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, 2024

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 2.02 Results of Operations and Financial Condition.

On November 14, 2024, TriSalus Life Sciences, Inc. (the "Company") issued a press release providing a business update and announcing its financial results for the quarter ended September 30, 2024. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 2.02 of this Current Report on Form 8-K, 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, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated November 14, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Date: November 14, 2024

TriSalus Life Sciences, Inc.

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

Exhibit 99.1

TriSalus Reports Q3 2024 Financial Results and Provides Business Update

- Reported Q3 and nine-month revenues of $7.3 million and $21.2 million respectively, up 42% and 66% year-over-year
- Provided 2025 guidance with expectations of over 50% annual sales growth, 20%+ reduction in operating expenses, positive full-year EBITDA, and positive cash flow in H2 2025
- Launched TriNav® LV Infusion System and TriGuide™ Guiding Catheter for larger vessels and complex cases, expanding the TriNav system's full access to the $375 million embolization market
- Initiated the PROTECT registry trial using the TriNav system to treat multinodular goiters, expanding the TriNav system's reach into the $400 million thyroid embolization market
- Presented positive Phase 1 data from PERIO-01 trial in patients with uveal melanoma with liver metastases (UM-LM) at the Society for Immunotherapy of Cancer (SITC) meeting and announced the strategic decision to seek a partner to drive further development of this indication
- Hosting earnings call on November 14, 2024 at 9:00 a.m. EST

DENVER, CO – November 14, 2024 – TriSalus Life Sciences Inc., (Nasdaq: TLSI), an oncology company integrating 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, 2024, and provided a business update.

"We enter the final quarter of 2024 with great momentum, both commercially and clinically, and we are positioned well for an even greater 2025," stated Mary Szela, President and Chief Executive Officer of TriSalus Life Sciences. "Commercially, we enjoyed a strong third quarter highlighted by 42% revenue growth. We recently launched the TriNav LV system to address patients with larger vessels, an opportunity we believe will meaningfully expand our addressable market and provide full access to the $375 million liver embolization market."

"With the successful completion of our Phase 1 dose escalation study enrollment in UM-LM, we are actively pursuing a strategic partnership for nelitolimod," continued Szela. "This follows the successful presentation of positive Phase 1 results from our PERIO-01 dose escalation study in UM-LM at SITC. Additionally, by mid-2025, we anticipate data from our Phase 1 study in locally advanced pancreatic cancer, which will guide our next steps."

“Our clinical development efforts for the TriNav system have expanded with the launch of the DELIVER program, starting with the PROTECT registry trial for patients with multinodular goiter. There is significant potential to broaden our addressable market by $400 million, and we are committed to providing further updates on PROTECT and additional programs within the DELIVER initiative.”

“Finally, we are initiating 2025 guidance that calls for greater than 50% revenue growth, a greater than 20% reduction in operating expenses, positive full-year EBITDA, and positive cash flow in the second half of the year,” concluded Ms. Szela.

Third Quarter Business Update

TriNav System Large Vessel Launch

TriSalus recently expanded its portfolio of Pressure-Enabled Drug Delivery™ (PEDD™) devices with the launch of the TriNav LV Infusion System and TriGuide Guiding Catheter to optimize therapeutic delivery for patients with larger vessels. The TriNav LV system is suitable for patients with vessels sized between 3.5 and 5.0mm and is expected to allow the Company to meaningfully expand its addressable liver embolization market. The TriGuide Guiding Catheter has a larger inner diameter, lubricious inner lining, and reverse curve design to support femoral access for the TriNav LV system, which the Company believes will enhance procedural efficiency. These new products are eligible for the same HCPCS reimbursement codes as existing TriNav products, enabling seamless integration into current billing structures.

DELIVER and PROTECT Updates

During the quarter, TriSalus advanced the DELIVER clinical program, a series of clinical trials designed to demonstrate enhanced safety and efficacy across a broad spectrum of complex, difficult-to-treat patients through investigator-initiated studies, further underscoring the impact of PEDD technology. A key focus of the DELIVER program is to investigate the potential of combining use of the TriNav system with these therapies to enhance effectiveness and address resistance mechanisms in challenging cancers.

The first of these is a registry study called PROTECT (Pressure Enabled Retrograde Occlusive Therapy with Embolization for Control of Thyroid Disease), which has been initiated, and TriSalus intends to enroll 100 patients across five leading academic sites. It is estimated that approximately 5% of adults have multinodular goiters, and the prevalence in adults over 50 is estimated to be up to 50%. The Company estimates that this could expand the addressable market by approximately 50,000 procedures, representing an incremental $400 million market opportunity and putting the Company’s total addressable market at more than $1 billion in the U.S. This new procedure utilizing the TriNav system is also eligible for the same Healthcare Common Procedure Coding System (HCPCS) reimbursement code allowing for seamless integration into current billing approaches.

