#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 5, 2024

### TRISALUS LIFE SCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)

6272 W. 91st Ave., Westminster, Colorado (Address of Principal Executive Offices) 001-39813 (Commission File Number) 85-3009869 (IRS Employer Identification No.)

> 80031 (Zip Code)

(888) 321-5212

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

 $\hfill\square$  Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

	Trading	Name of each exchange
Title of each class	symbol(s)	on which registered
Common Stock, \$0.0001 par value per share	TLSI	Nasdaq Global Market
Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of \$11.50 per	TLSIW	Nasdaq Global Market
shara		

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\boxtimes$ 

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.  $\Box$ 

#### Item 2.02. Results of Operations and Financial Condition.

TriSalus Life Sciences, Inc. (the "Company") may use a slide presentation, in whole or in part, from time to time in presentation to investors, analysts and others that includes preliminary sales information for the year ended December 31, 2023, as well as a business and product update. A copy of the slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein. A copy of the slide presentation is also available on the Company's website at https://trisaluslifesci.com/.

The information in this Item 2.02, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liabilities under that section, and shall not be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filings. This Current Report on 8-K will not be deemed an admission as to the materiality of any information contained in this Item 2.02, including Exhibit 99.1.

Description

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

Investor Presentation, dated January 2024. Cover page Interactive data file (embedded within the inline XBRL document).



#### SIGNATURES

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

Dated: January 5, 2024

#### TRISALUS LIFE SCIENCES, INC.

By:

/s/ Sean Murphy Sean Murphy Chief Financial Officer



## **TriSalus Life Sciences**

January 2024



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### Disclaimer

Certain statements in this presentation may constitute "forward looking statements" within the meaning of applicable United States federal securities laws. Forward loc include, but are not limited to, statements regarding TriSalus's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, st TriSalus's business strategy and clinical development plans; the safety and efficacy of TriSalus's product candidates; TriSalus's plans and expected timing with respect clinical trial enrolment and clinical trial results; the size and growth potential of the markets for TriSalus's products and TriSalus's ability to serve those markets; TriSalu with other companies; TriSalus's expected financial results as of and for the year and quarter ended December 31, 2023; TriSalus's projected financial results and exp. TriSalus's ability to partner with other companies; and TriSalus's products continuing to be subject to a favorable reimbursement environment. In addition, any stateme projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward looking statements. The words "continue," "could," "estimate," "expect," "may," "might,"" plan," "possible," "potential," "predict," "project," "should," "strive," "would" and similar expressions may identify statements, but the absence of these words does not mean that statement is not forward looking. Forward looking statements are predictions, projections and other st events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties.

Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed c forward looking statements due to various important factors, including, but not limited to: changes in business, market, financial, political and legal conditions; unfavora reimbursement environment for TriSalus's products; TriSalus's product candidates not achieving success in preclinical or clinical trials or not being able to obtain regul on a timely basis or at all; future clinical trial results/data may not be consistent with interim, initial or preliminary results/data or results/data from prior preclinical studie TriSalus's ability to maintain and grow its market share; the size of the addressable markets for TriNav and TriSalus's product candidates being less than TriSalus esti ability to successfully commercialize any product candidates that are approved; TriSalus's ability to continue to fund preclinical and clinical trials for its product candidates that are approved; and market conditions; the effects of competition on TriSalus's business; risks relating to the uncertainty of the projected financial information with respect to TriSalus; company to raise money to finance its operations in the future; and the outcome of any potential litigation, government and regulatory proceedings, investigations and carefully consider the risks and uncertainties described in the "Risk Factors" section of TriSalus's Quarterly Report on Form 10-Q for the quarter ended September 30, documents filed by TriSalus from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events a materially from those expressed or implied in the forward-looking statements. Forward looking statements speak only as of the date they are made. Readers are cauti reliance on forward looking statements, and TriSalus and its representatives assume no obligation and do not intend to update or revise these forward-looking statements result of new information, future events, or otherwise. Neither TriSalus or any of its representatives give any assurance that TriSalus will achieve its expectations.

Certain financial information and data contained in this presentation may be unaudited and may not conform to Regulation S-X promulgated under the Securities Act c Accordingly, such information and data may not be included in, may be adjusted in, or may be presented differently in, any documents filed with the SEC.



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	Commercial high growth MedTech business with pot upside from device + immunotherapeutic combination
Overcoming Key Mechanical & Biological Bottlenecks in the Treatment of Solid Tumors	Integrating unique device and therapeutic to overcor challenges with drug delivery to liver and pancreatic
	Lead program: SD-101, a TLR9 agonist: Phase 1 da proof of concept for mechanism and well tolerated sa
	Exclusive worldwide rights on all intellectual property overcoming mechanical and biologic barriers within the Microenvironment (TME) <sup>1</sup>
	Multiple value-creating opportunities (clinical data, sa and new product launches) anticipated over the next
<u></u> ▲TriSalus	
© 2024 TriSalus <sup>®</sup> Life Sciences. All Rights Reserved.	1. TriSalus has entered into an exclusive distribution agreement for PEDD devices in China.

