

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 7, 2023

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.)
2882 Sand Hill Road, Suite 106, Menlo Park, CA		94025
(Address of Principal Executive Offices)		(Zip Code)

Registrant’s Telephone Number, Including Area Code: (650) 460-8308

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 2.02 Results of Operations and Financial Condition.

On November 7, 2023, Summit Therapeutics Inc. (the “Company”) issued a press release announcing its financial results and operational progress for the third quarter 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 by reference into this Item 2.02 as if fully set forth herein.

The information in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be 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 the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated November 7, 2023
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 7, 2023

By: /s/ Ankur Dhingra
Chief Financial Officer
(Principal Financial Officer)



Summit Therapeutics Reports Financial Results and Operational Progress for the Third Quarter and Nine Months Ended September 30, 2023

Enrollment Initiated in Second Phase III Clinical Study for Ivonescimab, HARMONi-3

Continuing Enrollment of HARMONi Phase III Study, with Enrollment Completion Expected in Second Half of 2024

Manmeet S. Soni Joined Summit as COO, Invested \$5 Million in the Company

Dave Gancarz, Dr. Urte Gayko, Dr. Fong Clow, & Dr. Allen S. Yang Elevated to Leadership Positions

Dr. Jack West & Dr. Laura Chow Bolster Summit's Clinical Development Team with Combined 45+ Years of Lung Cancer, Immunotherapy, & Anti-Angiogenic Treatment Experience

Menlo Park, California, November 7, 2023 - Summit Therapeutics Inc. (NASDAQ: SMMT) ("Summit," "we," or the "Company") today reports its financial results and provides an update on operational progress for the third quarter and nine months ended September 30, 2023.

Operational & Corporate Updates

- Our operational progress with ivonescimab (SMT112), an innovative, potentially first-in-class 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:
 - We are actively engaged in development activities for SMT112. In just over nine months since we closed our in-licensing transaction for ivonescimab, we have:
 - Held multiple meetings with the US Food & Drug Administration (FDA) regarding our planned Phase III clinical program and incorporated this feedback accordingly,
 - Begun our clinical development in non-small cell lung cancer (NSCLC) in the following proposed indications:
 - Ivonescimab combined with chemotherapy in patients with epidermal growth factor receptor (EGFR)-mutated, locally advanced or metastatic non-squamous NSCLC who have progressed after treatment with a third-generation EGFR tyrosine kinase inhibitor (TKI) ("HARMONi" trial),
 - Ivonescimab combined with chemotherapy in first-line metastatic squamous NSCLC patients ("HARMONi-3" trial),
 - Launched the Phase III HARMONi clinical trial in less than 4 months of acquiring the rights to ivonescimab; enrollment is expected to complete in the second half of 2024
 - Commenced patient enrollment in the second Phase III clinical study, HARMONi-3.
 - Recapping our Collaboration and License Agreement with Akeso Inc. (Akeso) for ivonescimab (SMT112):
 - On December 5, 2022, Summit and Akeso entered into a Collaboration and License Agreement for ivonescimab.
 - The Collaboration and License Agreement with Akeso closed on January 17, 2023 after going effective following customary waiting periods.



