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): November 14, 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)**	**(IRS 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 obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ 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 2.02 Results of Operations and Financial Condition.

On November 14, 2023, TriSalus Life Sciences, Inc. ("Company") issued a press release announcing its financial results for the three and nine month periods ended September 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto 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 the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 14, 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.

TRISALUS LIFE SCIENCES, INC.

Date: November 14, 2023

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

Exhibit 99.1

TriSalus Reports Third Quarter 2023 Financial Results and Provides Business Update

Completed merger with MedTech Acquisition Corporation (MTAC) and started public trading August 11th

Reported 3Q23 revenues of $5.2 million in 3Q23, up 32% over prior year and nine-month year to date net revenues of $12.8 million, up 39% over prior year

Favorable Phase 1 uveal melanoma PERIO-01 data demonstrating median progression free survival (PFS) of 11.7 months, with an 81% Disease Control Rate and 1 year overall survival (OS) of 86%

Favorable Phase 1 pancreatic adenocarcinoma PERIO-03 data utilizing innovative FDA cleared pancreatic delivery device demonstrates initial safety, feasibility and immunologic response

Conference call November 14th at 9:00AM EDT

TriSalus Life Sciences Inc., (Nasdaq: TLSI), a publicly traded oncology company integrating its novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors, today announced its financial results for the third quarter ended September 30, 2023, and provided a business update.

“Today marks an important milestone for TriSalus as we host our first quarterly earnings call as a public company. I am proud of our team’s considerable progress in the commercialization of the TriNav® Infusion System, our Pressure Enabled Drug Delivery™ (PEDD™) method, which achieved $5.2 million in revenues in the quarter, up over 30% from the third quarter of 2022,” said Mary Szela, Chief Executive Officer of TriSalus. “We remain focused on integrating the TriNav system with immunotherapy to transform treatment for patients with liver and pancreatic tumors by solving two main barriers to tumor treatment in the tumor microenvironment (TME): mechanical barriers that limit drug delivery and biological barriers to driving immunosuppression.”

“Data from our three Phase 1/1b trials indicates that our innovative immunotherapy approach for liver and pancreas tumors has been well tolerated, with evidence of SD-101 being delivered into difficult to reach tumors, potentially overcoming limitations posed by intravenous or direct needle injection approaches. The mechanical and biologic TME barriers that TriSalus is targeting are commonly present in solid tumors, creating a significant opportunity to impact a large patient population across cancer types,” commented Steven Katz, MD, FACS, Chief Medical Officer of TriSalus.

Third Quarter 2023 and Subsequent Highlights

PERIO-01 Phase 1 Data Selected for Late Breaking Podium Presentation at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting

In November, TriSalus announced that SITC had selected the PERIO-01 Phase 1 data for a late breaking podium presentation and participation in the press conference of its 2023 annual meeting. The data demonstrated that delivery of SD-101 by TriNav plus systemic immune checkpoint inhibitor (ICI) in uveal melanoma with liver metastases (UMLM) patients results in clinical activity with median progression free survival (PFS) of 11.7 months, myeloid derived suppressor cell (MDSC) re-programming, and evidence of peripheral and intra-tumoral immune activation.

PERIO-03 Phase 1 Initial Safety and Feasibility Data Selected for Poster Presentation at SITC Annual Meeting

In November, the company presented data on its PERIO-03 Phase 1 clinical trial on pressure enabled intra-pancreatic delivery of SD-101 with checkpoint blockade for locally advanced pancreatic adenocarcinoma. The data demonstrated that TriNav pancreatic retrograde venous infusions (PRVI) of SD-101 were well tolerated in the initial three patients and infusions were associated with potentially favorable immune changes in the periphery and tumors. These findings support continuing with single-agent dose escalation and subsequent combination with systemic ICI.

The PERIO-03 Phase 1 study with single-agent SD-101 is expected to be completed at the end of 2023 with subsequent initiation of the Phase 1b PERIO-03 dose expansion beginning early 2024. In the expansion study, intravenous anti-PD-1 therapy will be added to SD-101 delivered by PEDD. The trial will target patients with unresectable, locally advanced pancreatic adenocarcinoma who failed or progressed on at least one line of standard therapy.

Jodi Devlin appointed as President, Commercial Operations

In September, TriSalus announced that Jodi Devlin was appointed as President, Commercial Operations. Ms. Devlin joined TriSalus with more than two decades of experience in building brands in a wide range of therapeutic areas, with expertise in developing and executing strategies across sales, marketing, medical affairs, market access, and policy for biotech and pharmaceutical products.

Financial Results

Revenue, all of which is from the sale of TriNav, was $5.2 million and $12.8 million, respectively, in the three and nine months ended September 30, 2023. These amounts represent growth vs. prior year of 32% in the third quarter and 39% for nine months year to date, primarily due to continued market share increases.