### Novel approach to overcome key treatment barriers in liver and pancreas tui



### Two important barriers to immunotherapy success in liver and pancreatic tur



#### 1. Mechanical Barrier 1-3

High intra-tumoral pressure in limits efficient drug delivery to

#### 2. Biologic Barrier<sup>4</sup>

Immunosuppression in TME lir of therapeutic agents

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Wilhelm et al. (2016) Nature Reviews Materials 1.5:16014.
 Sheth, et al. (2013). Journal of Vascular and Interventional R
 TriSalus data on file from pre-clinical and clinical studies.

- 4. Guha, Katz, et al. Cancer Gene Ther. 24, 114–120 (2017)

**SECTION 1** 

# **PEDD:** pressure enabled drug delivery

Overcoming the Mechanical Barrier for Drug Delivery to Liver and Pancreatic Tumors



### Addressing mechanical and biologic barriers in the TME of liver and pancrea



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### TriNav<sup>®</sup> Infusion System: a better solution for drug delivery



### PEDD procedures are routine and outpatient

#### ENABLES OPTIMIZATION OF CATHETER-BASED EMBOLIC AND DRUG DELIVERY BY ADDRESSING I BARRIER PRESENT ACROSS TUMOR TYPES



### PEDD drives more drug into high pressure solid tumors<sup>1</sup>

### OVERCOMING THE MECHANICAL BARRIERS IN THE TUMOR MICROENVIRONMENT (TME)



### FDA-cleared novel pancreatic infusion system

- Poor blood flow limits drug access to the pancreas1,2,3
- Pancreatic arteries difficult to access<sup>4,5</sup>
- Innovative retrograde venous approach eliminates . need for balloons that eliminate blood flow<sup>6,7</sup>
- Target vessel pressure monitoring for safety, . efficacy, and consistency
- Leveraging PEDD and SD-101 data from liver . trials
- Phase 1 locally advanced pancreas data from • MDACC was presented at SITC 2023



- 1. Rakesh Jain (2013) Normalizing Tumor Microenvironment to Treat Cancer: Bench to Beds 2205-2218
- 2. DuFort et al, Interstitial Pressure in Pancreatic Ductal Adenocarcinoma Is Dominated by a Journal 110 2106-2119 3. Soltani et al Numerical Modeling of Fluid Flow in Solid Tumors. PLoS ONE 6:6 e20344

- Solitani et al Numerical Modeling of Fluid Flow in Solid Tumors. PLoS ONE 6:6 e20344
   Homma, H. et al. Cancer 89, 303–313 (2000).
   Rosemurgy, A. S. et al. J Pancreat Cancer 3, 58–65 (2017).
   Piras, C., Paulo, D. N. S., Paulo, I. C. A. L., Rodrigues, H. & Silva, A. L. da. Acta Cirurgica
   Moody, A. R. & Poon, P. Y. American Journal of Roentgenology 158, 779–783 (1992). 5. C Imaging 35, 134–142 (2010).

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### Clinical and preclinical data demonstrate superiority of PEDD

OVERCOMING THE MECHANICAL TME BARRIER WITH MULTIPLE THERAPEUTICS

Therapeutic Modality	TriNav Improvement vs. Standard Catheter		
TACE	<b>60%</b> ↑	in therapeutic delivery to liver tumors <sup>1</sup> vs. standard catheter	Clinical liver study
TARE (Y-90)	33% -90% ↑	in MAA deposition in liver tumors <sup>2</sup> vs. standard catheter	Clinical liver study
Immunotherapy (SD-101)	High concentrations in liver tissues with low serum exposure	undetectable in serum after 4 hours in 97% of patients <sup>3</sup>	Clinical liver study
Chemotherapy	<b>6.7 – 10.1</b> fold ↑	improved delivery vs. systemic infusion <sup>4</sup>	Preclinical pancreas study

### TriSalus technology pipeline: opportunities for further expansion



▶ SECTION 2

# SD-101: Class C TLR9 Agonist

Overcoming the Biologic Barrier in Liver & Pancreas Tumors



Pipeline: potential commercial opportunities across range of liver and pancre PRESSURE ENABLED REGIONAL IMMUNO-ONCOLOGY (PERIO) TRIALS

