# 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): September 1, 2023**

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

| **Delaware** | **001-39813** | **85-3009869** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

| **6272 W. 91st Ave., Westminster, Colorado** | **80031** |
|---|---|
| **(Address of principal executive offices)** | **(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 obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

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

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

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

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

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

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

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01. Regulation FD.**

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. 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 7.01, 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 7.01, including Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Investor Presentation, dated September 2023. |
| 104 | Cover page Interactive data file (embedded within the inline XBRL document). |

**SIGNATURES**

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

Dated: September 1, 2023

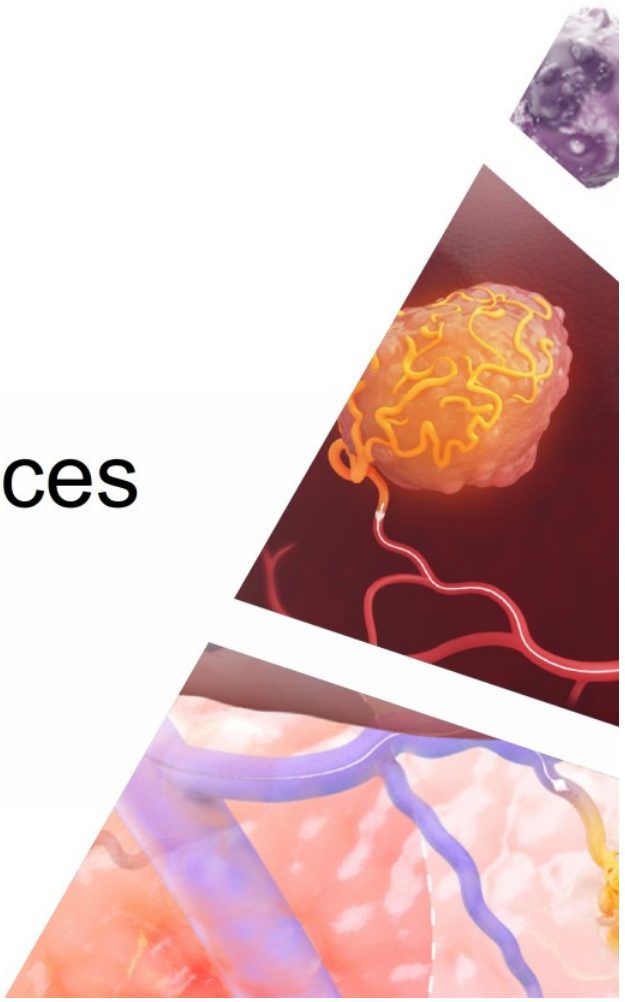
**TRISALUS LIFE SCIENCES, INC.**

By: /s/ Sean Murphy
Sean Murphy
Chief Financial Officer

TriSalus™
LIFE SCIENCES

# TriSalus Life Sciences

SEPTEMBER 2023



# Disclaimer

Certain statements in this presentation may constitute “forward looking statements” within the meaning of applicable United States federal securities laws. statements include, but are not limited to, statements regarding TriSalus’s expectations, hopes, beliefs, intentions or strategies regarding the future includin limitation, statements regarding: TriSalus’s business strategy and clinical development plans; the safety and efficacy of TriSalus’s product candidates; TriSalus expected timing with respect to clinical trials, clinical trial enrolment and clinical trial results; the size and growth potential of the markets for TriSalus’s prod ability to serve those markets; TriSalus’s ability to compete with other companies; TriSalus's projected financial results and expected cash runway;, TriSalus’s with other companies; and TriSalus’s products continuing to be subject to a favorable reimbursement environment. In addition, any statements that refer to forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward looking statements. The words “a “continue,” “could,” “estimate,” “expect,” “may,” “might,”“ plan,” “possible,” “potential,” “predict,” “project,” “should,” “strive,” “would” and similar expressi forward looking statements, but the absence of these words does not mean that statement is not forward looking. Forward looking statements are predictio other statements about future 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 e in the forward looking statements due to various important factors, including, but not limited to: changes in business, market, financial, political and legal co unfavorable changes in the reimbursement environment for TriSalus’s products; TriSalus’s product candidates not achieving success in preclinical or clinical t able to obtain regulatory approval, either on a timely basis or at all; future clinical trial results/data may not be consistent with interim, initial or preliminary results/data from prior preclinical studies or clinical trials; TriSalus’s ability to maintain and grow its market share; the size of the addressable markets for Tri product candidates being less than TriSalus estimates; TriSalus’s ability to successfully commercialize any product candidates that are approved; TriSalus’s ab fund preclinical and clinical trials for its product candidates; future economic and market conditions; the effects of competition on TriSalus’s business; risks r uncertainty of the projected financial information with respect to TriSalus; the ability of the company to raise money to finance its operations in the future; any potential litigation, government and regulatory proceedings, investigations and inquiries. You should carefully consider the risks and uncertainties descr Factors” section of the registration statement on Form S-4, which was declared effective by the United States Securities and Exchange Commission (the “SEC and other documents filed by TriSalus from time to time with the SEC. These filings identify and address other important risks and uncertainties that could c and results to differ materially from those expressed or implied in the forward looking statements. Forward looking statements speak only as of the date the Readers are cautioned not to put undue reliance on forward looking statements, and TriSalus and its representatives assume no obligation and do not inten revise these forward looking statements, whether as a result of new information, future events, or otherwise. Neither TriSalus or any of its representatives g that TriSalus will achieve its expectations.

