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 15, 2026

Summit Therapeutics Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	001-36866	37-1979717
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
601 Brickell Key Drive, Suite 1000, Miami, FL		33131
(Address of Principal Executive Offices)		(Zip Code)

Registrant's Telephone Number, Including Area Code: (305) 203-2034

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 Instruction 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, $0.01 par value per share	SMMT	The Nasdaq Stock Market LLC

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 November 15, 2026, Summit Therapeutics Inc. issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has issued a Complete Response Letter ("CRL") regarding the Biologics License Application ("BLA") for ivonescimab in combination with platinum-containing chemotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer, who have received prior epidermal growth factor receptor tyrosine kinase inhibitor therapy. The CRL indicates that the BLA cannot be approved in its present form, as the FDA determined that substantial evidence of effectiveness is not established in the absence of a statistically significant overall survival ("OS") improvement. The FDA indicated that the progression-free survival benefit in the absence of a statistically significant OS benefit does not support a positive benefit-risk profile in support of approval. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated November 15, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

SUMMIT THERAPEUTICS INC.

Date: November 16, 2026

By: /s/ Manmeet S. Soni

Chief Operating Officer, Chief Financial Officer and Director
(Principal Financial Officer)

Summit Therapeutics Provides Update Regarding Ivonescimab Biologics License Application

Complete Response Letter Received from FDA for BLA Application Based on HARMONi Study

Miami, Florida, November 15, 2026 – Summit Therapeutics Inc. (NASDAQ: SMMT) today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for ivonescimab in combination with platinum-containing chemotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), who have received prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy. Ivonescimab is a novel PD-1 x VEGF bispecific antibody.

"As a cancer survivor, I understand firsthand how important it is for patients to have access to multiple treatment options, particularly when they are facing diseases with significant unmet medical needs," emphasized Dr. Maky Zanganeh, President and Co-Chief Executive Officer of Summit Therapeutics. "Behind every diagnosis is a person, a family, and a community hoping for more time, more possibilities, and a better future. I know that hope is not simply an emotion; it is the possibility that another treatment, another scientific breakthrough, or another therapeutic option may make a meaningful difference in someone's life. Every additional treatment option matters. It represents another opportunity for patients and their families, especially those who have exhausted existing therapies or have limited alternatives. Our responsibility as an industry is to continue advancing science, challenging conventional thinking, and bringing innovative medicines to patients in need. For me, our mission is deeply personal to bring our innovative medicine to patients who may benefit most."

The CRL indicates that the BLA cannot be approved in its present form, as the FDA determined that substantial evidence of effectiveness is not established in the absence of a statistically significant overall survival (OS) improvement. The FDA indicated that the progression-free survival (PFS) benefit in the absence of a statistically significant OS benefit does not support a positive benefit-risk profile in support of approval.

Currently, there are no FDA-approved regimens that have demonstrated a statistically significant OS benefit in this patient setting. In the primary analysis for OS, ivonescimab in combination with chemotherapy showed a positive trend without achieving a statistically significant result. In a post-hoc analysis, longer-term follow-up of western patients demonstrated a consistent OS benefit across regions with a hazard ratio of 0.76 in the full population, the Asian patients, and the western patients.

The BLA was supported by data from HARMONi, a global, randomized, double-blind Phase III clinical trial evaluating ivonescimab combined with platinum-containing chemotherapy compared with placebo combined with platinum-containing chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with a third-generation EGFR TKI. The HARMONi study has two primary endpoints: PFS and OS. HARMONi met its PFS primary endpoint, becoming the first global Phase III study of an immunotherapy-based regimen to show a statistically significant PFS improvement in this setting. The primary PFS analysis was also supported by longer-term follow-up in a post-hoc analysis, which demonstrated a consistent magnitude of benefit with more mature data of western patients.

Ivonescimab in combination with chemotherapy demonstrated an acceptable and manageable safety profile, which was consistent with previous studies. Ivonescimab plus chemotherapy was well-tolerated with no new safety

signals and comparable rates of discontinuation and death between both arms. There were 16 patients (7.3%) who discontinued ivonescimab due to treatment-related adverse events (TRAEs) compared to 11 patients (5.0%) who discontinued placebo due to TRAEs. There were four patients (1.8%) in the ivonescimab plus chemotherapy arm and five patients (2.3%) in the chemotherapy alone arm who died as a result of TRAEs in this Phase III study.

