regulatory activities for TriNav, SD-101 and our other product candidates, and discovery research and development. Based on our history of losses, we do not expect that we will be able to fund our longer-term capital and liquidity needs through our cash balances and operating cash flow alone.

Until we can generate a sufficient amount of revenue, we will need to finance our operations through strategic alliance and licensing arrangements and/or public or private debt and equity financings. We will need to obtain substantial additional funding in connection with our continuing operations and planned activities, including to continue the clinical development of, and seek regulatory approval for, SD-101 in any indication, to expand our business, to respond to competitive pressure and to make acquisitions. The amount of capital we will need may change depending on, among other things, the success of our efforts to grow revenue, our efforts to continue to effectively manage expenses, the results of our research and development and clinical trials for product candidates, and costs arising from seeking regulatory approvals. We may not succeed in raising additional funds in a timely manner. The timing of our need for additional funds will depend on many factors, which are difficult to predict or may be outside of our control, including:

- the revenue received from sales of TriNav;
- the costs and timing of research and development programs, including for additional Pressure- Enabled Drug Delivery (“PEDD”) devices;
- the scope, progress, results, resources, time and costs of preclinical development, laboratory testing and clinical trials for our current and future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of the regulatory review and approval of SD-101 and any future product candidate;
- the timing of any milestone payments or royalties due to Dynavax; and
- the costs of operating as a public company.

If our estimates and predictions relating to any of these factors are incorrect, we may need to modify our business plans. Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales for SD-101 or any of our product candidates. In addition, SD-101 and any future product candidates, if approved, may not achieve commercial success.

Our commercial revenues from TriNav will not be sufficient to fund our planned research activities in the near term, if ever. Accordingly, we may try to raise additional funds through public or private financings, strategic relationships, or other arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, will depend upon many factors, including but not limited to, the market demand for Common Stock, which itself is subject to a number of development and business risks and uncertainties, as well as investor perception of our creditworthiness and prospects. It will also depend on a number of factors, including market conditions, interest rates, our operating performance and our credit rating. If we are unable to raise funds on acceptable terms, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements. This may seriously harm our business, financial condition and results of operations. If we are not able to continue operations, investors may suffer a complete loss of their investments in our securities.

If we raise additional funds through future issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of Common Stock. Any debt financing that we may secure in the future could involve significant fixed payment obligations and restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when needed, we may need to delay, reduce the scope of or put on hold one or more research and development programs or commercialization efforts while we seek strategic alternatives, and our ability to continue to support our business growth and to respond to business challenges and opportunities could be significantly impaired.

We may also need to seek collaborators for SD-101 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 SD-101 and any future product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. If we otherwise raise funds through collaborations, strategic alliances or licensing agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations and cause the price of Common Stock to decline. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, and the continued disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from geopolitical events, including the wars in Ukraine and Israel, and disruptions to the U.S. banking system due to bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank, Signature Bank, and First Republic Bank. Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry, or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy and business development efforts, which could jeopardize our ability to continue our business operations.

Our future capital needs may require us to sell additional equity or debt securities that may dilute our stockholders, adversely affect the market price of our Common Stock or introduce covenants that may restrict our operations or our ability to pay dividends.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, such offerings may reduce the market price of the Common Stock, and the terms may include a preference on liquidating distributions or a preference on dividend payments liquidation or other preferences that adversely affect your rights as a stockholder. Thus, existing holders of our Common Stock bear the risk of our future offerings reducing the market price of our Common Stock and diluting their shareholdings in us. For instance, in October 2023, we entered into a standby equity purchase agreement (the "Yorkville Purchase Agreement") with YA II PN, LTD., a Cayman Islands exempt limited partnership ("Yorkville"), whereby we have the right, but not the obligation, to sell to Yorkville up to $30.0 million of our Common Stock at our request, subject to terms and conditions specified in the Yorkville Purchase Agreement. In addition, the incurrence of indebtedness would result in increased fixed or variable payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business, including grants of security interests in our intellectual property. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to

relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

Because our decision to issue additional equity or debt securities in any future offering or to enter into any strategic partnership or licensing arrangement will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts or partnership and licensing arrangements. In addition, a significant decline in the trading price of our Common Stock could potentially impact our ability to use equity securities as consideration in acquisitions. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant rights to develop and market products or product candidates that we would otherwise develop and market ourselves.

We may issue additional Common Stock from time to time, including under our equity incentive plans. Any such issuances would dilute the interest of our stockholders and likely present other risks.

We may issue additional Common Stock from time to time, including under our equity incentive plans or as part of an acquisition. Common Stock reserved for future issuance under our equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to time-based and performance-based vesting conditions, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. We have filed a registration statement on Form S-8 under the Securities Act to register additional shares we may issue pursuant to our 2023 Equity Incentive Plan (the “2023 Plan”) and 2023 Employee Stock Purchase Plan. In addition, we may file one or more registration statements on Form S-8 under the Securities Act to register additional Common Stock or securities convertible into or exchangeable for Common Stock issued pursuant to our equity incentive plans. Any future Form S-8 registration statements will automatically become effective upon filing.

Accordingly, Common Stock registered under such registration statements may be immediately available for sale in the open market.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders if we issue equity securities, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integration;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and related regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, which could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to TriNav

Our revenue is primarily generated from sales of our TriNav device and we are therefore highly dependent on it for our success. Failure to achieve continued market acceptance of TriNav for any reason will harm our business and future prospects.

We began selling TriNav in 2020 in the United States, and sales of TriNav accounted for substantially all of revenue for the three and nine months ended September 30, 2023, and the year ended December 31, 2022. Sales of TriNav are expected to continue to account for primarily all of our revenue going forward. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption of TriNav by physicians and hospitals, among others.

TriNav is a relatively new drug delivery platform designed to overcome the barriers of the high pressure tumor microenvironment. As a result, physician awareness of TriNav, and experience with TriNav, is limited. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including:

- physician experience and hospital demand for our products and the extent of adoption of TriNav, including the rate at which physicians recommend TriNav for use on their patients;
- delays in, or failure to supply product, component and material deliveries by our third-party suppliers;
- positive or negative media coverage, or public, patient and/or physician perception, of TriNav or competing products and procedures;
- any safety or effectiveness concerns that arise regarding TriNav;
- the extent of reimbursement by CMS for purchases of TriNav, and specifically whether TriNav will be assigned a permanent reimbursement rate and at a comparable reimbursement price by CMS; and
- introduction of new products or procedures for delivering drugs into the tumor microenvironment that compete with TriNav.

There is no assurance that TriNav will achieve broad market acceptance among physicians and hospitals. Any failure of TriNav to satisfy physician or hospital demand or to achieve meaningful market acceptance will harm our business and future prospects.

Our business is dependent upon the continued adoption of TriNav by hospitals and physicians.

Our future growth and profitability largely depend on our ability to increase physician awareness and adoption of TriNav and on the willingness of physicians to recommend the device to more of their patients.

Physicians may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our product provides a safe and effective treatment alternative for drug delivery. Even if we are able to raise awareness and increase adoption of TriNav among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select TriNav for recommendation to patients for a variety of reasons, including:

- Long-standing relationships with competing companies and distributors that sell competitive products;
- Competitive response and negative selling efforts from providers of alternative catheter products;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack of sufficient clinical evidence, including long-term data, supporting the clinical benefits of TriNav;
- Reluctance to change to or use new products and procedures; and
- Time commitment and skill development that may be required to gain familiarity and proficiency with TriNav.

Physicians play a significant role in determining the course of a patient’s treatment and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing, and education efforts primarily on interventional radiologists with the goal of educating these physicians regarding the patient population that we believe would benefit from TriNav. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if treating physicians are not made aware of TriNav, they may not treat patients using our product, and those patients may instead not seek treatment at all or may be treated with alternative products or procedures. In addition, some physicians may choose to utilize TriNav on only a subset of their total patient population or may not adopt TriNav at all. If a physician experiences an adverse event in one or more of their TriNav patients or if any issues with the safety or efficacy of TriNav develop, physicians may not continue offering TriNav as a drug delivery method at the same rate or at all. If we are not able to effectively demonstrate that TriNav is beneficial in a broad range of patients, adoption of TriNav will be limited and may not occur as rapidly as we anticipate, which would have a material adverse effect on our business, financial condition, and results of operations. We cannot assure you that TriNav will achieve broad market acceptance among hospitals and physicians. Any failure of TriNav to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

In addition, the medical device industry's interactions and relationships with physicians are under increasing scrutiny by the Health and Human Services Office of the Inspector General ("OIG"), the Department of Justice ("DOJ"), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into purchase contracts with such hospital or health system. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

TriNav is currently subject to an uncertain reimbursement environment, and any change to TriNav's reimbursement status that reduces our level of reimbursement could cause TriNav revenue to materially decline and impede market adoption.

We presently benefit from various reimbursement codes in the United States, including the following:

- Healthcare Common Procedure Coding System Code: C1982; and
- Current Procedural Terminology for physicians to support reimbursement for physician- rendered healthcare services Codes: 37242 Mapping and 37243 Treatment.

Our approved TPT payment for TriNav was extended on December 29, 2022, through the Consolidated Appropriations Act of 2023 and allows for reimbursement payments in the amount of $7,750 for each catheter through December 31, 2023. The TPT allows for temporary payments above the standard prospective payment rate paid for the procedure (rather than as a cost included in the standard payment). The American Medical Association routinely creates these codes for emerging technology, services and procedures. On June 1, 2023, we applied for a new technology APC code with CMS and met with them on June 26, 2023, to review the application. If granted, the new technology APC code would allow for continuing reimbursement for the TriNav device at similar reimbursement rates for the period beginning January 1, 2024, but there can be no assurance that such code will be granted or that continuing reimbursement will be available at similar reimbursement rates or at all.

Any reduction in the amount of the reimbursement for TriNav will negatively impact the revenue we are able to generate from the sale of TriNav and may hinder our ability to recoup our total investment in TriNav notwithstanding regulatory approval of the product. If we are unable to promptly obtain coverage and profitable payment rates from hospital budgets or government-funded and private purchasers for TriNav or any future products, we may sell fewer units or need to sell them at a lower price. Such changes in revenues would have a material adverse effect on our operating results and our overall financial condition.

We currently have a limited marketing, sales and distribution organization. If we are unable to successfully grow our marketing, sales and distribution capabilities, then our product revenues related to TriNav, our results of operations and financial condition will suffer.

We currently have limited in-house sales and marketing capabilities. In the past, we have contracted with a limited number of third-party distributors for a significant portion of our commercial sales of TriNav. We currently have limited in-house sales and marketing capabilities. Our revenues and results of operations were adversely impacted after we discontinued our distributor agreement with Advanced Critical Devices ("ACD") in December 2022. Although we continue to further develop an in-house marketing organization and sales force with technical expertise and supporting distribution capabilities to commercialize TriNav, which will require significant capital expenditures, management resources and time, we may be unable to accurately predict the future level of demand for TriNav that will be generated by our existing or potential customers, or the future demand for our medical device products by these customers or new customers. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We may not be able to build an effective sales and marketing organization with supporting distribution capabilities in the United States, the European Union ("EU") or other key global markets in compliance with applicable legal requirements. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact our revenues, results of operations and financial condition.

Increases in costs, disruption of supply or shortage of materials could harm our business.