INDICATION	TRIAL DESIGN	IND ENABLING	PHASE 1	PHASE 2
Uveal Melanoma Liver Metastases (validation of combination)	SD-101 + PEDD HAI + CPI	Phase 1/1b PE	ERIO-01 Trial	
Hepatocellular Cancer (HCC) <sup>1</sup>	SD-101 + PEDD HAI + CPI	Phase 1b PERIC	D-02 Trial	
Intrahepatic Cholangiocarcinoma (ICC) <sup>1</sup>	SD-101 + PEDD HAI + CPI	Phase 1b PERIC	D-02 Trial	
Locally Advanced PDAC	SD-101 + PEDD PRVI + CPI	Phase 1/1b PERIO-0	03 Trial	

CPI = Checkpoint Inhibitors; HAI = Hepatic Arterial Infusion; PDAC = Pancreatic Ductal Adenocarcinoma; PRVI = Pancreatic Retrograde Venous Infusion; IND = Investigational New Dru 1. HCC and ICC will be studied jointly in phase 1b. Separate phase 2 studies will be opened for each indication.



### Clinical trials leverage established biology of SD-101

PEDD ENABLED REGIONAL IMMUNO-ONCOLOGY (PERIO) STUDIES

#### **Enrollment criteria**

- Liver or pancreas main site of disease
- Failure or refusal of standard treatment
- Good performance status

#### **Trial Design**

- Cohorts with SD-101/PEDD alone
- Cohorts with SD-101/PEDD + IV checkpoint
- Six outpatient SD-101 infusions in IR suite

#### Endpoint

- · Safety and dose determination
- Efficacy progression free survival
- ctDNA strong correlate for overall survival<sup>1,2,3</sup>
- Immune assays to confirm MoA





### SD-101 dual mechanism of action overcomes biological TME I



### Clinical proof-of-concept

#### DUAL MOA WITH POTENTIAL TO ENHANCE CHECKPOINT ACTIVITY BOTH IN TME AND SYSTEMICAI



### SD-101 clinical data consistent with established drug Mechanism of

- Optimal dose range predicted by preclinical models and known Mechanism of Action (MoA) – approach consistent with FDA Project Optimus, which supports role for Optimal Biological Dose-based (OBD-based) decisions
  - Accommodates non-linear dose effects
- 2. Immune markers and **liquid biopsies** (ctDNA) used to confirm SD-101 MoA as conventional scan-based RECIST ORR assessments less reliable (when immune cell infiltration distorts tumor size)
  - ctDNA levels in blood shown to be highly predictive of PFS and OS when imaging unreliable<sup>1,2,3</sup>

- SD-101 relieves immunosuppressi TME, may yield PFS/OS benefit in absence of robust RECIST ORR
- Liquid biopsy (ctDNA levels) more accurate predictor of survival than imaging (RECIST ORR)<sup>1,2,3</sup>
- Optimal dose determination for SD be driven by drug's biological effect not by MTD/DLT
- 1. Carvajal Nat Med 2022 2. Dawson NEJM 2013 3. Al-Showbaki JITC 2023

RP2D: recon MTD: maxim DLT: dose lir

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### SD-101 is highly distinct from other TLR9 agonists

PEDD ENABLES MECHANISM OF ACTION (MOA) THAT ALIGNS WITH LIVER AND PANCREAS BIOLO



### Liquid biopsy showing ctDNA reduction predicts survival in uveal m

PHASE 1 DATA CONSISTENT WITH CLINICAL ACTIVITY IN PREDICTED ACTIVE DOSE RANGE



### Dose optimization guided by clinical and immune signals

DOSE WITHIN PREDICTED RANGE ELICITS EXPECTED IMMUNE SIGNALS WITHIN LIVER METASTAS



### Durable disease control and PFS in phase 11

NEXT PHASE WILL FURTHER EXPLORE PFS CONVERSION INTO OS BENEFIT AS CIRCULATING TUN LEVELS MAY PREDICT<sup>2,3,4</sup>





71% 2L and beyond, including

59% ctDNA clearance<sup>1</sup> as bes response and 27% clearance at (13% with tebentafusp)<sup>2</sup>

ctDNA reported as predictor of stage IV uveal melanoma whe unreliable<sup>2</sup>

Even progressive disease pati may survive long term

6 of 7 of 2mg + nivo patients decrease in ctDNA including clearance as best on-treatme

1.	Patel SITC 2023	<ol><li>Dawsc</li></ol>
2.	Carvajal Nat Med 2022	4. Al-Sho

### SD-101 well tolerated with low level of serious adverse events

<b>TS-PERIO-01 Phase 1</b> (1L if Kimmtrak ineligible; 2L+ if Kimmtrak eligible)			
Society for Immunotherapy of Cancer	<b>TriSalus</b> (SD-101) N=56 (phase 1) <sup>1</sup>		
Stage IV UM LM population eligible	100%		
Grade 3 or 4 treatment related serious adverse events	11% (4% at optimal dose)		
Grade 2 or higher cytokine release syndrome	2%		