"We are disappointed for patients and their families awaiting additional treatment options in this setting," said Robert W. Duggan, Chairman and Co-Chief Executive Officer of Summit. "We chose to pursue an ivonescimab regimen here based on the opportunity to provide another treatment option to help patients in need. In doing so, we believe the global HARMONi study provided the basis for a treatment option that these patients needed."

"With five positive Phase III studies between Summit and Akeso, nothing changes with respect to our ever-growing belief in the opportunity for ivonescimab and our determination to advance ivonescimab's development," continued Robert Duggan. "Our mission remains to improve outcomes for patients facing significant unmet needs, which is work worth doing, and we will continue through our expansive clinical development program."

Summit is currently developing ivonescimab in NSCLC, colorectal cancer (CRC), urothelial carcinoma (UC), and renal cell carcinoma (RCC), specifically conducting multiregional Phase II or Phase III clinical trials in the following proposed indications or settings beyond the HARMONi study:

- HARMONi-3 (Phase III): ivonescimab combined with chemotherapy in patients with first-line metastatic NSCLC, with two distinct cohorts to be analyzed separately for squamous tumors and non-squamous tumors;

- HARMONi-7 (Phase III): ivonescimab monotherapy in patients with first-line metastatic NSCLC whose tumors have high PD-L1 expression;

- HARMONi-GI3 (Phase III): ivonescimab combined with chemotherapy in patients with first-line unresectable metastatic CRC;

- HARMONi-GU1 (Phase II / III): ivonescimab plus the antibody-drug conjugate (ADC) enfortumab vedotin (EV) in previously untreated patients with first-line metastatic UC; and

- SMT112-216 (Phase II): multiple ivonescimab-based combination treatment regimens in first-line patients with metastatic clear cell RCC (ccRCC) (SMT112-216 is also referred to as AK112-216 in China).

In addition, Summit is collaborating with other biopharmaceutical companies to test ivonescimab in combination with other novel compounds, including with:

- AstraZeneca and Daiichi Sankyo, planning to combine ivonescimab with DATROWAY® (datopotamab deruxtecan), a TROP-2 targeted ADC, in breast cancer and lung cancer, including the intent to initiate a Phase III study in first-line triple-negative breast cancer;

- AstraZeneca, planning to combine ivonescimab with the novel Claudin 18.2 targeted ADC, sonesitatug vedotin, in multiple gastrointestinal tumors;

- Revolution Medicines, combining ivonescimab with multiple RAS(ON) inhibitors, including a multi-selective inhibitor RASONQUE® (daraxonrasib), a G12D-selective inhibitor zoldonrasib, and a G12C-selective inhibitor elironrasib in multiple solid tumor settings;

- GSK, combining ivonescimab with the novel B7-H3 targeted ADC, risvutatug rezetecan, in multiple solid tumor settings; and

- Arcus Biosciences, planning to combine ivonescimab with the novel HIF-2α inhibitor, casdatifan, in ccRCC.

Finally, Summit is collaborating with two cooperative groups to evaluate ivonescimab in Phase III studies including biliary tract cancer (BTC) and head and neck squamous cell carcinoma (HNSCC), including with:

- GORTEC, a European Head and Neck Oncology and Radiotherapy Group based in France, to evaluate ivonescimab monotherapy and ivonescimab in combination with ligufalimab, Akeso's proprietary anti-CD47 monoclonal antibody, against monotherapy pembrolizumab in a randomized three-arm study in first-line advanced HNSCC. The Phase III study, GORTEC 2024-04 ILLUMINE (NCT07264075), is sponsored by GORTEC and is intended to be conducted in multiple countries in Europe and in China; Summit may consider the expansion of this study into the United States; and

- ECOG-ACRIN Cancer Research Group to evaluate ivonescimab in combination with chemotherapy compared to pembrolizumab or durvalumab in combination with chemotherapy in first-line advanced BTC in a registration-enabling Phase II / III clinical study, EA2251.

Ivonescimab is an investigational therapy that is not approved by any regulatory authority in Summit's license territories, including the United States and Europe. Ivonescimab was initially approved for marketing authorization in China in May 2024. Currently, there are no PD-1 x VEGF bispecific antibodies approved in the U.S.