We manufacture TriNav internally, and certain materials necessary to produce our products are sourced from a limited number of suppliers. Any disruption in the supply of materials from such suppliers could disrupt production of

our products until such time as a different supplier is fully qualified. As a result, we may experience an increase in costs or inability to meet customer demand. Furthermore, shortages or increased demand of such materials and other economic conditions, like inflation, may cause us to experience significant increases in the cost of materials. In the case of TriNav, substantial increases in the prices for materials used in our production would increase our operating costs and could reduce our margins if we cannot recoup any such increased costs through increased product pricing. Any attempts to increase product prices in response to increased material costs could result in cancellations of product orders and therefore materially and adversely affect our brand, business, prospects and results of operations.

Risks Related to SD-101 and Product Development

We are early in our pharmaceutical development efforts and we have only one pharmaceutical product candidate, SD-101, in early clinical development. If we are unable to advance our product candidates, including SD-101, in clinical development for any reason (including due to lack of funding), obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business, results of operations, financial condition and prospects may be materially adversely affected.

We are in the early stages of our development efforts and have only one product candidate, SD-101, in early clinical development. We have initiated Phase 1 and Phase 1b clinical trials for this product candidate, each of which are focused on a different target indication, specifically: uveal melanoma, intrahepatic cholangiocarcinoma and hepatocellular carcinoma. We will need to progress any early product candidates through IND-enabling studies and submit Investigational New Drug applications ("INDs") to the FDA prior to initiating their clinical development. Our ability to generate product revenues from our pharmaceutical candidates, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of these product candidates will depend on several factors, including the following:

- successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results;
- clearance of INDs by the FDA or similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- demonstrating the safety and efficacy in the proposed indications for use of our product candidates to the satisfaction of applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including New Drug Applications ("NDAs") from the FDA and maintaining such approvals;
- making arrangements with third-party manufacturers for, or establishing, clinical and commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our products following approval; and
- building and maintaining an organization of people who can successfully develop our product candidates.

The success of our business depends in part on the successful development, regulatory approval, and commercialization of our product candidate, SD-101, as well as any other future product candidates, which may never occur. We have not yet succeeded in, and we may not succeed in, obtaining marketing approval for SD-101. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate any revenue from our pharmaceutical development efforts and this may have a material adverse effect on our business, results of operations, financial condition and prospects.

Clinical trials of our product candidates or potential product candidates may fail to produce results necessary to support regulatory clearance or authorization.

We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in commercial gains. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical development process. Our products may produce undesirable adverse effects that could cause us, institutional review boards ("IRBs") or regulatory authorities to interrupt, delay or halt clinical trials. We, IRBs, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks. Our clinical trials may produce negative or inconclusive results or may demonstrate a lack of effect of our product candidates. Additionally, the FDA may disagree with our interpretation of the data from our pilot studies and clinical

trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or effectiveness, and may require us to pursue additional clinical trials, which could further delay the clearance or authorization of our product candidates. If we are unable to demonstrate the safety and effectiveness of product candidates in our clinical trials, we will be unable to obtain the regulatory clearances or authorizations we need to commercialize new products.

Interim, "topline" and preliminary data from clinical trials of our product candidates may change as more patient data becomes available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Preliminary or 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, interim and preliminary data should be viewed with caution until the final data is available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

Clinical development is a lengthy and expensive process with an uncertain outcome. In addition, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. Failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profiles and flaws in trial design, among others. To obtain the requisite regulatory approvals or clearances to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. The results of preclinical studies and early clinical trials of SD-101 and any future drug candidates may not be predictive of the results of later-stage clinical trials, making it impossible to predict when or if any of our product candidates will prove safe or effective in humans or receive regulatory approval or clearance. The results generated to date in preclinical studies for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier-stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier-stage clinical trials. Several companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval or clearance of these product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If the trials result in negative or inconclusive results, we or our collaborators or partners may decide, or regulators may require them, to discontinue trials of our drug candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval or clearance and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

Also, we cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including challenges resulting from COVID-19, labor shortages, and global supply chain interruptions. Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals or clearances.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence future product sales. We

may also find it difficult to enroll patients in our clinical trials, which could delay or prevent the development of our product candidates.

We may experience delays in clinical trials of our drug candidates. Planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract manufacturing organizations ("CMOs"), or contract research organizations ("CROs"), and clinical trial sites, or failure by such CMOs to complete the manufacturing of clinical trial materials or CROs to follow and carry out the clinical study protocol at each site in accordance with the terms of our agreements with them;
- delays in obtaining required IRB, approval at each site;
- difficulties or delays in having patients' complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- time required to add new clinical sites; or
- delays by prospective CMOs to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our drug candidates could be materially harmed, which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our drug candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our drug candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment is and completion of the trials are affected by a variety of factors, including:

- severity and prevalence of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the drug candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

SD-101 relies on oligonucleotide TLR agonists. Serious adverse event data relating to TLR agonists may require us to reduce the scope of or discontinue certain of our pre-clinical or clinical activities.

SD-101 is composed, in part, of TLR9 agonist CpG oligonucleotides. If SD-101 or any of our future product candidates in clinical trials or similar products from competitors produce serious adverse event data, we may be required to delay, discontinue, or modify many of our clinical trials or our clinical trial strategy. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance

in cardiac adverse events have been observed in patients in our clinical trials. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce the scope of or discontinue certain of our pre-clinical or clinical activities.

Our long-term prospects are dependent on the success of our development-stage products including SD-101, which depend on regulatory approval. Failure to maintain or obtain regulatory approvals would materially and adversely impact us and our business prospects.

Our long-term prospects are dependent on SD-101, currently our sole development-stage immune- oncology product candidate, and early-stage development is inherently risky. Even if we have early indications of success in clinical development, in order to be able to market SD-101 in the United States, we must obtain approval from the FDA, and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in respective geographic areas. Obtaining FDA marketing approval and corresponding foreign applications is highly uncertain and we may fail to obtain approval, or might obtain approval in a more limited indication than sought. The FDA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials or the development program are satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or proposed post-marketing study, or a conclusion that the data fails to meet statistical or clinical significance or safety requirements; acceptability of data generated at our clinical trial sites that are monitored by third-party CROs; and deficiencies in our manufacturing processes or facilities or those of our third-party contract manufacturers and suppliers, if any.

In the event that we determine to commercialize SD-101 outside the United States, such as in Europe, whether we can do so successfully will depend upon us receiving regulatory approval, which can be costly and time-consuming, and there is a risk that one or more regulatory bodies may require that we conduct additional clinical trials and/or take other measures which will take time and require us to incur significant additional expense. In addition, there is the risk that we may not receive approval in one or more jurisdictions.

In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by such authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after the completion of the trial. The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. Failure to maintain or obtain regulatory approvals would materially and adversely impact us and our business prospects.

Even if we obtain regulatory approval for our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community, which could materially adversely impact our business, results of operations and financial condition.

Our sole pharmaceutical product candidate, SD-101, may never be approved for marketing as a potential cancer treatment. To the extent SD-101 is approved for marketing as a potential cancer treatment, it may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether SD-101 is accepted in the market, including:

- the clinical indications for which SD-101 is approved;
- physicians, hospitals, cancer treatment centers and patients considering SD-101 as a safe and effective treatment;
- the potential and perceived advantages of SD-101 over alternative treatments;
- our ability to demonstrate the advantages of SD-101 over other cancer medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of SD-101 as well as competitive products;
- the cost of treatment in relation to alternative treatments;

- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If SD-101 is approved by the FDA but fails to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, our business and prospects will be adversely affected. Even if SD-101 achieves market acceptance, it may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than SD-101, are more cost-effective or render SD-101 obsolete.

In addition, although SD-101 differs in certain ways from other approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

If our products do not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community, this could materially adversely impact our business, results of operations and financial condition.

Risks Related to Our Business and Industry

Changes in existing third-party coverage or our inability to secure advantageous reimbursement codes may impact our ability to sell our products, which would materially and adversely impact our business, results of operations, financial condition and prospects.

Maintaining and growing sales of TriNav, and any future product candidates, depends, in part, on the availability of coverage and adequate reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. The process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure. A payor's decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide such coverage. Adequate third-party reimbursement may not be available to enable us to achieve profitability. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce any existing levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

For example, our TPT payment for TriNav was extended on December 29, 2022, through the Consolidated Appropriations Act of 2023 and allows for reimbursement payments in the amount of $7,750 for each catheter through December 31, 2023. On June 1, 2023, we applied for a new technology APC code with CMS. We met with CMS on June 26, 2023, to review the application. If granted, the new technology APC code would allow for continuing reimbursement for the TriNav device at similar reimbursement rates for the period beginning January 1, 2024. There can be no assurance that such code will be granted or that continuing reimbursement will be available at similar reimbursement rates or at all. If TriNav does not receive adequate reimbursement, this would materially and adversely impact our business, results of operations, financial conditions, and prospects. Additionally, the reimbursement process is complex and can involve lengthy delays. Also, third-party payors may reject, in whole or in part, requests for reimbursement based on determinations that certain amounts are not reimbursable under plan coverage, that services provided were not medically necessary, that additional supporting documentation is necessary, or for other reasons. Retroactive adjustments by third-party payors may be difficult or cost-prohibitive to appeal, and such changes could materially reduce the actual amount we receive. Delays and uncertainties in the reimbursement process may be out of our control and could have a material adverse effect on our business, prospects, results of operations and financial condition.

Moreover, the reimbursement by third-party payors for our product and the amount that we may receive in payment for our products may be materially and adversely affected by factors we do not control, including federal or state regulatory or legislative changes, and cost-containment decisions and changes in reimbursement schedules of third-party payors or product purchasers (such as hospitals). Lack of reimbursement or any reduction or elimination of these payments could have a material adverse effect on our business, prospects, results of operations and financial

condition. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures using our products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payors using a methodology that sets amounts based on the type of procedure performed, such as those utilized by government programs and in many privately managed care systems, will view the cost of our products to be justified so as to incorporate such costs into the overall cost of the procedure. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to achieve profitability.

Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors in the future.

The business and industry in which we participate are highly competitive. If we are unable to compete effectively, we will not be able to establish our products in the marketplace or maintain or grow our products' market share in the marketplace, and as a result, our business and results of operations will be adversely impacted.

The biopharmaceutical and medical device industries are characterized by intense competition and rapid innovation. Our competitors may be able to develop other devices or drugs that are able to achieve similar or better results. Potential competitors for TriNav and SD-101 include major multinational medical device and pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of these competitors have substantially greater financial, technical, and other resources than we do, such as larger research and development staff, experienced marketing and manufacturing organizations, well-established sales forces, and name recognition. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than SD-101 or may develop proprietary technologies or secure patent protection that we may need for the development of our drug delivery technologies and products or product candidates.

The availability and price, and in the case of SD-101, if approved, its FDA-approved labeling versus that of competitors of our competitors' products could limit the demand and the price we are able to charge for TriNav and SD-101, if approved. We may not be able to implement our business plan if the acceptance of TriNav or SD-101 is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment, or if physicians switch to other new drug or biologic products or drug delivery systems or choose to reserve TriNav and/or SD-101 for use in limited circumstances.

We may, in the future, enter into material collaborations, in-licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant or any future revenues. Alternatively, part of our strategy is to enter into such kinds of relationships with third parties involving our products and product candidates, and we may not be able to do so on acceptable terms or at all.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances to develop and/or commercialize our products or product candidates and/or to pursue new markets. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, and strategic alliances may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues or otherwise achieve their goals and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of

performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

Our business and growth strategy depend on the continued ability of TriNav to remain a preferred product among a community of established, board-certified physicians and other provider specialists and to expand such community. If we are unable to do so, our future growth would be limited and our business would be harmed.