- PEDD concentrates SD-101 in liv well tolerated systemic immune e
- SD-101 undetectable in serum af hours in 97% of subjects<sup>3</sup>
- Kimmtrak is approved for stage IN <50% of the population is eligible on HLA type
- Grade 3/4 adverse event rates wi immunotherapy in this population typically >30%<sup>4</sup>

1. Patel SITC 2023 2. Carvajal, Nature Medicine, Volume 28, November 2022;2364–2373 (2L patients) 3. Montazeri ASCO 2023 4.Nathan NEJM 2021

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### Unmet needs create broad market opportunities across multiple ind



### 2023 – 2024: Anticipated Key Milestones

Catalyst	Indication	Anticipated
Phase 1 PERIO Data	Uveal Melanoma	2H 2023 (Cor
Confirmation of optimal dose	Uveal Melanoma	1H 2024
Phase 1b PERIO Data	Hepatocellular Cancer and Intrahepatic Cholangiocarcinoma	1H 2024
Launch of TriNav Large	Hepatocellular Cancer and liver metastases	1H 2024
Phase 1 PERIO Data	Locally Advanced Pancreatic Cancer	2H 2024
Phase 1b with IV checkpoint	Locally Advanced Pancreatic Cancer	1H 2025

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### **Executive Team**



### Capital structure and liquidity as of September 30, 2023

Share Listing – Current	TLSI (Nasdaq)
Common Shares Outstanding	26.3M
Preferred Shares Outstanding	4.0M
Warrants Outstanding <sup>1</sup>	14.3M
Cash and Cash Equivalents	\$21.4M
Debt	\$0

1. Consists of 8.33M public warrants and 5.93M private warrants. All warrants have an exercise price of \$11.50

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## **Argot Partners**

New York 767 Third Avenue, 34th Floor New York, NY 10017

212.600.1902 trisalus@argotpartners.com





### Do liver tumors drive immunotherapy failure?



1. Yu J, Green MD, Li S, et al. Liver metastasis restrains immunotherapy efficacy via macrophage-mediated T cell elimination. Nat Med. 2021;27:152-164. https://doi.org/10.1038/s415

Botticelli A, Salati M, Di Pietro FR, et al. A nomogram to predict survival in non-small cell lung cancer patients treated with nivolumab. J Transl Med. 2019;17:99. https://doi.org/10.11
 Silva I, Lo S, Quek C, González M, Carlino M, Long G, and Menzies A. Site-specific response patterns, pseudoprogression, and acquired resistance in patients with melanoma treat combined with anti–PD-1 therapy. Cancer. 2019;126: 10.1002/cncr.32522

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### SD-101 program design: key considerations and takeaways

### METHODICAL AND DATA-DRIVEN DEVELOPMENT PLAN

Preclinical Foundation		Trial Design	Pharmacokinetics + Pharmacodynamics	Early Clinical POC	Efficacy and Potential Reg Endpoints
Predicted SE dose range v PEDD approa	<b>)-101</b> vith ach <sup>1</sup>	Single agent SD-101 dose- escalation	Liver tissue and serum SD-101 measurements	De-emphasis of ORR given DCR and PFS	PFS based on disease contro possible basis accelerated ap
Porcine PEDI SD-101 with supported do range	D of TriNav se	SD-101 re-escalation with single CPI and dual CPI	Liver tumor T cell, MDSC, and Treg levels signals align with pre- clinical data	ctDNA response favorable	OS for full app supported by c which has bee predictor of su UM <sup>1,2,3</sup>
Defined MoA MDSC deple by SD-101	for tion	Dose expansion at promising OBD	Systemic immune activation signals	Tolerable safety profile	
PFS – progression fr OS – overall survival CPI – checkpoint inhi TriSalus I © 20	ee survival bitor 24 TriSalus	<sup>®</sup> Life Sciences. All Rights Reserve	ed.	<ol> <li>Ghosh Cancer Gene Ther 2022</li> <li>Carvajal Nat Med 2022</li> <li>Dawson NEJM 2013</li> </ol>	

SD-101 deactivated key signaling molecule in MDSC to align with immunosuppression biology in liver and pancreas



# Preclinical PEDD liver metastasis model enabled rational selection dose range of 2-8 mg and support for use of PEDD



# SD-101 is distinct from other TLR9 agonists in murine liver tumor model PEI PEDD ENABLES MOA THAT ALIGNS WITH BIOLOGY IN LIVER AND PANCREAS