Gross margins were 89% in the third quarter ended September 30, 2023, and 84% for nine months year to date versus 82% and 84%, respectively, in the third quarter and year to date in 2022. The seven percent improvement in the third quarter of 2023 is due to increased factory volumes and improved operations efficiency.

Operating losses are $18.5 million and $40.0 million, respectively, for the third quarter and nine months ended September 30, 2023. These amounts include non-recurring professional service fee costs of $4.8 million in the quarter and $7.7 million year to date, primarily related to the completion of our deSPAC process in August 2023. These amounts compare to prior year losses of $8.1 million and $24.7 million, respectively. The Company increased investments in 2023 in R&D to support clinical program progress and in sales and marketing, primarily to expand its sales force to continue to increase market penetration.

Net losses attributable to common stockholders are $1.7 million and $27.0 million, respectively, for the third quarter and nine months ended September 30, 2023. These amounts compare to prior year losses of $8.1 million and $24.6 million, respectively. Net losses include the impact of a non-cash related gain on revaluation of contingent earnout liabilities of $19.9 million in the third quarter and nine-month period of 2023. In addition, net losses include the impact of non-cash related gains/(losses) associated with revaluation of tranche and warrant liabilities of ($2.8) million and $0.7 million, respectively, for the third quarter and nine-month period ending September 30, 2023. The nine-month period ending September 30, 2023 also includes a non-cash related loss on equity issuance of $4.2 million.

Basic and diluted loss per share for the three and nine months ended September 30, 2023, was $0.13 and $5.68, respectively, compared to a basic and diluted loss per share of $25.95 and $82.17 for the three and nine months ended September 30, 2022, respectively.

Conference Call

The event will be webcast live on the investor relations section of TriSalus' website at https://investors.trisaluslifesci.com/news-events/events-presentations. Following the conclusion of the event, a webcast replay will be available on the website for approximately 90 days. Interested parties participating by phone will need to register using this online form. After registering for the webcast, dial-in details will be provided in an auto-generated e-mail containing a link to the conference phone number along with a personal pin.

About TriSalus Life Sciences

TriSalus Life Sciences® is an oncology company integrating novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors.

The Company's platform includes devices that utilize a proprietary drug delivery technology and a clinical stage investigational immunotherapy. The Company's two FDA-cleared devices use its proprietary Pressure-Enabled Drug Delivery™ (PEDD) approach to deliver a range of therapeutics: the TriNav® Infusion System for hepatic arterial infusion of liver tumors and the Pancreatic Retrograde Venous Infusion System for pancreatic tumors. PEDD is a novel delivery approach designed to address the anatomic limitations of arterial infusion for the pancreas. The PEDD approach modulates pressure and flow in a manner that delivers more therapeutic to the tumor and is designed to reduce undesired delivery to normal tissue, bringing the potential to improve patient outcomes. SD-101, the Company's investigational immunotherapeutic candidate, is designed to improve patient outcomes by treating the immunosuppressive environment created by many tumors and which can make current immunotherapies ineffective in the liver and pancreas. Patient data generated during Pressure-Enabled Regional Immuno-Oncology™ (PERIO) clinical trials support the hypothesis that SD-101 delivered via PEDD may have favorable immune effects within the liver and systemically. The target for SD-101, TLR9, is expressed across cancer types and the mechanical barriers addressed by PEDD are commonly present as well. SD-101 delivered by PEDD will be studied across several indications in an effort to address immune dysfunction and overcome drug delivery barriers in the liver and pancreas.

In partnership with leading cancer centers across the country – and by leveraging deep immuno-oncology expertise and inventive technology development – TriSalus is committed to advancing innovation that improves outcomes for patients. Learn more at trisaluslifesci.com and follow us on Twitter and LinkedIn.

Forward Looking Statements

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the benefits and potential benefits of the Company's PEDD drug delivery technology and SD-101 investigational immunotherapy, the Company's business strategy and clinical development plans, the safety and efficacy of the Company's product candidates, the Company's plans and expected timing with respect to clinical trials. Risks that could cause actual results to differ from those expressed in these forward-looking statements include risks associated with clinical development and regulatory approval of drug delivery and pharmaceutical product candidates, including that future clinical results may not be consistent with patient data generated during the Company's PERIO clinical trials, the success cost and timing of all development activities and clinical trials, unexpected safety and efficacy data observed during clinical studies, changes in expected or existing competition, changes in the regulatory environment, unexpected litigation or other disputes, and other risks described in the Company's filings with the Securities and Exchange Commission under the heading "Risk Factors." All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made except as required by law.

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Financials

TriSalus Life Sciences

Condensed Consolidated Statement of Operations (unaudited, 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)
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

TriSalus Life Sciences

Condensed Consolidated Balance Sheets (in thousands)

	September 30, 2023 (unaudited)	December 31, 2022
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 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