Our success is dependent upon the continued ability of TriNav to remain a preferred product among a community of independent, established, board-certified physicians and other provider specialists who choose to use TriNav in their medical practice. Fulfilling our clinical and customer service obligations requires a robust supply of physicians. If we are unable to attract and engage with board-certified physicians and other healthcare professionals to expand our community, it would harm our business and ability to grow and would adversely affect our results of operations. In any particular market, the hospitals that purchase TriNav for use by these providers could demand higher payments or take other actions that could result in higher costs or difficulty meeting regulatory or accreditation requirements. Our ability to develop and maintain satisfactory relationships with these providers, and to attract and engage with new providers, also may be negatively impacted by other factors not associated with us, such as changes in Medicare and/or Medicaid reimbursement levels and other pressures on healthcare providers and consolidation activity among hospitals, physician groups and healthcare providers. The failure to maintain or to secure new cost-effective contracts with the hospitals may result in a loss of or inability to grow our customer base, higher costs and/or healthcare provider community disruptions, any of which could harm our business.

We generally do not have long-term contractual commitments from our customers, and our customers may choose not to enter into new agreements with us.

We generally do not have long-term contractual commitments with our customers. Our TriNav customers can terminate many of our consignment agreements with or without cause, in some cases subject only to 30 days' prior notice in the case of termination without cause. Although a substantial majority of our revenue is typically generated from existing customers, our engagements with our customers are typically for orders that are singular in nature. Large consignment orders may involve multiple deliveries or stages, and a customer may choose not to replace inventory with TriNav devices or may cancel or delay additional planned orders.

Even if we successfully deliver on contracted orders and maintain close relationships with our customers, a number of factors outside of our control could cause the loss of or reduction in business or revenue from our existing customers. The loss or diminution in business from any of our major customers could have a material adverse effect on our business, financial condition, results of operations and prospects. The ability of our customers to terminate agreements exacerbates the uncertainty of our future revenue. We may not be able to replace any customer that elects to terminate or not renew its contract with us.

We may be unable to effectively manage our growth or achieve anticipated growth.

The success of our future operating activities will depend upon our ability to expand our support system to meet the demands of our growing business. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing, research, drug development and regulatory affairs. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. We will be required to manage multiple relationships with various customers, clinical investigators, manufacturers and suppliers, consultants and other third parties. This expansion and these expanded relationships will require us to significantly improve or replace our existing managerial, operational and financial systems, procedures and controls; to improve the coordination between our various corporate functions; and to manage, train, motivate and maintain a growing employee base. The time and costs to effectuate these steps may significantly strain our management personnel, systems and resources, particularly given the limited amount of financial resources and skilled employees that may be available at the time. We may not be able to institute, in a timely manner or at all, the improvements to our managerial, operational and financial systems, procedures and controls necessary to support our anticipated increased levels of operations and to coordinate our various corporate functions, or that we will be able to properly manage, train, motivate and retain our anticipated increased employee base. Any failure by our management to effectively anticipate, implement, and manage changes required to sustain our growth would have a material adverse effect on our business,

financial condition, and results of operations. We cannot assure you that we will be able to successfully operate acquired businesses, if any, become profitable in the future, or effectively manage any other change.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our future performance depends to a large extent on the continued services of members of our current management including, in particular, our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer. If any of these key executive officers were to leave us, we would be forced to expend significant time and money in the pursuit of a replacement, which would result in both a delay in the implementation of our business plan and the diversion of limited working capital. The unique knowledge and expertise of these individuals would be difficult to replace. In the event that we lose the continued services of such key personnel for any reason, this could have a material adverse effect on our business, operations and prospects. In addition, we will be required over the longer-term to hire highly skilled managerial, scientific and administrative personnel to fully implement our business plan and growth strategies. Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific, technical and managerial personnel. If we cannot attract and retain such personnel, we will be unable to develop our product candidates and achieve regulatory clearance for them, which would have a material adverse effect on our business, financial condition, and results of operations.

As of October 16, 2023, we had approximately 106 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing, research, drug development and regulatory affairs. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, in a timely manner or at all. In particular, we have experienced a very competitive hiring environment. Many of the other biotechnology and medical device companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity incentive awards that vest over time. The value to employees of stock options or other equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams are at-will employees and may terminate their employment with us on short notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior personnel across the organization.

Workforce shortages may continue to negatively impact our operations.

Workforce shortages have resulted in staffing challenges experienced by us and by third parties that we utilize, including but not limited to manufacturing and testing organizations, CROs and clinical trial sites. If these challenges continue for any period of time, our anticipated timing of clinical trials and product development may be delayed and our product inventory may not meet demand.

If we fail to promote, protect, and maintain our brand in a cost-effective manner, we may lose market share and our ability to commercialize our products and revenues will suffer.

Our ability to further develop our business depends on our ability to build a strong and trusted brand. We are in the process of building our brand, and once achieved, we believe that developing, protecting, and maintaining awareness of our brand in a cost-effective manner will be critical to continuing to develop our business. Successful promotion of our brand will entail broadening our brand among physicians and hospitals and will depend largely on the effectiveness of our marketing efforts and the experience of physicians who use our products and product candidates in treating their patients. Our efforts to build our brand have involved significant expense, and we expect to increase our marketing spend in the near term. These brand promotion activities may not result in increased revenue and, even if they do, any increases may not offset the expenses incurred. Additionally, the successful protection and maintenance of our brand will depend on our ability to obtain, maintain, protect and enforce trademark and other intellectual property protection for our brand. If we fail to successfully promote, protect and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote, protect and maintain our brand, we may be unable to broaden the use of our products and product candidates among physicians and hospitals, which would have an adverse effect on our business, financial condition and results of operations.

The medical device and drug development industries are characterized by rapid, continuous innovation, and if we cannot keep pace with rapid innovation in those industries, our products and product candidates will become less competitive and our ability to commercialize our products and revenues will suffer.

The medical device and drug development industries are highly competitive and characterized by rapid and significant change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete or less competitive. Many of our current and potential competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Larger competitors may have substantially larger sales and marketing operations than we have or plan to have and may have greater name recognition. This may allow those competitors to spend more time with potential customers and to focus on a larger number of potential customers, which would give them a significant advantage over the sales and marketing team we would use in making sales.

Larger competitors may also have broader product lines, which enable them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical studies, obtaining FDA and foreign regulatory approvals or certifications and marketing approved or certified products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. There can be no assurance that other companies will not succeed in developing or marketing products that are more effective than our products or product candidates or that would render our products or product candidates obsolete or noncompetitive. Academic institutions, government agencies, and other public and private research organizations may seek patent protection regarding potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors. Our competitors may be better equipped than we are to respond to competitive pressures. Competition will likely intensify.

Additionally, many healthcare provider systems are consolidating to create new companies with greater market power, and we expect that to continue. As the healthcare provider systems consolidate, competition among suppliers to healthcare provider systems will become more intense. Healthcare provider systems may try to use their market power to negotiate price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue will decrease and our results of operations and financial condition will suffer.

The manufacturing of our product candidates may require outsourced, custom manufacturing, and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If our third-party manufacturers or suppliers encounter such difficulties, our ability to provide supply of product candidates for preclinical studies, clinical trials or products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

In the course of developing our product candidates, we expect that various aspects of the development program, such as manufacturing methods, may be altered along the way to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned preclinical studies or future clinical trials.

If either we or any third-party we rely on for materials used in the production of our product candidates is adversely affected by ongoing supply chain constraints, we and our third-party manufacturers may be unable to timely manufacture product candidates for our clinical trials. Although we are working to develop commercially viable manufacturing processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up or formulation, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials.

Any of these challenges could delay completion of preclinical studies or clinical trials, require bridging studies or trials, or the repetition of one or more studies or trials, increase development costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

We currently rely on, and may in the future rely on, third-party contractors, including certain sole-source suppliers and manufacturers, to supply and manufacture preclinical, clinical and commercial drug supplies for SD-101 and any future product candidates.

We do not currently have the internal infrastructure to supply or manufacture preclinical, clinical or commercial quantities of our drug candidate, SD-101. While we have a supply of SD-101 sufficient for our ongoing clinical trials, we do not currently have a supplier for SD-101. If we are not able to establish a reliable supplier for SD-101 before our supply is exhausted, our clinical trials may be delayed.

We may be unable to establish agreements and validate third-party manufacturers and suppliers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers and suppliers entails additional risks, including, but not limited to:

- reliance on the third party for sufficient quantity and quality;
- the possible breach of the manufacturing or supply agreement by the third party;
- failure to manufacture or supply SD-101 according to our specifications, schedule or at all;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or comparator not being properly identified;
- misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions; and
- the reliance on the third party for regulatory compliance, quality assurance and safety reporting.

Thus, our current and anticipated future dependence upon others for the manufacture or supply of SD-101 or other product candidates and materials may adversely affect our development timeline, our future profit margins or our ability to commercialize SD-101 or any future product candidates that receive marketing approval on a timely and competitive basis.

We may rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. We may also have sole-source suppliers for one or more of our other product candidates. Some of the active pharmaceutical ingredients (“APIs”) and other substances and materials used in our product candidates are currently available only from one or a limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers.

In the event an existing supplier or manufacturer fails to supply or manufacture, as applicable, product or product candidate on a timely basis or in the requested amount, fails to meet regulatory requirements or our specifications, becomes unavailable through business interruption or financial insolvency or loses regulatory status as an approved source, or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement suppliers, manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases, we may be required to get regulatory approval to use alternative suppliers and manufacturers, and this process of approval could delay the production of our products or development of product candidates indefinitely. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

Although we are ultimately responsible for ensuring compliance with regulatory requirements such as current Good Manufacturing Practices (“cGMPs”), we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs for production. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If our contract suppliers or manufacturers fail to achieve and maintain compliance with applicable laws and regulatory requirements, our business could be adversely affected in a number of ways, and cause, among other things:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- third-party manufacturing facilities or our own facilities to be subjected to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates;
- suspension of manufacturing of our products or product candidates;
- revocation of obtained approvals; and
- inability to meet commercial demands for our products or product candidates in the event of approval.

Further, if the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws and regulatory requirements, or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates and could entail higher costs or result in us being unable to effectively commercialize our approved products on a timely basis, or at all.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future, but supply and manufacturing arrangements do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. We and our contract suppliers and manufacturers may attempt to improve production processes, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes. While we attempt to build in certain contractual obligations on such third-party suppliers and manufacturers, we may not be able to ensure that such third parties comply with these obligations. Depending on the extent of any difficulties encountered, we could experience an interruption in clinical or commercial supply, with the result that the development, regulatory approval or commercialization of our products or product candidates may be delayed or interrupted.

Our risk management processes and procedures may not be effective.

While we have dedicated resources to develop risk management processes and procedures intended to identify, measure, monitor and control the types of risk we are subject to, including liquidity risk, strategic risk, operational risk, cybersecurity risk, healthcare regulatory compliance risk, product liability risk, and reputational risk, those procedures may not be effective.

Risk is inherent in our business, and therefore, despite our efforts to manage risk, there can be no assurance that we will not sustain unexpected losses. We could incur substantial losses and our business operations could be disrupted to the extent our business model, operational processes, control functions, technological capabilities, risk analyses, and business/product knowledge do not adequately identify and manage potential risks associated with our business operations and strategic initiatives. There also may be risks that exist, or that develop in the future, that we have not appropriately anticipated, identified or mitigated, including when processes are changed or new products are introduced. If our risk management framework does not effectively identify and control our risks, we could suffer unexpected losses or be adversely affected, which could have a material adverse effect on our business, financial condition, and results of operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely may process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, which could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of- service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications and electrical failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion

payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks and other threats to our business operations. We may rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. We may also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business, including clinical trial sites and investigators, contractors, manufacturers, suppliers, and consultants. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

There can be no assurance that the information security measures we have adopted will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, including government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm (including but not limited to damage to our patient, partner, or employee relationships); monetary fund diversions; interruptions in our operations (including availability of data and interruptions to our clinical trial operations); financial loss; delay in the development and commercialization of our products and product candidates; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Natural or man-made disasters and other similar events may significantly disrupt our business, and negatively impact our business, financial condition and results of operations.