- Summit received the rights to develop and commercialize ivonescimab (SMT112) in the United States, Canada, Europe, and Japan. Akeso retained development and commercialization rights for the rest of the world, including China.
 - In exchange for these rights, Summit committed to an upfront payment of \$500 million, which was paid in two installments.
 - The first installment worth \$300 million was paid in January in conjunction with the closing of the transaction. Of the \$300 million paid to Akeso by Summit, Akeso opted, in accordance with the Collaboration and License Agreement, to receive 10 million shares in lieu of a cash payment of \$25.1 million; the remaining \$274.9 million was paid by Summit to Akeso in cash.
 - The second installment of \$200 million was paid on March 6, 2023 in cash.
 - Going forward, Akeso will be eligible to receive regulatory and commercial milestones of up to \$4.5 billion. In addition, Akeso will receive low double-digit royalties on net sales in the Summit territories.
 - In June 2023, promising Phase II data from AK112-201, a study of Chinese subjects conducted and analyzed by our partners, Akeso, was presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. In addition to encouraging data in multiple indications within NSCLC, a portion of the updated data presented at ASCO supports Summit's HARMONi-3 clinical trial in first-line metastatic squamous NSCLC.
 - Over 950 patients have been treated with ivonescimab in clinical studies in China and Australia, with enrollment beginning recently in Summit's license territories.
 - Akeso has a rich and diversified antibody drug pipeline with over 30 internally discovered drug candidates in various stages of development, including six bispecific antibodies. Akeso has taken part in over 80 clinical trials for 17 drug candidates, including 14 pivotal trials. Akeso has two drugs approved for oncology indications in China: a PD-1 inhibitor and a novel PD-1 / CTLA-4 bispecific antibody. Akeso has over 2,700 employees.
 - In the beginning of Q4, we announced that we have bolstered our leadership and clinical experience at Team Summit:
 - Manmeet S. Soni has joined the Company as our Chief Operating Officer. Mr. Soni has over 20 years of financial and operational leadership experience. He was President, Chief Operating Officer, & Chief Financial Officer at Reata Pharmaceuticals, Inc., which was sold to Biogen Inc. for \$7.5 billion. Prior to Reata, Mr. Soni was the CFO at Alnylam Pharmaceuticals, Inc. and Ariad Pharmaceuticals, Inc., the latter of which was purchased by Takeda Pharmaceutical Co. Ltd. for \$5.4 billion in 2017. Mr. Soni was also the CFO at Pharmacyclics, Inc., which, along with the leadership of Robert W. Duggan and Dr. Maky Zanganeh, was sold to AbbVie Inc. for \$21 billion in 2015. In addition to his continuing board service to Summit, he serves on the Board of Directors of Pulse Biosciences, Inc. In conjunction with joining Summit as COO, Mr. Soni invested \$5.0 million in the Company via a private placement.
 - Based on the accomplishments of the Company, including our deal to in-license ivonescimab and the operational progress that has been achieved since, the following elevated appointments have been made from current leaders at Team Summit:
 - Dave Gancarz as Chief Business & Strategy Officer
 - Urte Gayko, PhD, as Chief Regulatory, Quality, & Pharmacovigilance Officer
 - Fong Clow, DSc, as Chief Biometrics Officer
 - Allen S. Yang, MD, PhD, as Chief Medical Officer
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- H. Jack West, MD, joined Summit as Vice President of Clinical Development. Dr. West brings over 25 years of experience as a practicing thoracic oncologist; he joined Summit from City of Hope, one of the nation's leading cancer treatment and research centers. At City of Hope, he was the Vice President of Network Strategy at AccessHope, as well as an Associate Professor and practicing medical oncologist. Prior to joining City of Hope, Dr. West spent over 15 years at Providence Health & Services, including time as the Medical Director of the Thoracic Oncology Program. As a practicing physician, Dr. West earned his medical degree from Harvard Medical School, was the Howard Hughes Medical Student Research Fellow at Massachusetts General Hospital, and did his medical oncology fellowship training at the University of Washington Fred Hutchinson Cancer Research Center.
- Laura Chow, MD, joined Summit as Senior Vice President of Clinical Development. Dr. Chow brings nearly two decades of experience as a practicing medical oncologist and clinical researcher. She was previously a professor and Director of the Head & Neck and Lung Cancer Program at Dell Medical School and University of Texas at Austin. Prior to joining the University of Texas, Dr. Chow was a professor at the University of Washington Fred Hutchinson Cancer Research Center where she was a clinical researcher in lung cancer, thyroid cancers, head and neck cancers, and novel immunotherapies and anti-angiogenic agents. Dr. Chow has participated in advisory boards for multiple novel immunotherapies, including the early PD-1 therapies that now represent some of the most significant cancer therapies in present time. Dr. Chow earned her medical degree from the University of British Columbia and performed her residency at the University of Alberta.

Financial Highlights

- Aggregate cash and cash equivalents, restricted cash, short-term investments, and receivables on September 30, 2023 totaled \$200.5 million as compared to \$654.7 million on December 31, 2022.
 - Our cash, cash equivalents, restricted cash, and short-term investments on September 30, 2023 was \$198.9 million as compared to \$648.6 million on December 31, 2022. Accounts receivable and research and development tax credits receivable on September 30, 2023 were \$1.6 million as compared to \$6.1 million on December 31, 2022.
 - Our short-term investments consist of U.S. treasury securities.
 - Our current notes payable balance at September 30, 2023 was \$100.0 million, which is due in September 2024.
 - Based on our current cash and investments position, current operating plans, and with the \$100.0 million notes payable due in September 2024, we have sufficient funds to operate into the second half of 2024.
 - Net loss for the three and nine months ended September 30, 2023 was \$21.3 million and \$578.4 million, respectively. Net loss for the three and nine months ended September 30, 2022 was \$21.4 million and \$59.6 million, respectively.
 - The net loss for the nine months ended September 30, 2023 includes one-time in-process research and development expenses associated with the in-licensing of ivonescimab from Akeso of \$520.9 million.
 - Operating cash outflow for the nine months ended September 30, 2023 and 2022 was \$57.3 million and \$46.8 million, respectively.
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Third Quarter 2023 Earnings Call

Summit will host an earnings call this morning, Tuesday, November 7, 2023, at 9:00am ET. The conference call will be accessible by dialing (888) 210-3702 (toll-free domestic) or (646) 960-0191 (international) using conference code 5785899. A live webcast and instructions for joining the call are accessible through Summit's website www.smmmtx.com. An archived edition of the webcast will be available on our website after the call.