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# Well-Positioned to Create Value by Improving Outcomes for Patients with Liver and Pancreatic Tumors

- Fast-growing, commercial Medtech business w potential upside from promising immunotherap
- Multiple value-creating opportunities (sales gro product launches, therapeutic validation) antici next 18 months
- Targeting both rare diseases and large markets unmet needs
- Merging of device and therapeutic expertise to efficacy with less toxicity
- Lead therapeutic SD-101, TLR9 agonist, data promising efficacy and a well-tolerated safety p
- Funding expected through mid-2024 to allow k for the technology and combination

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# Our Company is Focused on Areas of Greatest Unmet

Novel Combination Approach combines innovative Pressure Enabled Drug Delivery™ (PEDD) delivery technology with a promising therapeutic, SD-101, TLR9 agonist

PEDD Technology On-market + Therapeutic (SD-101, TLR9 Agonist) In Clinical Development

**Chemoembolization and Radioembolization For Hepatocellular Cancer**

Increased Therapeutic Delivery

**Potential Market $800MM (includes pancreas)**

**Uveal Melanoma Liver Metastases**

**5-year survival**

16%[1]

**Hepatocellular Carcinoma**

**5-year survival**

21%[1]

**Panc Canc**

**Potential Market $15B+ Across Indicatio**

1. American Cancer Society, National Cancer Institute SEER Database as of August, 2023,

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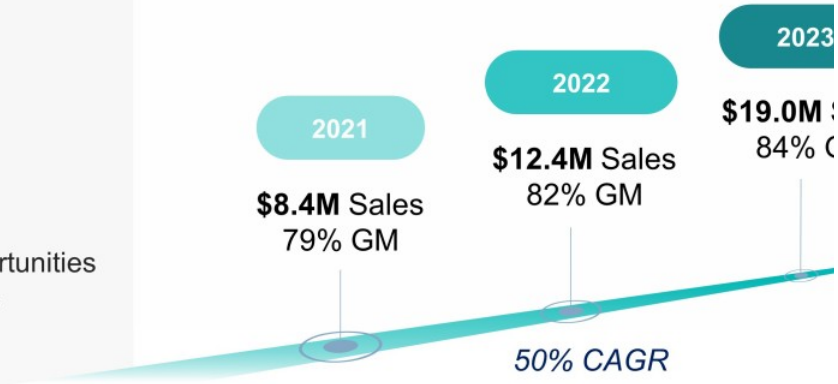
# TriNav: A Better Solution for Drug Delivery

- Drug delivery technology to overcome the barriers of the high-pressure tumor microenvironment (“TME”)
- Atraumatic, self-expanding/collapsing SmartValve technology
- Clinically validated in multiple studies
- Additional technology expansion opportunities with potential immunotherapy partners

**TriNav**
Commercial-stage FD
technology using the p
approach

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# Our Drug Delivery Technolog

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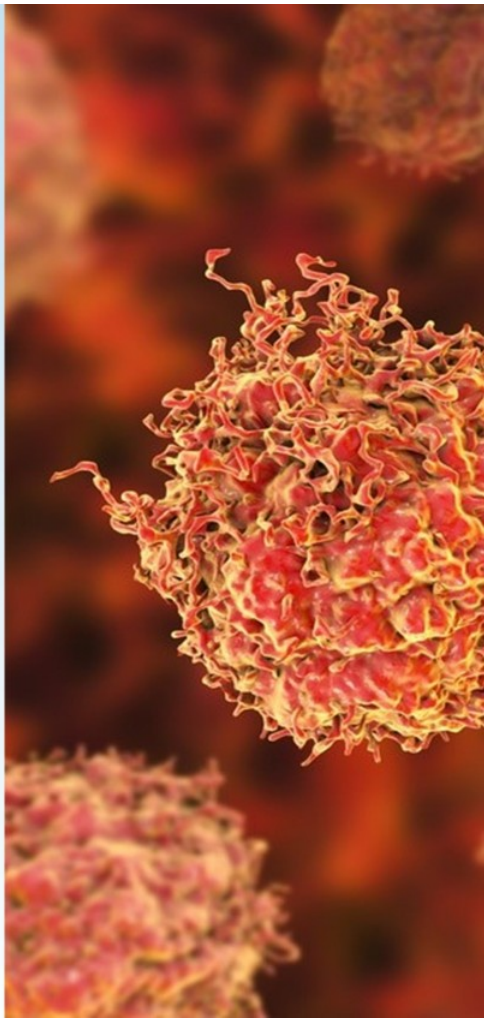
# The Problem We Are Solving…

<1%

of the IV dose ends
up in solid tumors



Source: Wilhelm et al. (2016) Analysis of nanoparticle delivery to tumours. *Nature Reviews Materials* 1.5:16014.