Our ability to make, move and sell products in coordination with our suppliers, manufacturers and business partners is critical to our success. Damage or disruption to our collective supply, manufacturing or distribution capabilities resulting from weather, any potential effects of climate change, natural disasters, pandemics or other outbreaks of contagious diseases, fire, explosion, cyber-attacks, terrorism, strikes, repairs or enhancements at facilities manufacturing or delivering TriNav or other reasons could impair our ability to manufacture, sell or timely deliver TriNav to customers and patients. Further, such damage or disruption to the supply, manufacturing, or trial sites of SD-101 could impair our ability to complete our clinical trials on a timely basis, if at all.

We rely on a limited number of third-party suppliers and manufacturers. Adverse events affecting such suppliers or manufacturers may limit our ability to obtain the materials they supply or manufacture for us, or alternatives at competitive prices, or at all. Competitors can be affected differently by weather conditions and natural disasters depending on the location of their suppliers and operations. Failure to take adequate steps to reduce the likelihood or mitigate the potential impact of such events, or to effectively manage such events if they occur, particularly when materials are sourced from a single location or supplier or produced by a single manufacturer, could adversely affect our business, financial condition, results of operations and/or require additional resources to restore our supply chain or manufacturing capabilities, as applicable.

Any acquisitions, strategic investments, entries into new businesses, joint ventures, divestitures, and other transactions could fail to achieve strategic objectives, disrupt our ongoing operations, result in operating difficulties, liabilities and expenses, harm our business, or negatively impact our results of operations.

We may evaluate and consider strategic transactions, combinations, acquisitions, dispositions, joint ventures or similar transactions. These transactions could be material to our financial condition and results of operations if consummated. If we are able to identify an appropriate business opportunity, we may not be successful in negotiating favorable terms and/or consummating the transaction and, even if we do consummate such a transaction, we may be unable to obtain the benefits or avoid the difficulties and risks of such transaction. Any strategic transaction, combination, acquisition, disposition, joint venture or similar transaction will involve risks encountered in business relationships, including:

- difficulties in assimilating and integrating the operations, personnel, systems, data, technologies, products and services of the acquired business;
- inability of the acquired technologies, products or businesses to achieve expected levels of revenue, profitability, productivity or other benefits;
- difficulties in retaining, training, motivating and integrating key personnel;
- diversion of management's time and resources from our normal daily operations;
- difficulties in successfully incorporating licensed or acquired technology and rights into our operations;
- difficulties in maintaining uniform standards, controls, procedures, and policies within the combined organizations;
- difficulties in retaining relationships with customers, employees, and suppliers of the acquired business;
- risks of entering markets in which we have no or limited prior experience;
- regulatory risks, including remaining in good standing with existing regulatory bodies or receiving any necessary pre-closing or post-closing approvals, as well as being subject to new regulators with oversight over an acquired business;
- assumption of contractual obligations that contain terms that are not beneficial to us, require us to license or waive intellectual property rights, or increase our liability;
- failure to successfully further develop any acquired product candidates or technology;
- liability for activities of the acquired or disposed of business before the acquisition or disposition, including patent and trademark infringement claims, violations of laws, regulatory actions, commercial disputes, tax liabilities, assumed debt and other known and unknown liabilities;
- difficulty in separating assets and replacing shared services;
- potential disruptions to our ongoing businesses; and
- unexpected costs and unknown risks and liabilities associated with the specific transaction.

We may not make any strategic transactions, combinations, acquisitions, dispositions, joint ventures or similar transactions, or any future transactions, combinations, acquisitions, dispositions, joint ventures or similar transactions may not be successful, may not benefit our business strategy, may not generate sufficient revenue to offset the associated costs, or may not otherwise result in the intended benefits.

It may take us longer than expected to fully realize the anticipated benefits and synergies of these transactions, including the Business Combination, and those benefits and synergies may ultimately be smaller than anticipated or may not be realized at all, which could adversely affect our business and operating results.

Any strategic transactions, combinations, acquisitions, dispositions, joint ventures or similar transactions may also require us to issue additional equity securities, spend our cash, or incur debt (and increase our interest expense), liabilities, and amortization expenses related to intangible assets or write-offs of goodwill, which could adversely affect our results of operations and the interests of holders of our indebtedness and dilute the economic and voting rights of our stockholders.

In addition, we cannot assure you that any future acquisition of new businesses, products, product candidates or technologies will lead to the successful integration of any products, product candidates or technologies acquired with our existing operations or the successful development of new or enhanced products or that any new or enhanced products, if developed, will achieve market acceptance or prove to be profitable. Further, we may also choose to divest certain businesses or product lines that no longer fit with our strategic objectives. If we decide to sell assets or a business, we may have difficulty obtaining terms acceptable to us in a timely manner, or at all. Additionally, the terms of such potential transactions may expose us to ongoing obligations and liabilities.

Risks Related to Our Legal and Regulatory Environment

We are subject to numerous complex regulatory requirements, and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The research, pre-clinical testing, clinical trials, manufacturing, marketing and distribution of medical devices, human drugs and biologics and combination products are subject to regulation by numerous governmental authorities in the United States and other jurisdictions, if we desire to export the resulting products to such other jurisdictions. These regulations govern or affect the testing, manufacture, safety, effectiveness, labeling, storage, record-keeping, approval or clearance, distribution, advertising and promotion of product candidates, as well as safe working conditions. In some cases, the FDA requirements have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. The FDA and foreign regulatory authorities have substantial discretion to require additional testing, to delay or withhold registration and marketing approval or clearance and to otherwise preclude distribution and sale of a product. In addition, regulatory approval or clearance could impose limitations on the indicated or intended uses for which product candidates may be marketed, and impose post- approval requirements. Our failure to obtain approval or clearance, significant delays in the approval or clearance process, or our failure to maintain approval or clearance in any jurisdiction will prevent us from selling any applicable products in that jurisdiction. We would not be able to realize revenues for those new products in any jurisdiction where we do not have approval or clearance.

Even after a product candidate has been approved, the FDA and comparable governmental authorities subject such product to continuing review and regulatory requirements including, for example, the reporting of safety issues or adverse events associated with use of an approved drug or cleared or approved device.

These authorities may, in certain circumstances, require us to conduct and report the results of certain clinical studies or trials and to commit to voluntarily conducting additional clinical trials. Developments following regulatory approval or clearance may adversely affect sales of our products.

Failure to comply with, or changes to applicable regulatory requirements may result in a variety of consequences, including the following:

- restrictions on our products or the manufacturing processes of such products;
- warning letters, untitled letters and cyber letters;
- withdrawal of a product from the market;
- voluntary or mandatory recall of a product;
- fines;
- suspension or withdrawal of regulatory approvals or clearances for a product;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;

- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization;
- denial of permission to file an application or supplement in a jurisdiction;
- debarment, exclusion from participation in federal healthcare programs, exclusion or debarment from government contracting, consent decrees, or corporate integrity agreements;
- seizure or detention of products; and
- injunctions or the imposition of civil or criminal penalties against us.

More stringent oversight by the FDA and other agencies in recent years has resulted in increased enforcement activity, which increases our compliance risk.

To the extent that we or our partners do not perform particular regulated functions themselves but contract out to third parties, including contract manufacturers, contract research organizations, clinical trial sites, and laboratories, we or our partners may be held responsible for such third parties' failure to follow the applicable regulatory requirements.

The complexity of a combination product that includes a drug and a medical device presents additional, unique development and regulatory challenges, which may adversely impact our development plans and our ability to obtain regulatory approval or clearance of our product candidates.

We may decide to pursue marketing authorization for a combination product comprised of drug candidates and medical devices. A combination product includes, among other possibilities, a combination of a drug and device intended to be used together, according to their proposed labeling where both are required to achieve the intended use, indication or effect.

Developing and obtaining regulatory approval or clearance for combination products pose unique challenges because they involve components that are regulated by the FDA pursuant to different regulatory frameworks and by different FDA centers. As a result, such products raise regulatory, policy and review management challenges. For example, because divisions from both FDA's Center for Drug Evaluation and Research and FDA's Center for Devices and Radiological Health must review submissions concerning product candidates that are combination products comprised of drug and devices, the regulatory review and approval or clearance process for these products may be lengthened. In addition, differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post- approval modifications. Similarly, the device components of our product candidates will require any necessary approvals or clearances or other marketing authorizations or certifications in other jurisdictions, which may prove challenging to obtain.

We intend to use the FDA's expedited drug development programs for SD-101 but may not be able to achieve expedited development or approval for this product candidate.

The FDA has established various expedited drug development programs to facilitate more rapid and efficient development, review and approval of certain types of drugs. Such programs include fast track designation, breakthrough therapy designation, accelerated approval, and priority review. We intend to use one or more expedited drug development programs for SD-101. The FDA has broad discretion on whether or not to admit a drug candidate for these programs, so even if we believe a particular product candidate is eligible for an expedited drug development program, we cannot assure you that the FDA would agree. Even if any of our product candidates is admitted to any of the expedited drug development programs, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve such product candidates.

Fast track designation is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. Programs with fast track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. If any of our product candidates receive fast track designation but do not continue to meet the criteria for fast track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply or due to other issues, we will not receive the benefits associated with the fast track program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

FDA may award breakthrough therapy designation to a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary

clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Designation as a breakthrough therapy is within the discretion of the FDA. Even if one or more of our product candidates qualify as breakthrough therapies pursuant to FDA standards, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek breakthrough therapy designation for one or more of our current or future product candidates, there can be no assurance that we will receive breakthrough therapy designation.

If any of our programs or product candidates receive fast track or breakthrough therapy designation by the FDA or similar designations by other regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track or breakthrough therapy designation does not ensure that a product candidate will receive marketing approval or that approval will be granted within any particular time frame. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development program upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of SD-101 or any future product candidates. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Even if we receive orphan drug designation for any of our product candidates, we may be unable to maintain the benefits associated with such designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the EU, may also designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA's Committee for Orphan Medicinal Products evaluates orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers, and it may entitle the therapeutic to exclusivity. Regulatory authorities may not grant our requests for orphan designation or may require submission of additional data before making such determination.

Even if we receive orphan drug designation for any of our product candidates, there is no guarantee that it will obtain approval or orphan drug exclusivity for such product candidates. Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product candidates from competition because different therapies can be approved for the same condition and the same therapy could be approved for different conditions. Even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease for which it received orphan designation. On January 24, 2023, the FDA announced its intention to apply its existing regulations and long-standing approach to grant orphan drug exclusivity based on the indications for which the drug is approved rather than granting the exclusivity for the entire rare disease or condition that was the subject of the orphan drug designation, in response to the U.S. Court of Appeals for the Eleventh Circuit's September 30, 2021, decision in *Catalyst P harms., Inc. v. Becerra*. Moreover, 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 if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. 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.

Further, under the Inflation Reduction Act of 2022 ("IRA"), orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is

for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Disruptions at the FDA, SEC and other government agencies (e.g., CMS) caused by funding shortages or global health concerns could hinder our ability to hire and retain key leadership and other personnel, prevent new products 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 our business.

The ability of the FDA to review and approve new products 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 new medical devices, drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times, certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, 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 our business.