The Company anticipates opening additional DELIVER studies in the first half of 2025 and will provide more details as those studies commence.

PERIO Trial Update

TriSalus presented Phase 1 results from the PERIO-01 clinical trial at the recent SITC meeting. This dose escalation trial investigated the use of the PEDD method of nelitolimod in patients with UM-LM. The results suggested that PEDD-administered nelitolimod, combined with immune checkpoint inhibitors, provides promising clinical benefits and durable survival in heavily pretreated patients with UM-LM and a favorable safety profile. The Company is actively exploring strategic partnerships to advance this indication further.

The Company also completed enrollment of 13 patients in its PERIO-03 Phase 1 dose escalation study of nelitolimod in locally advanced pancreatic cancer. Evidence gathered thus far supports a strong safety profile and further exploration of nelitolimod combined with the TriNav pancreatic infusion technology. The Company will outline the next steps once the final data are available in mid-2025.

Financial Results for Q3 2024

Revenue, all from the sale of the TriNav system, was $7.3 million and $21.2 million, respectively, for the three and nine months ended September 30, 2024. These were up 42% and 66%, respectively, compared to the same periods in 2023. Revenue growth was driven primarily by increased selling resources and increased market share.

Gross margins were 86% and 86% for the three and nine months ended September 30, 2024, respectively, compared to 89% and 84%, respectively, for the same periods in 2023. The year-to-date improvement is due to increased factory volumes and improved operational efficiency.

Operating losses were $8.7 million and $28.6 million, respectively, for the three and nine months ended September 30, 2024, respectively, compared to losses of $18.6 million and $40.2 million, respectively, for the same periods in 2023. These amounts include non-cash stock compensation and depreciation expenses of $1.6 million and $4.3 million for the three- and nine-month periods in 2024 and $0.4 million and $0.9 million for the same periods in 2023. Current year reductions in operating losses are due to increased sales, reduced general and administrative expenses due to non-recurrence of prior year costs related to becoming a public company, and reduced research and development spending associated with the ramp-down of clinical trial spending.

Net losses available to common stockholders were $2.4 million and $19.9 million, respectively, for the three and nine months ended September 30, 2024, compared to losses of $1.4 million and $23.7 million, respectively, for the same periods in 2023. Net losses in 2024 include non-cash related gains on change in fair value of various derivatives of $7.3 million and $10.5 million, respectively, for the three and nine months ended September 30, 2024, compared to gains of $17.1 million and $16.4 million, respectively, for the same periods in 2023. The basic and diluted loss per share for the three and nine months ended September 30, 2024, were $0.12 and $0.91, respectively, compared to $0.14 and $5.72 for the three and nine months ended September 30, 2023, respectively.

On September 30, 2024, cash and cash equivalents totaled $11.3 million. The Company expects existing liquidity sources and $25 million of available capacity on the OrbiMed debt facility to provide sufficient cash runway throughout 2025. In addition, the company expects to be EBITDA positive for 2025 and achieve positive cash flow by the second half of 2025, extending total cash runway beyond 2025.

2025 Guidance

The Company is providing guidance for 2025 for the first time, including:

- Sales are expected to grow by more than 50% in 2025, driven by further market share increases in the TriNav system, the commercial launch of the TriNav LV system, and the TriNav target market expansion driven by the DELIVER program.
- Operating expenses are expected to decline greater than 20% in 2025 due to reductions in R&D associated with completing the PERIO Phase 1 trials and reductions in G&A expenses due to the non-recurrence of certain costs related to becoming a public Company.
- The Company expects to achieve positive full-year EBITDA and positive cash flow in the second half of the year.

Conference Call

TriSalus will host a webcast to discuss its third quarter 2024 financial results and business highlights on November 14, 2024, at 9:00 a.m. EST. The webcast can be accessed 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. 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 and 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. The PEDD technology 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. Nelitolimod, 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 nelitolimod delivered via the PEDD technology may have favorable immune effects within the liver and systemically. The target for nelitolimod, TLR9, is expressed across cancer types and the mechanical barriers addressed by the PEDD technology are commonly present as well.