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# High Intratumoral Pressure Within the Tumor Limits Drug Upta


The **pressure** within th
tumor can be higher th
patient's blood pressu
limiting drug uptake

Wilhelm et al. (2016) Analysis of nanoparticle delivery to tumours. Nature Reviews Materials 1.5:16014.
Sheth, Rahul A., Robin Hesketh, David S. Kong, Stephan Wicky, and Rahmi Oklu. 2013. "Barriers to Drug Delivery in Interventional Oncology." Journal of Vascular and Interventional Radiology 24 (8): 1201–7.

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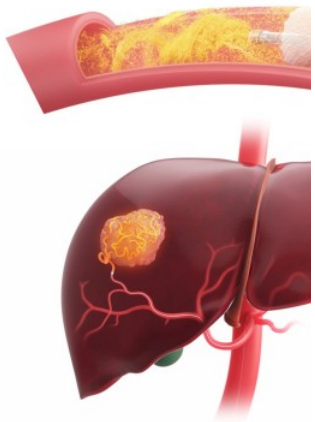
# TriSalus' PEDD Approach Works in Sync with the Cardiac Cycle to Modu Pressure and Flow to Overcome These Barriers

**TriNav delivery technology demonstrated to:**

- Work in sync with the cardiac cycle[1*]
- Atraumatically increase local vascular pressure at the target location close to the tumor[2‡]
- Infuse therapeutics into resistive tumor vessels to enable deeper perfusion and improve therapeutic delivery[3,4,5]
- Modulation of intravascular pressure gradient and flow[2]
- Positive impact on T:N ratio for improved accuracy and predictability[3,4]



- PEDD = Pressure-Enabled Drug Delivery.


1. Data on file, TriSalus™ Life Sciences, 2019
*Study Design: Ultrasound was employed in a porcine model to image tip performance in relation to the cardiac cycle
2. Data on file, TriSalus™ Life Sciences, 2019
‡ Study Design: Pressure wire introduced during planning angiogram to measure pressure of PEDD with SmartValve tip collapsed, expanded and during high-pressure saline flush
3.Titano JJ, et al. Cardiovasc Intervent Radiol. 2019;42:560-568.
4. Pasciak AS, et al. J Vasc Interv Radiol. 2015;26:660-669.
5.Katz et al. "HITM-SURE: Phase Ib CAR-T hepatic artery infusion trial for stage IV adenocarcinoma using Pressure-Enabled Drug Delivery technology." SITC (2018) Poster Presentatio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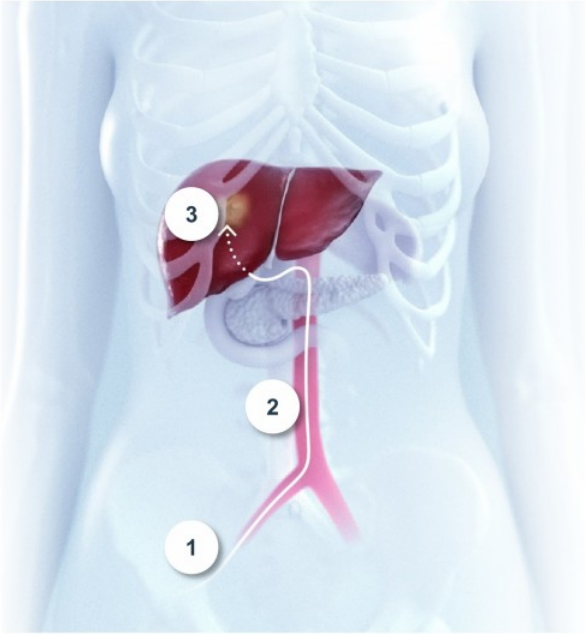
# PEDD Procedures are Routine Interventional Radiology Liver Procedures Done in an Outpatient Setting

- PEDD is used during SoC interventional radiology procedures
- Optimizes therapeutic delivery – local administration of chemotherapy or radiation beads to the tumor
- SD-101 infusions delivered via PEDD into the liver or pancreas with systemic checkpoint inhibitors