Separately, in response to the COVID-19 pandemic, the FDA had to postpone inspections of foreign and domestic manufacturing facilities and products. While such inspections have resumed, the FDA may use remote interactive evaluations where in-person inspections are not feasible or may defer action due to factors including travel restrictions. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting business as usual or conducting 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 our business.

Accordingly, if we or any future collaborators experience delays in obtaining approval or clearance or if we or they fail to obtain approval or clearance of SD-101 or any future product candidates, the commercial prospects for these product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval or clearance process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals or clearances for the commercialization of SD-101 or any future product candidates. If we or any future collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals or clearances, we or they will not be able to commercialize SD-101, and our ability to generate revenue will be materially impaired.

The activities associated with SD-101 or other product candidates' development and commercialization, including testing, manufacturing, safety, efficacy, record keeping, labeling, storage, approval or clearance, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States. Additionally, in order to commercialize, develop, market and sell our products in the EU, Canada, the United Kingdom, China or other countries and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals or clearances and comply with numerous and varying regulatory requirements for comparable regulatory authorities in these other countries.

Failure to obtain marketing approval or clearance for SD-101 or any future product candidates will prevent us from commercializing them. We have not received approval to market SD-101 from regulatory authorities in any jurisdiction. We have limited experience in the designing of clinical trials, in obtaining authorization and in conducting clinical trials in various countries and expect to rely on third-party CROs to assist us in this process. Securing marketing approval or clearance requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy.

SD-101 or any future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining

marketing approval or clearance or prevent or limit commercial use. The success of our product candidates will depend on several additional factors, including:

- successful completion of preclinical studies;
- successful initiation of, patient enrollment in, and completion of clinical trials that demonstrate their safety and efficacy;
- receiving marketing approvals or clearances from applicable regulatory authorities;
- obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates;
- completing any post-marketing studies required by applicable regulatory authorities;
- making and maintaining arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval or clearance;
- obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;
- competing effectively with other cancer therapies, including with respect to the sales and marketing of our product candidates, if approved;
- obtaining licenses to any third-party intellectual property we deem necessary or desirable; and
- obtaining any necessary third-party agreements to register SD-101 as part of a combination therapy.

Many of these factors are beyond our control, including the time needed to adequately complete preclinical studies, clinical testing and the regulatory submission process, our ability to obtain and protect intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval or clearance, even if we expend substantial time and resources seeking such approval or clearance. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We or any future third-party collaborators may not obtain approvals or clearances from regulatory authorities outside the United States on a timely basis, if at all. Approvals or clearances by the FDA does not ensure approval or clearance by regulatory authorities in other countries or jurisdictions, and approval or clearance by one regulatory authority outside the United States does not ensure approval or clearance by regulatory authorities in other countries or jurisdictions or by the FDA. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or clearance or, if approved, commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects.

We may in the future develop product candidates in combination with other therapies and that may expose us to additional risks.

We may develop future product candidates for use in combination with one or more currently approved therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs that we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates.

Even if we obtain regulatory approval or clearance for SD-101 or any future product candidates, such product candidates will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approval or clearance for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping.

These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals or clearances that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval or clearance, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, that may require surveillance requirements regarding monitoring the safety and efficacy of the product candidate. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval or clearance for any future product candidates we may develop, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA may also require a Risk Evaluation and Mitigation Strategies ("REMS") as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

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 or clearance 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 or clearance that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;
- suspension or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects.

In particular for TriNav and the pancreatic retrograde venous infusion ("PRVI") device and any future medical device product candidate, we and our third-party suppliers are required to comply with the FDA's Quality System Regulation ("QSR"). These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we or our manufacturers fail to adhere to QSR requirements in the United States, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA assesses compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and

regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the enforcement actions listed above. Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

If any of our product candidates receives marketing approval or clearance and we or others later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval or clearance, and we or others later discover that such product candidates are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals or clearances of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- requirements that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to approval or clearance or post-marketing studies required by regulatory authorities of such product;
- adverse impact on the product’s competitiveness;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could harm our business, financial condition, results of operations and prospects.

Healthcare reform and other governmental and private payor initiatives may have an adverse effect upon, and could prevent, the commercial success of our products or product candidates.

In the U.S. and in certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably, such as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, or collectively the Affordable Care Act (“ACA”).

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. For example, the former Trump administration issued various Executive Orders which eliminated cost-sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. Further, on December 20, 2019, the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax, was signed into law. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the ACA would have on our business, especially under the Biden administration.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach the required goals, thereby triggering the legislation’s

automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2032 unless additional congressional action is taken.

There has been increasing legislative and enforcement interest in the U.S. with respect to prescription- pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. It is unclear what effect such legislative and enforcement interest may have on prescription devices. Further, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify the prior administration's executive and administrative actions.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on reimbursement price that we receive for any cleared, authorized, or approved device, which could have an adverse effect on patients for our products or product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory clearance, authorization, or approval and that may affect our overall financial condition and ability to develop product candidates. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates that we may develop may lose any regulatory clearance, authorization, or approval that may have been obtained and we may not achieve or sustain profitability.

TriNav and the PRVI device must be manufactured in accordance with federal and foreign regulations, and we or any of our suppliers or third-party manufacturers could be forced to recall the products or terminate production if we fail to comply with these regulations.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. For the FDA, the authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or another third-country competent authority. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or another third-country competent authority. If the FDA disagrees with our determinations, the FDA could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report recalls. We are also required to follow detailed recordkeeping requirements for all firm- initiated medical device corrections and removals.

If treatment guidelines for the cancer indications that we are targeting change or the standard of care evolves, we may need to redesign our preclinical or clinical trials of, or seek new marketing authorization from, the FDA for any approved products.

If treatment guidelines for the cancer indications that we are targeting change or the standard of care evolves, We may need to redesign TriNav, the PRVI device or any product candidates and seek new clearances or approvals from the FDA for any approved products. Our 510(k) clearances from the FDA for TriNav, TriNav Large and the PRVI device are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of TriNav and the PRVI device could be diminished, and our business could suffer. Competition by other forms of cancer treatment, for example, the development of new and more efficacious systemic therapies, could reduce the use of regional therapy as a standard of care in certain indications. Changes in treatment guidelines or standard of care may also impact product coverage and/or reimbursement by payers.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delays.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval or clearance and commercialization, it is common that various aspects of the development activities, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results.

Any of these changes could cause SD-101 or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, including comparability testing, to bridge earlier clinical data obtained from SD-101 produced under earlier manufacturing methods or formulations, and regulatory authorities may disagree on the interpretation of results from this testing. This could delay the 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 SD-101 or any future product candidates and jeopardize our ability to commence sales and generate revenue.

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians and third-party payors in the United States and elsewhere, will play a primary role in the recommendation of TriNav and the PRVI device and prescription of any product candidates for which we obtain marketing approval or clearance. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws, data privacy and security laws, transparency laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute TriNav and the PRVI device, and any other any future products candidates once they have obtained marketing authorization. We are also subject to healthcare regulation and enforcement by the U.S. federal government and the states and any other countries in which we conduct our business, including our research, and the sales, marketing and distribution of TriNav, the PRVI device or any future products candidates once they have obtained marketing authorization.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

If the physicians or other providers or entities with whom we do, or expect to do, business are 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. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have a material adverse effect on our ability to compete in the marketplace.

We could be subject to litigation that could have an adverse effect on our business and operating results.

We are, from time to time, involved in litigation. The numerous operating hazards inherent in our business increase our exposure to litigation, which may involve, among other things, contract disputes, personal injury, environmental, employment, warranty and product liability claims, tax and securities litigation, patent infringement and other intellectual property claims and litigation that arises in the ordinary course of business. Our management cannot predict with certainty the outcome or effect of any claim or other litigation matter. Litigation may have an adverse effect on us because of potential negative outcomes such as monetary damages or restrictions on future operations, the costs associated with defending the lawsuits, the diversion of management's resources and other factors.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We are developing additional sizes of, and uses for, the TriNav device. Our product candidates may be used in connection with medical procedures in which it is important that those products function with precision and accuracy. If our existing TriNav device or our product candidates, if approved, do not function as designed, or are designed improperly, we may be forced by regulatory agencies to withdraw such products from the market. In addition, the use of our product candidates in clinical trials, the sale of any products for which we obtain marketing approval, and other liability risks that are inherent in the testing, manufacturing, marketing and sale of medical devices exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- injury to our reputation;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources, and the inability to commercialize any product candidate;
- decreased demand for a product candidate, if approved for commercial sale; and
- loss of revenue.

Although we currently carry clinical trial insurance and product liability insurance which we believe to be reasonable, such insurance may not be adequate to cover all liability that we may incur. An inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators.

We may be subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "processing") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information and patient data (collectively, "sensitive data").

Our data processing activities may subject us to data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws).

For example, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information.

Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states also exempt some data processed in the context of clinical trials through laws like the California Consumer Privacy Act, these developments may further complicate compliance efforts, and may increase legal risk and compliance costs to us and the third parties upon whom we rely. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU's General Data Protection Regulation ("EU GDPR") imposes strict requirements for processing personal data, and, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, we could face significant adverse consequences.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may also be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Changes in tax law and differences in interpretation of tax laws and regulations may adversely impact our financial statements.

We operate in multiple jurisdictions and are subject to tax laws and regulations of the U.S. federal, state and local and non-U.S. governments. U.S. federal, state and local and non-U.S. tax laws and regulations are complex and subject

to change and varying interpretations. U.S. federal, state and local and non-U.S. tax authorities may interpret tax laws and regulations differently than we do and challenge tax positions that we have taken. This may result in differences in the treatment of revenues, deductions, credits and/or differences in the timing of these items. The differences in treatment may result in payment of additional taxes, interest or penalties that could have an adverse effect on our financial condition and results of operations. Further, future changes to U.S. federal, state and local and non-U.S. tax laws and regulations could increase our tax obligations in jurisdictions where we do business or require us to change the manner in which we conduct some aspects of our business.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited.

We have incurred financial losses during our history. Unused federal net operating losses ("NOLs") for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. These factors could limit our ability to use our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations.

Risks Related to Our Intellectual Property

Failure to obtain, adequately protect, maintain or enforce our intellectual property rights could substantially harm our business and results of operations.

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 a combination of patents, trademarks, trade secret protection and confidentiality agreements, including in-licenses of intellectual property rights of others, to protect our current or future platform technologies, products, product candidates, methods used to manufacture our current or future product candidates and methods for treating patients using our current or future product candidates.

We own or in-license patents and patent applications relating to our platform technologies, products and product candidates. There is no guarantee that any patents covering our platform technologies or product candidates will issue from the patent applications we own, in-license or may file in the future, or, if they do, that the issued claims will provide adequate protection for our platform technologies or product candidates, or any meaningful competitive advantage. Further, there cannot be any assurance that such patents issued will not be infringed, designed around, invalidated by third parties or effectively prevent others from commercializing competitive technologies, products or product candidates.

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 our research and development output before it is too late to obtain patent protection. The patent applications that we own or in- license may fail to result in issued patents, and, even if patents are issued, 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 its scope can be reinterpreted after issuance. We do not have exclusive control over the preparation, filing and prosecution of patent applications under certain of our in-license agreements, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents that we out-licenses 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 our 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 platform technologies, our product candidates, or the use of our technologies. We thus cannot know with certainty whether we or our licensors were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office ("USPTO") might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. 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 correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent or to prevent our 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 biotechnology and medical device companies like us 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. The relevant patent laws and their interpretation, both inside and outside of the United States, are also uncertain. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our platform technology or product candidates and could affect the value of such intellectual property. Our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe, misappropriate or otherwise violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our platform technology, product candidates, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may file or license in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Additionally, third parties, including our former employees and collaborators, may challenge the ownership or inventorship of our patent rights to claim that they are entitled to ownership and inventorship interest, and we may not be successful in defending against such claims. However, we are not currently facing any such challenges. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block —in some cases— potential competitors from practicing the claimed inventions of the issued patents.