About Ivonescimab

Ivonescimab, known as SMT112 in Summit's license territories, North America, South America, Europe, the Middle East, Africa, and Japan, and as AK112 outside of Summit's license territories, is a novel, potential first-in-class investigational bispecific antibody combining the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects associated with blocking VEGF into a single molecule. By design, ivonescimab displays unique cooperative binding to each of its intended targets with multifold higher affinity to PD-1 when in the presence of VEGF.

This design is intended to differentiate ivonescimab as there is potentially higher expression (presence) of both PD-1 and VEGF in tumor tissue and the tumor microenvironment (TME) as compared to normal tissue in the body. Summit believes ivonescimab's specifically engineered tetravalent structure (four binding sites) enables higher avidity (accumulated strength of multiple binding interactions) in the TME (Zhong, *et al*, iScience, 2025). This tetravalent structure, the intentional novel design of the molecule, and bringing these two targets into a single bispecific antibody with cooperative binding qualities have the potential to direct ivonescimab to the tumor tissue versus healthy tissue. The intent of this design, together with a half-life of 6 to 7 days after the first dose (Zhong, *et al*, iScience, 2025) increasing to approximately 10 days at steady state dosing, is to improve upon previously established efficacy thresholds, side effects, and safety profiles associated with prior approved drugs to these targets.

Ivonescimab was invented by Akeso Inc. (HKEX Code: 9926.HK) and is currently utilized in multiple Phase III clinical trials. Over 5,000 patients have been treated with ivonescimab in clinical studies globally, and over 100,000 patients when considering those treated in a commercial setting in China, as noted by Akeso.

Ivonescimab is an investigational therapy that is not approved by any regulatory authority in Summit's license territories, including the United States and Europe. Ivonescimab was initially approved for marketing authorization in China in May 2024.

About Summit Therapeutics Inc.
Summit Therapeutics Inc. is a biopharmaceutical oncology company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs.

Summit was founded in 2003 and the company's shares are listed on the Nasdaq Global Market (symbol "SMMT"). Summit is headquartered in Miami, Florida, with additional offices in Palo Alto, California, Princeton, New Jersey, Dublin, Ireland, and Oxford, UK.

For more information, please visit https://www.smmttx.com and follow Summit on X @SMMT_TX.

Summit Forward-Looking Statements
Any statements in this press release about the Company's future expectations, plans and prospects, including but not limited to, statements about the clinical and preclinical development of the Company's product candidates, entry into and actions related to the Company's partnership with Akeso Inc. and other collaborations, the Company's anticipated spending and cash runway, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, the expected timing of BLA submissions or FDA decisions, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), or the AstraZeneca private placement, the expected proceeds, uses thereof and possibility that the proceeds will not be sufficient to fund operations as long as anticipated, dilution to existing stockholders and potential adverse effects on the market price of the Company's common stock, including from future sales by AstraZeneca, AstraZeneca's ownership and contractual rights, including Third Party acquisition participation, registration rights and potential conflicts of interest, the Company's reliance on third parties for the supply of third party products and other contributions to certain combination clinical trials, the Company's estimates regarding stock-based compensation, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the Company's ability to sell shares of our common stock under the ATM Program, the conditions affecting the capital markets, general economic, market, industry, or political conditions, including the effects of geopolitical developments, domestic and foreign trade policies, and monetary policies, the results of our evaluation of the underlying data in connection with the development and commercialization activities for ivonescimab, the outcome of discussions with regulatory authorities, including the Food and Drug Administration, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials, the results of such trials, and their success, global public health crises, that may affect timing and status of our clinical trials and operations, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of

early clinical trials or preclinical studies will be indicative of the results of later clinical trials, whether business development opportunities to expand the Company's pipeline of drug candidates, including without limitation, through potential acquisitions of, and/or collaborations with, other entities occur, expectations for regulatory approvals, laws and regulations affecting government contracts and funding awards, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of filings that the Company makes with the Securities and Exchange Commission. Summit defines a "positive study" as a clinical study with one or more prespecified primary endpoints in which one of those endpoints achieves a statistically significant benefit according to the protocol or statistical analysis plan. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ivonescimab. Accordingly, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release and should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

Summit Therapeutics and the Summit Therapeutics logo are registered trademarks, of Summit Therapeutics Inc. and/or its affiliates in the USA. © 2026 Summit Therapeutics Inc. All Rights Reserved.

Summit Therapeutics' Media & Investor Contacts:
Nathan LiaBraaten
Senior Director, Investor Relations

Tracy Jones
Director, Media & Public Relations

investors@smmttx.com
media@smmttx.com