**Performed for tumo**
**be surgically remov**

1. A small puncture is
the femoral artery

2. X-rays are used to
a catheter to the sit

3. Enhanced pressure
maximize dose to t

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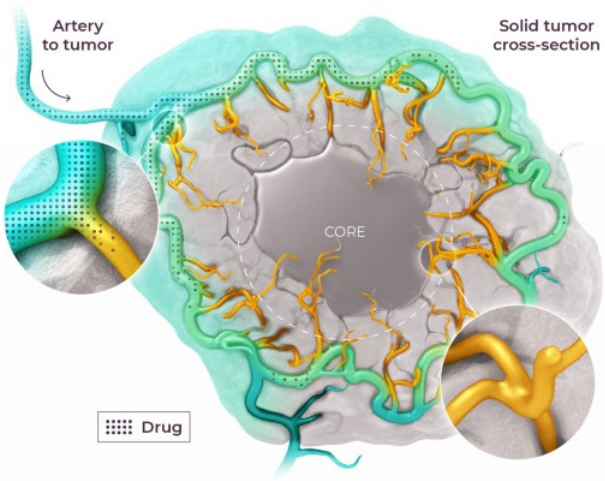
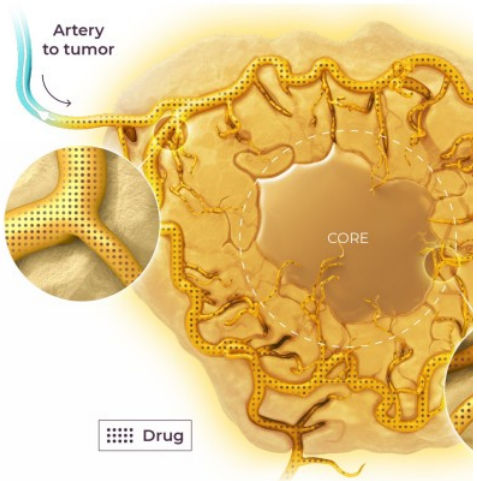
# Enhanced Delivery Pressure to Improve Therapeutic Penetrati

**STANDARD CATHETER**




Drug flows around tumor limiting therapeutic effectiveness

**PEDD**
Pressure Enabled Drug Delivery




Collapsed vessels opened for deep throughout vasculature of the

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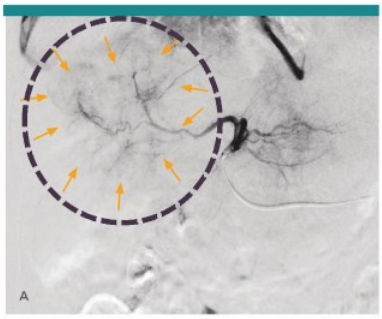
Conceptual. For illustrative purposes

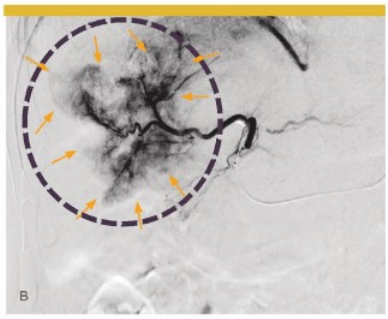
# PEDD Drives More Therapeutic Into High Pressure Tumors[1]

Same liver cancer patient treated with different devices.

**Standard Catheter**




**PEDD**




Interventional radiologist injected contrast dye into tumor vessels.

**Angiogram of tumor demonstrating that**

- ↑ Delivery of contr into liver tumor
- ↑ Opening of colla tumor vessels
- ↓ Reflux of contras into normal liver

1. TriSalus images and data on file.

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# PEDD Increases Delivery of Multiple Therapeutics Versus Star Technology

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

TACE = Transarterial chemoembolization, TARE = Transarterial radioembolization

1. Titano JJ, et al. Cardiovasc Intervent Radiol. 2019;42:560-568.
2. Pasciak AS, et al. J Vasc Interv Radiol. 2015;26:660-669.
3. TriSalus clinical data on file
4. Increased therapeutic levels compared to existing delivery methods. Shankara Narayanan JS, Vicente DA, Ray P, et al. Pressure-enabled delivery of pancreatic cancer mouse model. Surgery. 2020;168(3):448-456. Data on file, Porcine Animal Model, TriSalus Life Sciences, 2019.