The issuance, scope, validity, enforceability and commercial value of our pending patent rights are uncertain. The standards applied by 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. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. 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 we may obtain from our owned or in-licensed patent applications. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Further, patents and other intellectual property rights in the pharmaceutical, biotechnology and medical device space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our products, product candidates and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors or other parties with similar technology. Additionally, our competitors may initiate legal proceedings, such as declaratory judgment actions in federal court or reexaminations or an *inter partes* review at the USPTO in an attempt to invalidate or narrow the scope of our patents. However, we are not currently facing any such proceedings. Furthermore, our competitors or other parties may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our products, product candidates and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product candidate may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

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 products 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 products or product candidates that we may develop. Likewise, if patent applications we own or have in-licensed with respect to our development programs and current or future products 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 products 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 may be unable to prevent competitors from entering the market with a product that is similar or identical to any of our products or current or potential future product candidates or from utilizing technologies similar to those in our products or current product candidates.

The filing of a patent application or the issuance of a patent is not conclusive as to our 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 products and product candidates, or allow third parties to compete directly with us without payment to us. 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 products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, we currently co-own certain patents and patent applications with third parties and may in the future co-own additional patents and patent applications 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 conditions.

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 expiration or loss of patent protection may adversely affect our future revenues.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order to improve the probability that our product candidates are able to become profitable. Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our products and product candidates.

The patent positions of biotechnology and medical device companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U.S. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our products and product candidates may be impaired.

As of October 4, 2023, we owned at least 122 registered patents. Our issued U.S. patents expire between 2023 and 2040. All of our solely-owned granted U.S. and foreign patents that relate to composition of matter for SD-101 will expire in December 2023. Upon expiration of the patents covering SD-101, third parties, including other biopharmaceutical companies, will be able to obtain or use SD-101 other than to the extent we have other patent protection, including through our method of use patents for pressure controlled therapeutic delivery. In addition, certain of our patents relating to the use of TriNav will expire beginning in 2031, with additional patents relating to TriNav expiring in 2036 and 2038. While we are seeking additional patent coverage, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We also intend to apply for orphan drug designation and orphan designation in the U.S. and EU, respectively, which, if granted, would extend the exclusivity period beyond the initial five years of regulatory exclusivity from the date of approval in the U.S. and beyond the eight years of data exclusivity from the date of approval in Europe; however, there can be no assurance that we will ever obtain approval or orphan drug exclusivity for such product candidates. Without patent protection of our product candidates, we may be open to competition from generic versions of such methods and compositions. As of October 4, 2023, we have at least 69 pending patent applications and four U.S. provisional patent applications. We do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology and drugs, in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. Even if we are successful in obtaining a patent, patents have a limited lifespan. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection of our product candidates, we may be open to competition from generic versions of such methods and compositions.

There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to our product candidates. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non-infringing manner is increased.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the

FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, 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 our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following expiration of our regulatory exclusivity and our patent expiration, and launch their product earlier than might otherwise be the case.

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 covering our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does and novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions. Further, future licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products or product candidates and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and medical device products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Furthermore, while it intends to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products and product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our products and product candidates in all of our expected significant foreign markets.

Additionally, the requirements for patentability may differ in certain countries. Generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensees or any future licensors to engage in complex, lengthy and costly litigation or other proceedings. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensees or any future licensors may have limited remedies if patents are infringed or if we and our licensees or any future licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights in some regions of the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of the contributors to our intellectual property, including patents and applications, were previously employed at universities or other biotechnology, pharmaceutical or medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not

contain a self-executing assignment of intellectual property rights, or if such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our products or product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Our business model may require reliance on third parties and the need to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed, and if we are unable to protect the confidentiality of our trade secrets, the value of our intellectual property could be materially adversely affected and our business would be harmed.

In addition to seeking patents for some of our products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in seeking to develop and maintain a competitive position. Because we rely on third parties to manufacture our product candidates and we may collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

Since our inception, we have sought to contract with manufacturers to supply commercial quantities of pharmaceutical formulations. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers and suppliers. We believe that these disclosures, while necessary for our business, may result in the attempt by potential manufacturers and suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing and supplier rights.

We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or 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 such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know-how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our trade secrets or other proprietary and confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek to market generic versions of SD-101 or any other product candidate for which we may in the future obtain approval by submitting abbreviated new drug applications ("ANDAs") or biosimilar applications to the FDA or new products that use our approved products as the reference listed drug, in each case where our

competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with SD-101 and any future product candidates we may develop. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if patents are valid and enforceable, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non-infringing manner is increased.

Additionally, competitors could purchase TriNav or our other products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights.

We have in the past been, and may in the future be, subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and licensed patents have in the past been, and in the future may be, challenged in the courts or patent offices in the United States and abroad. For example, in October 2017, an individual filed a suit against Legacy TriSalus in the United States District Court, District of Colorado asserting joint inventorship of six patents assigned to Legacy TriSalus. The individual sought to be added as a co-inventor and co-owner of the patents in question. A stipulated dismissal order was entered in June 2021 with the court dismissing the plaintiff's case with prejudice. In the future, we may face similar or other challenges by third parties, former employees or collaborators with respect to ownership interest in the patents and intellectual property that we own or license at the time. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our products or product candidates. While it is our policy to require employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as Legacy-TriSalus owned. To the extent that we license intellectual property from a third party, such licensors may face similar obstacles. In addition, we have not updated the records in certain foreign patent offices to reflect our ownership of certain foreign patents relating to SD-101, but have recorded our ownership for at least the unexpired foreign patents acquired from Dynavax relating to composition of matter for SD-101 in Australia, Canada, Austria, Germany, Denmark, Estonia, the UK, Hong Kong, Ireland, Luxembourg, Portugal, New Zealand, and Singapore. Failure to update such ownership may result in a purchaser potentially acquiring rights in such patents that are adverse to our interests. Litigation may be necessary to defend against any claims challenging inventorship or ownership and such litigation may be costly. If we fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates.

To the extent undertaken, we cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until 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. In addition, certain United States patent applications can remain confidential until patents issue. Therefore, patent applications covering our products and product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products and product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and product candidates. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure

to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. 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 products or product candidates that are held to be infringing. We might, if possible, also be forced to redesign products or product candidates so that we no longer infringe 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.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations.

Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to:

- the scope of rights granted under the 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 agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect 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.

If we fail to comply with our obligations under any agreements, we may be required to pay damages and could lose intellectual property rights that are necessary or useful for developing and protecting our product candidates.

Dynavax has represented to us that we were given all intellectual property rights related to SD-101 pursuant to the Dynavax Agreement. Pursuant to the Dynavax Agreement, we are obligated to pay up to $250 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of products containing the SD-101 compound.

Additionally, we are responsible for prosecution and maintenance of the acquired patents with obligations to keep Dynavax reasonably informed of the status thereof. Any future collaboration agreements or 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.

If we breach any such material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and any 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 technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

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

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the

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

- others may be able to make formulations that are similar to our product candidates or other formulations but that are not covered by the claims of our patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;
- we or any current or future strategic partners and/or collaborators might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own;
- we or any of our current or future strategic partners and/or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;
- our competitors might conduct research and development activities in the United States and in other countries that provide a safe harbor from patent infringement claims for such activities, as well in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our existing or intended commercial markets;
- third parties performing manufacturing or testing for us using our product candidates could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

The validity, scope and enforceability of any of our patents can be challenged by third parties and any lawsuits to protect or enforce our patents could be expensive, time consuming and unsuccessful.

Competitors or other third parties may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In a 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, lack of novelty, obviousness or non-enablement. 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 following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a federal court against a U.S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. 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. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain product candidates or aspects of the TriNav or other technology. Such a loss of patent protection could compromise our ability to pursue our business strategy.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could

require us to cease using the technology or to attempt to license rights from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone, with our licensees, or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our products or product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future products or product candidates.

If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party submits an application under Section 505(b)(2) or an ANDA, for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with respect to our New Drug Application ("NDA") for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid or unenforceable, is called a "paragraph IV certification." If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us within 20 days once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may be issued in the future, within our portfolio which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our product candidates. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our product candidates, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing the applicable product candidate. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.

Our commercial success will largely depend on our ability to retain with respect to TriNav and other device technologies, and obtain with respect to SD-101 and other product candidates, market exclusivity in the United States and other countries. Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, certain of our product candidates may be eligible for marketing exclusivity.

The Federal Food, Drug and Cosmetic Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA or Section 505(b)(2) NDA for a new chemical entity, or NCE. An NCE is a drug that contains no active moiety (the molecule or ion responsible for the action of the drug substance) that has been approved by FDA in any other NDA submitted under section 505(b) of the FDC Act. During the five-year NCE exclusivity period, the FDA may not accept for review or approve an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a paragraph IV certification of patent invalidity, unenforceability, or non-infringement to one of the patents listed in the Orange Book, with the FDA by the innovator NDA holder.

The FDC Act also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations for a previously-approved active moiety, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a Section 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Three- year exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original conditions of use, i.e., original indications.

If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our approval to obtain approval of competing products and launch their product earlier than might otherwise be the case.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental 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 governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations 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.

If our trademarks 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.

We rely on trademarks as one means to distinguish any of our products or product candidates that are approved for marketing from the products of our competitors. TriNav® and Pressure-Enabled Drug Delivery™ (PEDD™) are our trademarks and, in the United States, our trademarks may be challenged, infringed, circumvented or declared descriptive or generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

Risks Related the Ownership of Our Securities

We have limited experience operating as a United States public company and may not be able to adequately develop and implement the governance, compliance, risk management and control infrastructure and culture required for a public company, including compliance with the Sarbanes Oxley Act.

We have limited experience operating as a United States public company. Certain of our executive officers lack experience in managing a United States public company, which makes their ability to comply with applicable laws, rules and regulations uncertain. Our failure to comply with all laws, rules and regulations applicable to United States public companies could subject us and our management to regulatory scrutiny or sanction, which could harm our reputation and share price.

We have limited experience preparing and filing periodic or other reports with the SEC or complying with the other requirements of United States federal securities laws applicable to public companies. We also have limited experience establishing and maintaining the disclosure controls and procedures and internal controls over financial reporting applicable to a public company in the United States, including the Sarbanes- Oxley Act. Although we are in the process of developing and implementing our governance, compliance, risk management and control framework and

culture required for a public company, we may not be able to meet the requisite standards expected by the SEC and/or our investors. We may also encounter errors, mistakes and lapses in processes and controls resulting in failures to meet the requisite standards expected of a public company.

As a United States public reporting company, we incur significant legal, accounting, insurance, compliance, and other expenses. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. Compliance with reporting, internal control over financial reporting and corporate governance obligations requires members of our management and our finance and accounting staff to divert time and resources from other responsibilities to ensure these new regulatory requirements are fulfilled.

If we fail to adequately implement the required governance and control framework, we could be at greater risk of failing to comply with the rules or requirements associated with being a public company. Such failure could result in the loss of investor confidence, could harm our reputation, and cause the market price of our securities to decline. Other challenges in complying with these regulatory requirements may arise because we may not be able to complete our evaluation of compliance and any required remediation in a timely fashion. Furthermore, any current or future controls may be considered as inadequate due to changes or increased complexity in regulations, our operating environment or other reasons.