Summit Therapeutics' Mission Statement

To build a viable, long-lasting health care organization that assumes full responsibility for designing, developing, trial execution and enrollment, regulatory submission and approval, and successful commercialization of patient, physician, caregiver, and societal-friendly medicinal therapy intended to: improve quality of life, increase potential duration of life, and resolve serious medical healthcare needs. To identify and control promising product candidates based on exceptional scientific development and administrative expertise, develop our products in a rapid, cost-efficient manner, and to engage commercialization and/or development partners when appropriate.

We accomplish this by building a team of world class professional scientists and business administrators that apply their experience and knowledge to this mission. Team Summit exists to pose, strategize, and execute a path forward in medicinal therapeutic health care that places Summit in a well-deserved, top market share, leadership position. Team Summit assumes full responsibility for stimulating continuous expansion of knowledge, ability, capability, and well-being for all involved stakeholders and highly-valued shareholders.

About Ivonescimab

Ivonescimab, known as SMT112 in the United States, Canada, Europe, and Japan (Summit's license territories), and as AK112 in China and Australia, 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. Ivonescimab was discovered by Akeso Inc. (HKEX Code: 9926.HK) and is currently engaged in multiple Phase III clinical trials. Summit has begun its clinical development of ivonescimab in NSCLC, commencing enrolling in its license territory in 2023 in two Phase III clinical trials. Over 950 patients have been treated with ivonescimab in clinical studies in China and Australia, with enrollment beginning recently in Summit's license territories.

About Summit Therapeutics

Summit was founded in 2003 and our shares are listed on the Nasdaq Global Market (symbol 'SMMT'). We are headquartered in Menlo Park, California, and we have additional offices in Oxford, UK.

For more information, please visit <https://www.smmmtx.com> and follow us on X (formerly Twitter) @summitplc.

Contact Summit Investor Relations:

Dave Gancarz
Chief Business & Strategy Officer
investors@smmmtx.com

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., 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 impact of the COVID-19 pandemic on the Company's operations and clinical trials, potential acquisitions 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 results of our evaluation of the underlying data in connection with the development and commercialization activities for SMT112, 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, and global public health crises, including the coronavirus COVID-19 outbreak, 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" section of filings that the Company makes with the Securities and Exchange Commission. 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 SMT112. 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, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

In thousands, except per share data

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	\$ —	\$ 220	\$ —	\$ 705
Operating expenses:				
Research and development	15,323	17,049	34,657	46,613
In-process research and development	—	—	520,915	—
General and administrative	5,434	5,573	18,690	19,165
Total operating expenses	20,757	22,622	574,262	65,778
Other operating income, net	265	5,462	822	13,283
Operating loss	(20,492)	(16,940)	(573,440)	(51,790)
Other (expense) income, net	(776)	(4,445)	(4,921)	(7,763)
Net loss	<u>\$ (21,268)</u>	<u>\$ (21,385)</u>	<u>\$ (578,361)</u>	<u>\$ (59,553)</u>
Basic and diluted loss per share	\$ (0.03)	\$ (0.10)	\$ (0.98)	\$ (0.37)
Comprehensive loss:				
Net loss	\$ (21,268)	\$ (21,385)	\$ (578,361)	\$ (59,553)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	108	(49)	(20)	(1,020)
Reclassification of cumulative currency translation gain to other (expense) income, net	—	—	(419)	—
Net changes related to short-term investments	6	—	9	—
Comprehensive loss	<u>\$ (21,154)</u>	<u>\$ (21,434)</u>	<u>\$ (578,791)</u>	<u>\$ (60,573)</u>



CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION
(Unaudited)
In thousands

	September 30, 2023		December 31, 2022	
Cash, Restricted Cash, Short-term Investments	\$	198,945	\$	648,607
Total assets	\$	218,476	\$	664,168
Total liabilities	\$	119,097	\$	537,514
Total stockholders' equity	\$	99,379	\$	126,654

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS INFORMATION
(Unaudited)
In thousands

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	\$ (57,301)	\$ (46,773)
Net cash used in investing activities	(648,342)	(634)
Net cash provided by financing activities	80,261	100,184
Effect of exchange rate changes on cash	567	(2,597)
(Decrease) increase in cash and cash equivalents	\$ (624,815)	\$ 50,180