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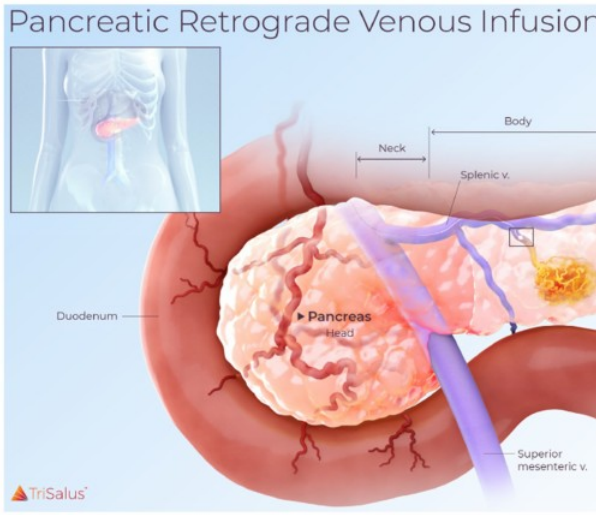
# FDA Cleared Novel Pancreas Infusion System

- Poor blood flow limits drug access to the pancreas[1-3]
- Pancreatic arteries difficult to access[4,5]
- Innovative retrograde venous approach eliminates need for balloons[6,7]
- Leveraging PEDD and SD-101 experience from liver trials to
- Phase 1 locally advanced pancreas data from MDACC to be presented at SITC 2023





1. Rakesh Jain (2013) Normalizing Tumor Microenvironment to Treat Cancer: Bench to Bedside in Biomarkers. 31:17 2205-2218
2. DuFort et al, Interstitial Pressure in Pancreatic Ductal Adenocarcinoma Is Dominated by a Gel-Fluid Phase. Biophysical Journal 110 2106-2119
3. Soltani et al Numerical Modeling of Fluid Flow in Solid Tumors. PLoS ONE 6:6 e20344
4. Homma, H. et al. Cancer 89, 303–313 (2000).
5. Rosemurgy, A. S. et al. J Pancreat Cancer 3, 58–65 (2017).
6. Piras, C., Paulo, D. N. S., Paulo, I. C. A. L., Rodrigues, H. & Silva, A. L. da. Acta Cirurgica Brasileira 25, 105–110 (2010).
7. Moody, A. R. & Poon, P. Y. American Journal of Roentgenology 158, 779–783 (1992). 5. Okahara, M. et al. Abdom Imaging 35, 134–142 (2010).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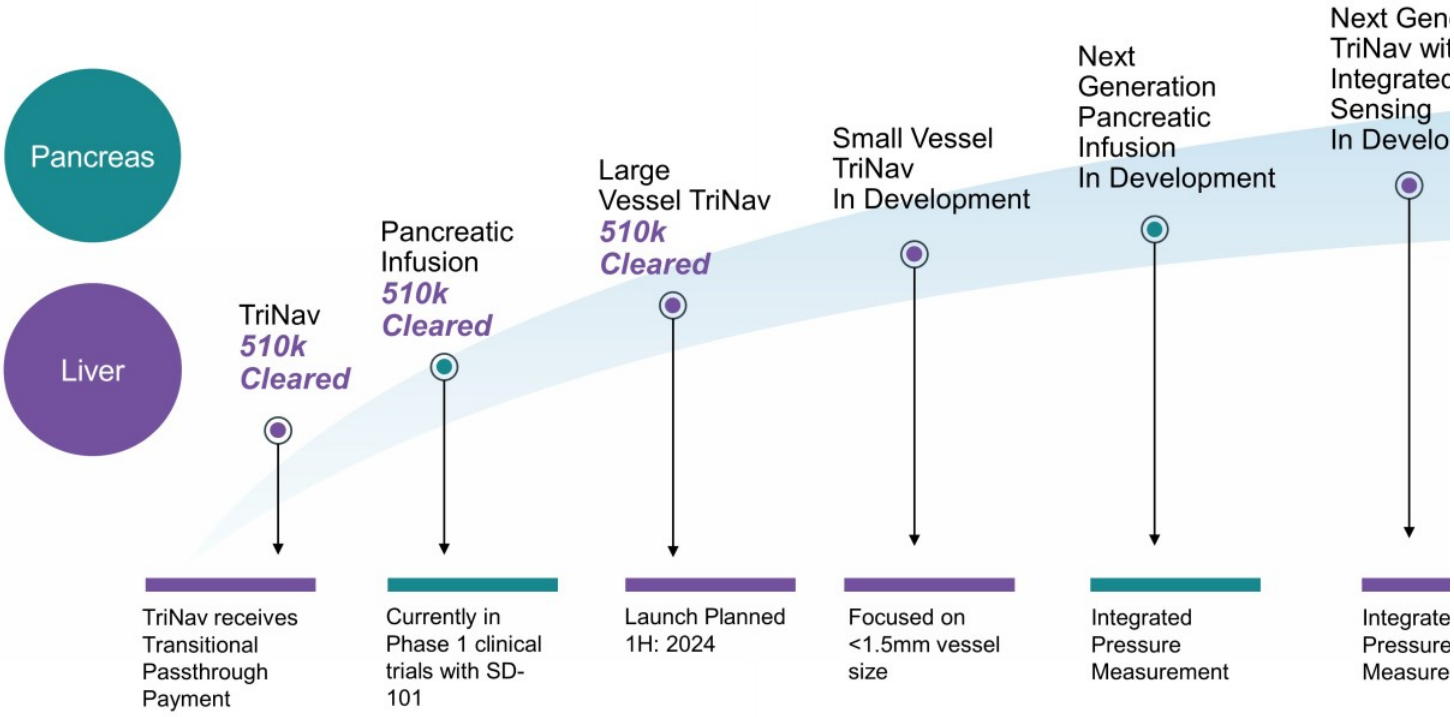
# TriSalus Technology Pipeline