Due to inadequate governance and internal control policies, misstatements or omissions due to error or fraud may occur and may not be detected, which could result in failures to make required filings in a timely manner and make filings containing incorrect or misleading information. Any of these outcomes could result in SEC enforcement actions, monetary fines or other penalties, as well as damage to our reputation, business, financial condition, operating results and share price.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management now devotes substantial time to new compliance initiatives and corporate governance practices. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act, which could result in sanctions or other penalties that would adversely impact our business.

As a public company, and particularly after we are no longer an “emerging growth company,” we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs resulting from public company reporting obligations under the Securities Act and the Exchange Act, and regulations regarding corporate governance practices. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the rules of the SEC, the listing requirements of the Nasdaq Stock Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have begun to hire additional accounting, finance, and other personnel in connection with becoming a public company, and our management and other personnel devotes a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We cannot predict or estimate the amount of additional costs we will incur as a result of becoming a public company or the timing of such costs. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the Board or committees of the Board or to serve as executive officers, or to obtain certain types of insurance, including directors’ and officers’ insurance, on acceptable terms.

Pursuant to Sarbanes-Oxley Act Section 404, we are required to furnish a report by our management on our internal control over financial reporting beginning with the filing of our Annual Report on Form 10-K with the SEC for the year ending December 31, 2023. In order to continue to maintain effective internal controls to support growth and public company requirements, we will need additional financial personnel, systems and resources. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act within the prescribed period, we are engaged in a process to enhance our documentation and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve

control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal control over financial reporting is effective as required by Sarbanes-Oxley Act Section 404. Our management has identified material weaknesses and in the future, our management may identify one or more material weaknesses, which could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Our management has identified material weaknesses in its internal control over financial reporting and we may identify additional material weaknesses in the future. If we fail to remediate the material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the financial statements would not be prevented or detected on a timely basis.

In connection with our audited consolidated financial statements for the years ended December 31, 2021 and December 31, 2022, management identified, material weaknesses in its internal control over financial reporting with respect (i) to a lack of sufficient number of trained resources with the appropriate skills and knowledge and with assigned responsibilities and accountability for the design and operation of internal controls over financial reporting and (ii) to inadequate internal controls over the valuation of the warrant and tranche rights and obligations liabilities resulting from the series B-2 preferred stock financing, each described in more detail under the heading Part I - Item 4. Controls and Procedures in this Quarterly Report on Form 10-Q.

To the extent reasonably possible given our limited resources, we intend to take measures to cure the aforementioned weaknesses, including, but not limited to, increasing the capacity and quantity of our qualified financial personnel to ensure that accounting policies and procedures are consistent across the organization and that we have adequate control over our Exchange Act reporting disclosures. Our management developed a remediation plan, and we are taking steps to remediate each of the material weaknesses described above. The material weaknesses will be considered remediated when our management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are designed and operating effectively. Our management will continue to monitor the effectiveness of the remediation plan and will make the changes it determines to be appropriate. Although our management intends to complete this remediation process as quickly as practicable, it cannot at this time estimate how long it will take, and initiatives may not prove to be successful in remediating the material weaknesses.

Furthermore, we cannot assure you that the remediation measures taken to date, and the actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weaknesses in our internal controls over financial reporting described above or that we will prevent or avoid potential future material weaknesses. Further, additional weaknesses in our disclosure controls and internal controls over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in material errors in our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the listing requirements of Nasdaq, investors may lose confidence in our financial reporting and our stock price may decline as a result. In addition, we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities as well as shareholder litigation which would require additional financial and management resources, and investors may lose confidence in our financial reporting and our stock price may decline as a result. As a result, our ability to obtain financing, or financing on favorable terms, could be materially and adversely affected, which in turn, could materially and adversely affect our business, financial condition and the market value of our common stock and require us to incur additional costs to improve our internal control systems and procedures. In addition, perceptions of us among customers, partners, investors, securities analysts and others could also be adversely affected.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required to comply with the requirements of the Sarbanes-Oxley Act, including, among other things, maintaining effective disclosure controls and procedures and internal control over financial reporting. We continue to develop and refine our disclosure controls and other procedures that are designed to ensure

that the information we are required to disclose in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers.

We must continue to improve our internal control over financial reporting. Our management will be required to make a formal assessment of the effectiveness of our internal control over financial reporting pursuant to Sarbanes-Oxley Act Section 404(a), and we may in the future be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with these requirements within the prescribed time period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

There is a risk that we will not be able to conclude, within the prescribed time period or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act.

Any failure to implement and maintain effective disclosure controls and procedures and internal control over financial reporting, including the identification of one or more material weaknesses, could cause investors to lose confidence in the accuracy and completeness of our financial statements and reports, which would likely adversely affect the market price of our Common Stock. In addition, we could be subject to sanctions or investigations by the stock exchange on which our Common Stock is listed, the SEC and other regulatory authorities.

The price of our Common Stock and Public Warrants has been and may continue to be volatile.

The price of our Common Stock and Public Warrants has been and may continue to be volatile. From August 11, 2023, the date our Common Stock and Public Warrants began trading on Nasdaq following the Business Combination, through October 31, 2023, our stock price has fluctuated from a low of $4.12 to a high of $16.24 per share, and the price of our Public Warrants has fluctuated from a low of $0.09 to a high of $0.48 per Public Warrant. The price of our Common Stock and Public Warrants may continue to fluctuate in the future due to a variety of factors, including, without limitation:

- the volume and timing of sales of TriNav or other products;
- the introduction of new products or product enhancements by us or others in our industry;
- the timing and results of clinical trials of any of our product candidates;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- establishment or termination of collaborations for our product candidates or development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the level of expenses related to any of our product candidates or development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;

- that the information we are required to disclose in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers.

We may be unable to maintain the listing of our securities on Nasdaq in the future.

We cannot guarantee that our securities will continue to be listed on Nasdaq. If we fail to meet the requirements of the applicable listing rules, such failure may result in a suspension of the trading of our shares or delisting in the future. This may further result in legal or regulatory proceedings, fines and other penalties, legal liability for us, the inability for our stockholders to trade their shares and negatively impact our share price, reputation, operations and financial position, as well as our ability to conduct future fundraising activities. If Nasdaq delists our securities and we are not able to list our securities on another national securities exchange, we expect that our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a limited amount of news and analyst coverage for the company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, higher interest rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, Russia's ongoing incursion of Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets; it is possible that the war in Israel may have similar effects. There have also recently been disruptions to the U.S. banking system due to bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank, Signature Bank, and First Republic Bank. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, higher inflation could also increase customers' operating costs, which could result in reduced budgets for customers and potentially less demand for our products and services. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition.

If our operating and financial performance in any given period does not meet the guidance provided to the public or the expectations of investment analysts, the market price of Common Stock may decline.

We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will consist of forward-looking statements, subject to the risks and uncertainties described in this filing and in our public filings and public statements. The ability to provide this public guidance, and the ability to accurately forecast our results of operations, will be impacted by a number of factors, many of which are out of our control. Actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic or regulatory uncertainty. If, in the future, our operating or financial results for a particular period do not meet any guidance provided or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of Common Stock may decline as well. Even if we issue public guidance, there can be no assurance that we will continue to do so in the future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of our securities. This risk is especially relevant for us because life sciences companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our securities.

Securities research analysts may establish and publish their own periodic projections of us. These projections may vary widely and may not accurately predict the results that we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline. While we expect research analyst coverage to continue, if analysts cease to continue coverage of us, the market price and volume for our securities could be adversely affected.

Sales of our Common Stock and/or Warrants or the perception of such sales, by us or selling securityholders, in the public market or otherwise, could cause the market price for our securities to decline, even though selling securityholders would still realize a profit on sales at lower prices. Resales of the securities offered may cause the market price of such securities to drop significantly, even if our business is doing well.

The sale of our Common Stock in the public market or otherwise, or the perception that such sales could occur, could harm the prevailing market price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our Common Stock may cause the market price of our securities to drop significantly, even if our business is doing well.

Certain selling securityholders acquired securities at prices that are significantly less than the current trading price of our Common Stock. Accordingly, certain of the Selling Securityholder could still realize a profit on sales at lower prices.

In addition, the selling securityholders named in the registration statement we have filed (as may be amended from time to time) relating to the offer and sale from time to time by selling stockholders or their permitted transferees (the "Resale S-1") hold a large portion of our outstanding Common Stock. Given the substantial number of shares of Common Stock being registered for potential resale by selling securityholders pursuant to the Resale S-1, the sale of shares by the selling securityholders of a large number of shares, or the perception in the market that the selling securityholders of a large number of shares intend to sell shares, could increase the volatility of the market price of our Common Stock or result in a significant decline in the public trading price of our Common Stock. Even if our trading price is significantly below $10.00 per share, the offering price for the units offered in the initial public offering of MTAC, the purchasers of which exchanged their MTAC shares for our Common Stock in the Business Combination, the selling securityholders may still have an incentive to sell our shares of our Common Stock because they purchased the shares at prices that are significantly lower than the purchase prices paid by our public investors or the current trading price of our Common Stock. While certain of the selling securityholders may experience a positive rate of return on their investment in our Common Stock as a result, the public securityholders may not experience a similar rate of return on the securities they purchased due to differences in their purchase prices and the trading price. For example, based on the closing price of our Common Stock of $4.30 as of October 31, 2023, assuming all shares held by the Sponsor that are subject to vesting and forfeiture are fully vested, the original holder of the Founder Shares would experience a potential profit of up to approximately $4.30 per share that they purchased prior to the initial public offering of MTAC, or up to approximately $18.7 million in the aggregate (not giving effect to the issuance of Common Stock issuable upon exercise of the Warrants held by them).

Our stockholders will be able to sell all of their securities held for so long as the Resale S-1 is in effect, subject to any applicable lock-up restrictions. Such restrictions began at the Closing and end on the earliest of (i) 365 days after the date of the Closing; (ii) the first day after the date on which the closing price of the Common Stock equals or exceeds $12.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the date of the Closing; or (iii) the date on which we complete a liquidation, merger, capital stock exchange, reorganization or other similar transaction that results in all of our public shareholders having the right to exchange their Common Stock for cash, securities or other property. Even if the trading price of our Common Stock falls to or significantly below the current trading price, the selling securityholders may still have an incentive to sell and profit due to the nominal purchase prices paid by such selling securityholders, which are significantly lower than the purchase prices paid by the public securityholders. Certain of our selling securityholders acquired the Common Stock at prices that are significantly lower than the current trading price of our Common Stock.

Our Warrants are exercisable for Common Stock, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our shareholders.

Our Public Warrants and Private Placement Warrants became exercisable on September 10, 2023 in accordance with the terms of that certain warrant agreement, dated December 17, 2020 by and between us and Continental Stock Transfer & Trust Company, as warrant agent (the “Warrant Agreement”). The exercise price of the Warrants is $11.50 per share, or approximately $164.0 million in the aggregate, assuming none of the Warrants are exercised through “cashless” exercise. We believe the likelihood that warrant holders will exercise their warrants, and therefore the

amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock. So long as the trading price for our Common Stock is less than $11.50 per share, meaning the Warrants are "out of the money," we believe holders of our Warrants that were issued will be unlikely to exercise their warrants on a cash basis. On October 31, 2023, the last reported sales price of our Common Stock was $4.30 per share and the last reported sales price of our Public Warrants was $0.27 per warrant, both of which are lower than the exercise price of the Warrants.

To the extent such Warrants are exercised, additional Common Stock will be issued, which will result in dilution to the holders of Common Stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of Common Stock.

We are 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," our securities may be less attractive to investors and it may be more difficult to compare our performance with other public companies.

