

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 22, 2026

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

Delaware
(State or other jurisdiction of
incorporation or organization)
6272 W 91st Ave, Westminster, Colorado
(Address of principal executive office)

001-39813
(Commission
File Number)

85-3009869
(I.R.S. 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 obligations of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communication 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	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 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 8.01 Other Events.

On September 22, 2026, TriSalus Life Sciences, Inc. (the “Company”) issued a press release announcing that it has received U.S. Food and Drug Administration (“FDA”) 510(k) clearance for its TriNav Advance device. With FDA clearance, the Company expects to commence commercialization. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit Number	Description
99.1	Press Release dated September 22, 2026
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: September 22, 2026

TriSalus Life Sciences, Inc.

By: /s/ David Patience

Name: David Patience

Title: Chief Financial Officer

TriSalus Life Sciences Receives FDA Clearance for TriNav® Advance, Strengthening Comprehensive Pressure-Enabled Drug Delivery™ (PEDD™) Portfolio for Liver Embolization

WESTMINSTER, Colo. – September 22, 2026 – TriSalus Life Sciences, Inc. (Nasdaq: TLSI) (the "Company"), an oncology company integrating novel delivery technology with standard-of-care therapies and its investigational immunotherapeutic to transform treatment for patients with solid tumors, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for TriNav® Advance, the newest addition to its Pressure-Enabled Drug Delivery™ (PEDD) portfolio.

TriNav® Advance expands TriSalus' portfolio of PEDD devices, adding access to small, distal vessels, via a compatible delivery microcatheter, while preserving PEDD's enhanced therapeutic delivery and off-target protection. Interventional radiologists can now pair TriNav Advance with a compatible microcatheter of their choice, giving them flexibility across a broader range of procedures and anatomies.

With this addition, TriSalus offers a complete portfolio addressing liver-directed therapy cases and its indication supports a broader range of embolization procedures beyond the liver. The Company intends to initiate a limited market release of the TriNav Advance device over the coming weeks.

TriNav Advance can be used in two configurations to match vessel anatomy and treatment goals:

- **Telescoping:** Used with a compatible microcatheter, with the TriNav Advance SmartValve positioned proximal to the delivery site - enabling selective delivery to smaller, distal vessels while maintaining the benefits of PEDD.
- **High-flow:** Used like a standard TriNav device, without an additional microcatheter, for easy infusion through a large lumen.

"TriNav® Advance enhances our Pressure-Enabled Drug Delivery™ portfolio in support of the full range of liver embolization procedures," said Mary Szela, President and Chief Executive Officer of TriSalus. "We are proud of the range of tools we offer to physicians and believe TriNav Advance will catalyze further adoption across these procedures. We're excited to broaden our portfolio in a way that can meaningfully benefit both physicians and patients."

"The TriNav® Advance clearance marks a seminal moment for TriSalus Life Sciences, enabling us to expand our impact, particularly in cases involving tortuous anatomies," said Richard Marshall, M.D., Chief Medical Officer of TriSalus. "We believe that physicians can now optimize therapeutic delivery in difficult cases while limiting exposure to unaffected anatomical structures, which has been central to what makes PEDD clinically meaningful. This is a natural extension of the technology into cases we haven't been able to fully address before."

About TriSalus Life Sciences

TriSalus Life Sciences® is an oncology focused medical technology company seeking to transform outcomes for patients with solid tumors by integrating its innovative delivery technology with standard-of-care therapies, and with its investigational immunotherapeutic, nelitolimod, a class C Toll-like receptor 9 agonist, for a range of different therapeutic and technology applications. The Company's platform includes devices that utilize a proprietary drug delivery technology and a clinical stage investigational immunotherapy. The Company's three FDA-cleared devices use its proprietary Pressure-

Enabled Drug Delivery™ (PEDD) approach to deliver a range of therapeutics: the TriNav® Infusion System and TriNav Infusion System LV 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. The Company has completed three Phase 1 clinical trials and will begin exploring partnership opportunities for development.

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, TriNav® system and nelitolimod investigational immunotherapy, 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 cost and timing of all development activities and clinical trials, unexpected safety and efficacy data observed during clinical studies, 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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Source: TriSalus Life Sciences, Inc.