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# Significant Potential Upside from SD-101, a TLR9 agonist, in Clinical Development

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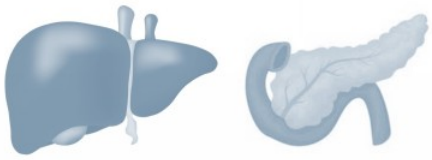
# SD-101: U.S. Addressable Market Across Indications ≥

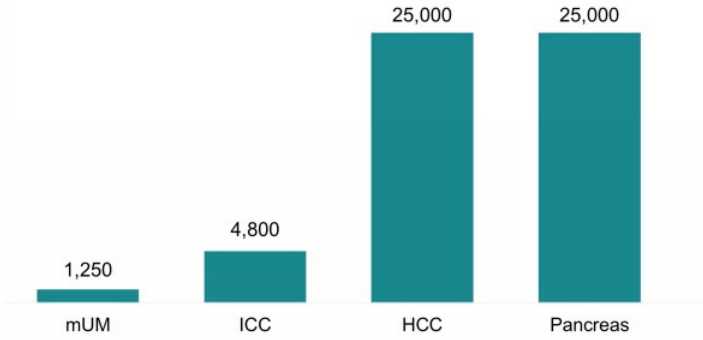
- Addressing unresectable disease in liver and pancreas



- Target indications all areas of high unmet need with poor overall survival
- Addressable population >80,000[1] in the U.S.
- High global incidence in key targeted indications provides significant opportunity ex-US

1. SEER Database 2023

**SD-101 Addressable Patient Population**




Source: SEER database

Addressable market includes **uveal melanoma liver intrahepatic cholangiocarcinoma, HCC, PDAC** and **liver metastases**

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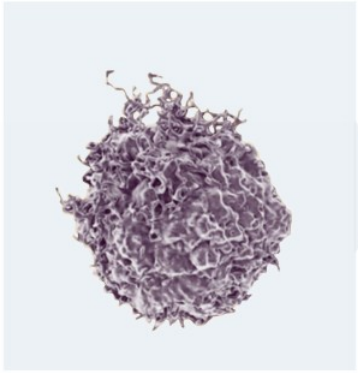
# SD-101 + PEDD Turns “Cold” Tumors “Hot”

**Unresponsive “cold” Tumor Pre-SD-101**



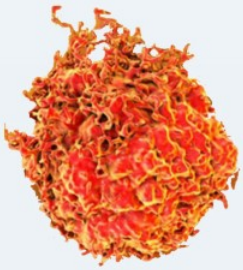
MDSC accumulation, T cell paucity, and immunotherapy failure

**TriSalus PEDD + SD-101**

- Broad immune stimulation
- MDSC elimination
- Improved potential for checkpoint inhibitor durable response

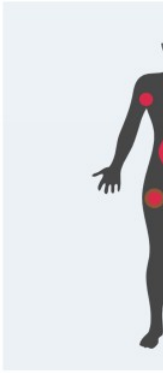
PEDD unlocks dual mechanism of action in liver and pancreas

**Responsive “hot” Tumor Post-SD-101**



MDSC depletion, T cell infiltration, and higher likelihood of checkpoint response

**SD-101 via P Systemic Im**



Systemic immur evidenced by ctl SD-101 and 59%

1. Montazeri. ASCO 2023

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# SD-101 Dual Mechanism of Action Chosen for Liver and

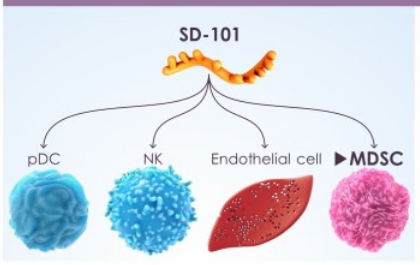
**SD-101** reprograms the TME through multiple mechanisms