We qualify as an emerging growth company under SEC rules. As an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These provisions include: (1) presenting only two years of audited financial statements; (2) presenting only two years of related selected financial data and "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure; (3) an exemption from compliance with the auditor attestation requirement in the assessment of internal control over financial reporting pursuant to Section 404 of Sarbanes-Oxley; (4) not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; (5) reduced disclosure obligations regarding executive compensation arrangements in periodic reports, registration statements, and proxy statements; and (6) 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, the information we provide will be different than the information that is available with respect to other public companies that are not emerging growth companies. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for the Common Stock, and its market price may be more volatile. We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of MTAC's initial public offering (i.e., December 31, 2025), (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common equity that is held by non-affiliates exceeds $700 million as of the end of the prior fiscal year's second fiscal quarter; and (2) the date on which we will have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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 (1) 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 (2) our annual revenues exceeded $100 million during such completed fiscal year and the market value of 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 that we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Our Warrants may not be exercised at all or may be exercised on a cashless basis and we may not receive any cash proceeds from the exercise of the Warrants.

The exercise price of the Warrants may be higher than the prevailing market price of the underlying shares of common stock. The exercise price of the Warrants is subject to market conditions and may not be advantageous if the prevailing market price of the underlying shares of common stock is lower than the exercise price. The cash proceeds associated with the exercise of Warrants to purchase our Common Stock are contingent upon our stock price. The value of our Common Stock will fluctuate and may not align with the exercise price of the Warrants at any given time. As of October 31, 2023, the last reported sales price of our Common Stock was $4.30 per share. So long as the trading price of our Common Stock is less than $11.50, meaning the Warrants are "out of the money," meaning the exercise price is higher than the market price of our common stock, we believe that holders of the Warrants are unlikely to choose to exercise their Warrants. As a result, we may not receive any proceeds from the exercise of the Warrants.

Furthermore, to the extent that the Private Placement Warrants or Conversion Warrants are exercised on a "cashless basis," we may not receive cash upon their exercise. A cashless exercise allows holders of such warrants to convert the warrants into shares of our Common Stock without the need for a cash payment. Instead of paying cash upon exercise, the warrant holder would receive a reduced number of shares based on a predetermined formula. As a

result, the number of shares issued through a cashless exercise will be lower than if the Private Placement Warrants or Conversion Warrants were exercised on a cash basis, which could impact the cash proceeds we receive from the exercise of such warrants.

The Public Warrants may only be exercised for cash provided there is then an effective registration statement registering the shares of common stock issuable upon the exercise of such warrants. If there is not a then-effective registration statement, then such Public Warrants may be exercised on a "cashless basis," pursuant to an available exemption from registration under the Securities Act.

Anti-takeover provisions contained in our Certificate of Incorporation and Bylaws, as well as provisions of Delaware law, could limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our Certificate of Incorporation and Bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the Board or taking other corporate actions, including effecting changes in our management. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together these provisions may discourage transactions that otherwise could involve the payment of a premium over prevailing market prices for our securities. These provisions include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the Board;
- the right of the Board to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on the Board;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may only be called by a majority of the Board, the chairperson of the Board, or our chief executive officer which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the ability of the Board to issue shares of preferred stock, including "blank check" preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- limitation of the liability of, and the indemnification of, our directors and officers;
- the ability of the Board to amend our Bylaws, which may allow the Board to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the Bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to the Board or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in the Board, and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the potential acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control of us or changes in our Board and our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"), which prevents some stockholders who hold more than 15% of our outstanding Common Stock from engaging in certain business combinations without approval of the holders of substantially all of our Common Stock. Any provision of our Certificate of Incorporation and Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for stockholders to receive a premium for their shares of Common Stock and could also affect the price that some investors are willing to pay for Common Stock.

Our Certificate of Incorporation designates the Delaware Court of Chancery or Delaware state or United States federal district courts as the sole and exclusive forum for substantially all disputes between us and our

stockholders, which could limit such stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, other employees or other stockholders.

Our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for state law claims for (i) any derivative claim or cause of action brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, other employees or stockholders, us or our stockholder; (iii) any action against us or any of our current or former directors, officers or other employees asserting a claim arising pursuant to any provision of the DGCL, our Certificate of Incorporation or Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction on the Delaware Court of Chancery; and (vi) any action asserting a claim against us or any of our current or former directors, officers or other employees governed by the internal affairs doctrine or otherwise related to our internal affairs.

The foregoing provisions will not apply to any claims as to which the Delaware Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of such court, which is rested in the exclusive jurisdiction of a court or forum other than such court.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules or regulations promulgated thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such Securities Act claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring, holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the forum provisions in our Certificate of Incorporation. Although we believe these exclusive forum provisions will benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the 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 any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Furthermore, investors cannot waive compliance with the federal securities laws and rules and regulations promulgated thereunder.

Our Certificate of Incorporation, to the extent permitted by applicable law, contains provisions renouncing our interest and expectation to participate in certain corporate opportunities identified or presented to our non- employee directors or stockholders.

Our officers and directors and their respective affiliates may hold, and may, from time to time in the future, acquire interests in or provide advice to businesses that directly or indirectly compete with certain areas of our business. Our Certificate of Incorporation provides that we renounce, to the fullest extent permitted by Delaware or other applicable law, any expectancy that any of our non-employee directors, stockholders or the affiliates of such stockholders will offer any corporate opportunity of which such director or stockholder may become aware to us except with respect to a corporate opportunity that was offered to a director solely in his or her capacity as our director and (i) such opportunity is one we are legally and contractually permitted to undertake and (ii) the director is permitted to refer that opportunity to us without violating any legal obligation. As a result, these arrangements could adversely affect our business, results of operations, financial condition or prospects if attractive business opportunities are allocated to any of our non-employee directors, stockholders or the affiliates of such stockholders instead of to us.

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

Subscription Agreements

In connection with the Business Combination and pursuant to the Subscription Agreements, the Preferred Stock PIPE Investors purchased from the Company an aggregate of 4,015,002 shares of Preferred Stock at a purchase price of $10.00 per share, resulting in an aggregate purchase price of $40,150,020. The sale of the PIPE Shares was made pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act and/or Rule 506(c) promulgated thereunder.

Standby Equity Purchase Agreement

In October 2023, the Company entered into the Yorkville Purchase Agreement with Yorkville, whereby it has the right, but not the obligation, to sell to Yorkville up to $30.0 million of shares of Common Stock at the Company's request any time during the 24 months following the execution of such purchase agreement, subject to certain conditions. As of the date of this Quarterly Report on Form 10-Q, no sales have been made under the Yorkville Purchase Agreement. Yorkville represented to the Company, among other things, that it is an institutional "accredited investor" as defined in Rule 501(a)(3) of Regulation D under the Securities Act. The securities are being issued and sold by the Company to Yorkville in reliance upon the exemption from the registration requirements of the Securities Act afforded by Section 4(a)(2) of the Securities Act.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not applicable

Item 5. Other Information

None

Item 6. Exhibits

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
2.1#	Agreement and Plan of Merger, dated as of November 11, 2022, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	2.1	November 14, 2022
2.2	First Amendment to Agreement and Plan of Merger, dated as of April 4, 2023, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	10.1	April 5, 2023
2.3	Second Amendment to Agreement and Plan of Merger, dated as of May 13, 2023, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	10.1	May 13, 2023
2.4	Third Amendment to Agreement and Plan of Merger, dated as of July 5, 2023, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	10.1	July 6, 2023
3.1	Second Amended and Restated Certificate of Incorporation of TriSalus Life Sciences, Inc.	Form 8-K	001-39813	3.1	August 16, 2023
3.2	Amended and Restated Bylaws of TriSalus Life Sciences, Inc.	Form 8-K	001-39813	3.2	August 16, 2023
3.3	Form of Certificate of Designations, Preferences, and Rights of Series A Convertible Preferred Stock of TriSalus Life Sciences, Inc.	Form 8-K	001-39813	3.3	August 16, 2023
4.1	Specimen Common Stock Certificate	Form 8-K	001-39813	4.1	August 16, 2023
4.2	Specimen Warrant Certificate	Form 8-K	001-39813	4.2	August 16, 2023
4.3	Warrant Agreement, dated December 17, 2020, by and between MTAC and Continental Stock Transfer & Trust Company.	Form 8-K	001-39813	4.1	December 23, 2020
10.1*	TriSalus Life Sciences, Inc. 2023 Equity Incentive Plan	Form 8-K	001-39813	10.21	August 16, 2023
10.2*	Form of Stock Option Grant Notice and Form of Stock Option Agreement under 2023 Equity Incentive Plan	Form 8-K	001-39813	10.22	August 16, 2023
10.3*	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Agreement under 2023 Equity Incentive Plan	Form 8-K	001-39813	10.23	August 16, 2023
10.4*	TriSalus Life Sciences, Inc. 2023 Employee Stock Purchase Plan	Form 8-K	001-39813	10.24	August 16, 2023
10.5*	Form of Indemnification Agreement by and between TriSalus Life Sciences, Inc. and its directors and executive officers	Form 8-K	001-39813	10.25	August 16, 2023
10.6*	Non-Employee Director Compensation Policy	Form 8-K	001-39813	10.26	August 16, 2023

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
10.7*##	Executive Employment Agreement, Dated August 28, 2023, by and between TriSalus Life Sciences, Inc. and Jodi Devlin	Form S-1/A	333-274292	10.14	October 18, 2023
10.8	Form of Subscription Agreement (Initial)	Form 8-K	001-39813	10.1	June 8, 2023
10.9	Form of Subscription Agreement (Subsequent)	Form 8-K	001-39813	10.2	July 6, 2023
10.10	Standby Equity Purchase Agreement, by and between TriSalus Life Sciences, Inc. and YA II PN, LTD.	Form 8-K	333-269138	99.1	October 3, 2023
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	Inline XBRL Instance Document.				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

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* Indicates management contract or compensatory plan or arrangement.

\# Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request; provided, however, that MTAC may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act, as amended, for any schedule or exhibit so furnished.

Certain portions of this Exhibit have been omitted in accordance with Regulation S-K Item 601(b)(10)(iv) because they are not material and are the type of information that the Registrant treats as private or confidential. The Registrant agrees to furnish supplementally an unredacted copy of the Exhibit, or any section thereof, to the SEC upon request.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 14th day of November, 2023.

TriSalus Life Sciences, Inc.

By: /s/ Sean Murphy

Name: Sean Murphy

Title: Chief Financial Officer

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

I, Mary Szela, certify that:

1. I have reviewed this Form 10-Q of TriSalus Life Sciences, Inc.

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15€ and 15d-15€) for the registrant and have:

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

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

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

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

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

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

Date: November 14, 2023

/s/ Mary Szela

Mary Szela

Chief Executive Officer

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

I, Sean Murphy, certify that:

1. I have reviewed this Form 10-Q of TriSalus Life Sciences, Inc.

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15€ and 15d-15€) for the registrant and have:

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

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

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

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

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

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

Date: November 14, 2023

/s/ Sean Murphy

Sean Murphy

Chief Financial Officer

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Mary Szela, Chief Executive Officer of TriSalus Life Sciences, Inc. (the "Company") certifies that, to the best of her knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Report"), The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 14, 2023

/s/ Mary Szela

Mary Szela

Chief Executive Officer and Director
(Principal Executive Officer)

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of TriSalus Life Sciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sean Murphy, Chief Financial Officer of TriSalus Life Sciences, Inc. (the "Company") certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act of 1934; and

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

Date: November 14, 2023

/s/ Sean Murphy

Sean Murphy

Chief Financial Officer and Director
(Principal Financial Officer)

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of TriSalus Life Sciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."