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 Company's guidance for its financial performance in 2025, the benefits and potential benefits of the Company's PEDD drug delivery technology, TriNav system and nelitolimod investigational immunotherapy, the expected timing for reporting results from the Company's clinical trials for nelitolimod, the Company's goal of finding a strategic partner to advance nelitolimod in UM-LM, the ability of TriNav LV to expand the Company's addressable market, the expected benefits from the Company's DELIVER program including the incremental market opportunity expected from the PROTECT study, the Company's expected timing to open additional DELIVER studies, statements regarding the Company's cash runway, the Company's expectation that TriNav LV will seamlessly integrate into the current billing structures and the Company's ability to execute on its strategy. 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 clinical trials, the risk that the Company may not be successful in identifying a strategic partner to advance PERIO-01, the risk that the Company may not achieve its projected financial results for 2025, the size and growth of the market for the Company's products and the rate and degree of market acceptance thereof, the cost and timing of all development activities and clinical trials, unexpected safety and efficacy data observed during clinical studies, the risks associated with the credit facility, including the Company's ability to remain in compliance with all its obligations thereunder to avoid an event of default, the risk that the Company will continue to raise capital through the issuance and sale of its equity securities to fund its operations, the risk that the Company will not be able to achieve the applicable revenue requirements to access additional financing under the credit facility, changes in expected or existing competition or market conditions, changes in the regulatory environment, unexpected litigation or other disputes, unexpected expensed costs, 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.

Financials

TriSalus Life Sciences

Condensed Consolidated Statement of Operations (unaudited, in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue	$ 7,349	$ 5,193	$ 21,170	$ 12,790
Cost of goods sold	1,004	589	2,887	2,023
Gross Profit	6,345	4,604	18,283	10,767
Operating expenses:				
Research and development	4,219	9,506	14,729	22,066
Sales and marketing	6,138	4,689	18,829	11,430
General and administrative	4,727	9,025	13,310	17,498
Loss from operations	(8,739)	(18,616)	(28,585)	(40,227)
Other income (expense):				
Interest income	158	116	347	187
Interest expense	(1,142)	(4)	(2,022)	(13)
Loss on equity issuance				(5,691)
Extinguishment of tranche liability		19		1,520
Change in fair value of SEPA, warrant, and revenue base redemption liabilities	4,974	(2,831)	(1,521)	660
Change in fair value of contingent earnout liability	2,360	19,904	12,061	19,904
Other expense, net	(13)	(13)	(210)	(56)
Loss before income taxes	(2,402)	(1,425)	(19,930)	(23,716)
Income tax benefit (expense)	3		(7)	(8)
Net loss available to common stockholders	$ (2,399)	$ (1,425)	$ (19,937)	$ (23,724)
Deemed dividend related to Series B-2 preferred stock down round provision				(2,981)
Undeclared dividends on Series A preferred stock	(803)	(458)	(2,405)	(458)
Net loss attributable to common stockholders	$ (3,202)	$ (1,883)	$ (22,342)	$ (27,163)
Net loss per common share, basic and diluted	$ (0.12)	$ (0.14)	$ (0.91)	$ (5.72)
Weighted average common shares outstanding, basic and diluted	26,501,597	13,173,422	24,588,500	4,749,849

TriSalus Life Sciences

Condensed Consolidated Balance Sheets (unaudited, in thousands)

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	11,288	11,777
Accounts receivable	4,912	3,554
Inventory, net	3,999	2,545
Prepaid expenses	3,609	2,986
Total current assets	23,808	20,862
Property and equipment, net	1,818	2,091
Right-of-use assets	1,427	1,179
Other assets	424	466
Total assets	27,477	24,598
Liabilities and Stockholders' Deficit		
Current liabilities:		
Trade payables	1,446	3,391
Accrued liabilities	7,877	10,556
Short-term lease liabilities	266	351
Other current liabilities	329	389
Total current liabilities	9,918	14,687
Long-term debt, net of unamortized discount and debt issuance costs	21,678	
Revenue base redemption liability	426	
Long-term lease liabilities	1,506	1,244
Contingent earnout liability	6,571	18,632
Warrant and SEPA liabilities	7,812	17,100
Total liabilities	47,911	51,663
Stockholders' deficit:		
Preferred Stock, Series A, $0.0001 par value per share, $10.00 liquidation value per share. Authorized 10,000,000 shares at September 30, 2024, and December 31, 2023, respectively; issued and outstanding, 3,985,002 and 4,015,002 shares at September 30, 2024 and December 31, 2023, respectively.		
Common stock, $0.0001 par value per share. Authorized 400,000,000 shares at September 30, 2024 and December 31, 2023, respectively; issued and outstanding, 30,469,664 and 26,413,213 shares at September 30, 2024, and December 31, 2023, respectively	3	2
Additional paid-in capital	249,004	222,437
Accumulated deficit	(269,441)	(249,504)
Total stockholders' deficit	(20,434)	(27,065)
Total liabilities and stockholders' deficit	27,477	24,598

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