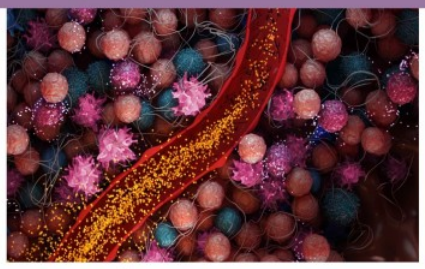
**1.** SD-101 binds to TLR9

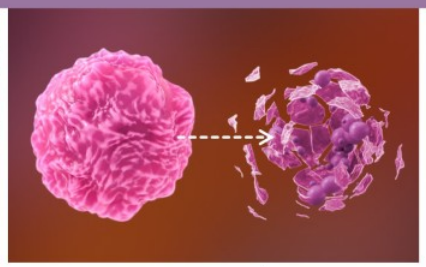
**2.** Broad TME activation by SD-101 via PEDD

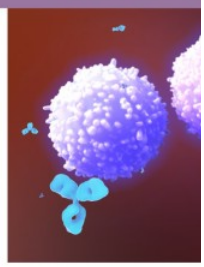
**3.** MDSC elimination

**4.** T cells accu tumor for C







SD-101 acts on multiple cell types

**Dual mechanism of action**

CPI molec T cells recru

Tumor microenvironment (TME)

TME = tumo
CPI = check

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# Pipeline Designed to Enable Immunotherapy in Liver and Panc Tumors

| INDICATION | TRIAL DESIGN | IND ENABLING | PHASE 1 | PHASE 2 | PHASE 3 | ANTICIPATED |
|---|---|---|---|---|---|---|
| Uveal Melanoma Liver Metastases (Validation of combination) | SD-101 + PEDD HAI + CPI | Phase 1/1b PERIO-01 Trial | | | | • 2H 2023: Phas<br>• 2H 2023: Initiat Line Focus) |
| Hepatocellular Cancer (HCC)[1] | SD-101 + PEDD HAI + CPI | Phase 1b PERIO-02 Trial | | | | • 1Q 2024: Phas |
| | SD-101 + PEDD HAI + Y-90 | Phase 1b/2 PERIO-Y Trial | | | | • 1H 2024: Initiat |
| Intrahepatic Cholangiocarcinoma (ICC)[1] | SD-101 + PEDD HAI + CPI | Phase 1b PERIO-02 Trial | | | | • Awaiting Phase |
| Locally Advanced PDAC | SD-101 + PEDD PRVI + CPI | Phase 1/1b PERIO-03 Trial | | | | • 2H 2024: Initiat |

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.

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# Studies Run by Internationally Renowned Cancer Cent

COLUMBIA UNIVERSITY
IRVING MEDICAL CENTER

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

MASSACHUSE
GENERAL HO

UW Medicine
UNIVERSITY OF WASHINGTON
MEDICAL CENTER

Stanford
MEDICINE

Jefferson
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

BROWN
Alpert Medical Schoo

SYLVESTER
COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

Pitt
Medicine

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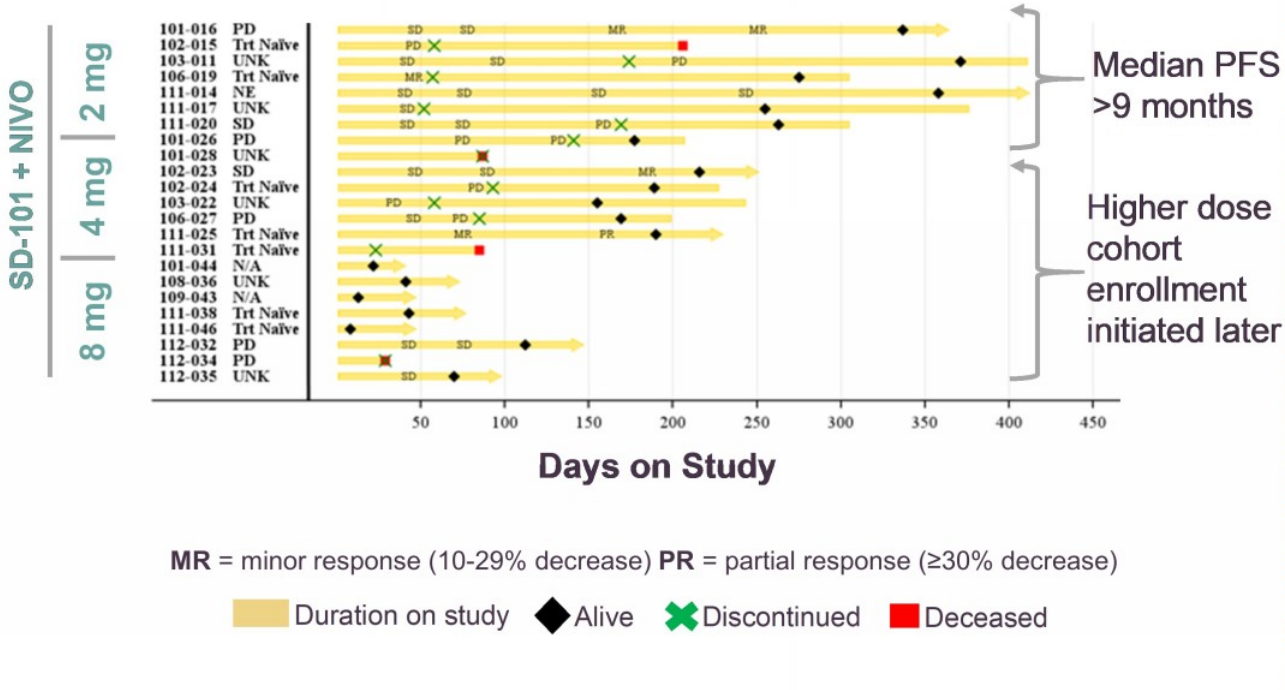
# SD-101: Longer than expected survival times in metastatic uveal melanom liver metastases




**MR** = minor response (10-29% decrease) **PR** = partial response (≥30% decrease)

Duration on study ◆ Alive ✖ Discontinued ■ Deceased

2023 AS
ANNUAL M

21% ctDNA cl
with tebentafu
patients

ctDNA Report
overall surviva
melanoma[2]

| Lines of Pr Treatmen |
|---|
| 0 |
| 1 |
| 2 |
| 3 |
| 5 |

1.Montazerri ASCO 2023. 2 Carvajal Nat Med 2022

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# SD-101 Well Tolerated with Low Level of Serious AE's

| TS-PERIO-01 Phase 1 (1L if Kimmtrak ineligible; 2L+ if Kimmtrak eligible) | TriSalus (SD-101) N=39 (phase 1) | Immunocore (Kimmtrak) N=378 (2:1 RCT) | Ideaya (Ph2 interim) N=37 |
|---|---|---|---|
| **Stage IV UM LM population eligible** | 100% | ~ 50% (HLA-0201+) | ~ 50% (HLA-0201-) |
| **Serious adverse event rate related to drug** | 5% | 44%[1] | >31%[2] |
| **Grade 2 or higher cytokine release syndrome** | 2% | 76% | N/A |

1. Carvajal, Nature Medicine, Volume 28, November 2022;2364–2373 2. Company website

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2023 A
ANNUAL

PEDD c
SD-101
well-tole
immune

# 2023 – 2024: Anticipated Key Milestones

| Catalyst | Indication | Anticipated Ti |
|---|---|---|
| Phase 1 PERIO Data | Uveal Melanoma | 2H 2023 |
| Initiation of Phase 2 | Uveal Melanoma | 1H 2024 |
| Launch of TriNav Large | Hepatocellular Cancer | 1H 2024 |
| Initiation of Phase 1 Y-90 + SD-101 | Hepatocellular Cancer | 1H 2024 |
| Phase 1 PERIO Data | Locally advanced Pancreatic Cancer | 2H 2024 |
| Enrollment in Phase 2 | Locally advanced Pancreatic Cancer | 2H 2024 |

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# Executive Team

**Mary Szela**
CEO & President

**Sean Murphy**
Chief Financial Officer

**Steven Katz, MD, FACS**
Chief Medical Officer, Chairman of SAB

**Jim Alecxih**
President, Device Technology

**Jennifer Stevens**
Chief Regulatory Officer

**Bryan Cox, PHD**
Chief of Research

# Board of Directors

**Mats Wahlstrom**
Chairman

**Mary Szela**

**Sean Murphy**

**Kerry Hicks**

**Andrew C. von Eschenbach**

**Anil Singhal**

**Kelly Martin**

**David Matlin**

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# Capital Structure and Share Information as of August 3

| Share Listing – Current | TLSI (Nasdaq) |
|---|---|
| Common Shares Outstanding | 26.4M |
| Preferred Shares Outstanding | 4.0M |
| Market Cap | $171.6M |
| Warrants Outstanding [a] | 14.3M |
| Cash and Cash Equivalents | $27.4M |
| 2023 Q2 Cash Burn [b] | $9.3M |
| Current Price | $6.52 |
| Average Daily Volume [c] | 49K |
| Debt | $0 |

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

b. Net cash used in operating activities per cash flow statement for quarter ending June 30, 2023

c. For trading period August 1 to August 31, 2023


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# TriSalus: Focused on Innovative Approaches to Improving Outcomes for Patients with Liver and Pancreas Tumors

- Medtech focused on growth and innovation
- Multiple value-creating opportunities anticipate next 18 months
- Targeting multiple high value markets, all chara high unmet need
- Deep device and therapeutic expertise focused simultaneously ↑ efficacy and ↓ toxicity
- Funding expected through mid-2024 to allow k

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# Thank You!