Aktis Oncology Reports Financial Results and Business Highlights for First Quarter 2026

05/11/2026

- Announced two-trial clinical development strategy for AKY-2519 enabling evaluation in multiple patient segments
- Initiated Phase 1b clinical trial of AKY-2519 in metastatic castration-resistant prostate cancer (mCRPC); expect preliminary data in 2027
- Announced AKY-2519 clinical imaging and dosimetry data presentation at upcoming 2026 ASCO Annual Meeting
- Enrolling patients with Nectin-4 expressing tumors in ongoing Phase 1b clinical trial of AKY-1189; expect preliminary data in first quarter 2027

BOSTON, May 11, 2026 (GLOBE NEWSWIRE) -- Aktis Oncology, Inc. (NASDAQ:AKTS) (Aktis or the Company), a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large populations, including those not addressed by existing platform technologies, today reported financial results and business highlights for the first quarter ended March 31, 2026.

"We continue to build momentum toward delivering a new class of radiopharmaceuticals targeting tumor types with large patient populations, leveraging our differentiated miniprotein radioconjugate platform and patient-first end-to-end supply chain," said Matthew Roden, Ph.D., President and Chief Executive Officer of Aktis Oncology. "Last week, we announced the initiation of our Phase 1b clinical trial of AKY-2519 in patients with mCRPC. This is the first of two trials in our clinical development strategy designed to expand the breadth of tumors studied and augment speed to data, with preliminary data from the mCRPC trial anticipated in 2027. We plan to initiate a second Phase 1b basket trial of AKY-2519 in additional solid tumors in the second half of this year. We also look forward to presenting our first AKY-2519 clinical imaging and dosimetry data for AKY-2519 at ASCO, which informed our clinical development strategy."

Dr. Roden continued, "AKY-2519 marks the second program we have advanced from our proprietary miniprotein radioconjugate platform to the clinic in the last twelve months. In parallel, we continue to enroll patients in our ongoing Phase 1b trial of AKY-1189 targeting Nectin-4 expressing tumors, with preliminary data expected in the first quarter of 2027. We remain focused on generating clinical data intended to support advancement of both programs and maximizing the potential clinical benefit for patients."

Q1 and recent business highlights

AKY-1189 highlights

AKY-1189 is a novel, clinical-stage miniprotein radioconjugate designed to selectively deliver actinium-225 (^{225}Ac) to Nectin-4 expressing tumors.

- Received Fast Track designation from the U.S. Food and Drug Administration (FDA) for AKY-1189 for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have progressed on or after prior systemic therapies.
- Enrolling patients in the ongoing Phase 1b clinical trial of AKY-1189 in patients with locally advanced or mUC, breast cancer, non-small cell lung cancer, colorectal cancer, cervical cancer, and head and neck cancer.
- Expect to report preliminary data from the Phase 1b trial in the first quarter of 2027.

AKY-2519 highlights

AKY-2519 is a novel, clinical-stage miniprotein radioconjugate designed to selectively deliver ^{225}Ac to B7-H3 expressing tumors, including prostate, lung, and other solid tumors.

- Received FDA clearance for the Company's Investigational New Drug (IND) applications to proceed to a Phase 1b clinical trial with AKY-2519[1].
- Announced two-trial clinical development strategy for AKY-2519, which was informed by insights from the Company's clinical advisory boards and reflects the distinct treatment patterns and clinical needs of patients with mCRPC compared to other solid tumor patients. This strategy is designed to enable the broad evaluation of AKY-2519 in multiple patient segments while efficiently generating indication-relevant data.
- Initiated Phase 1b, multicenter, open label clinical trial of AKY-2519 in PLUVICTO®-naïve and PLUVICTO-experienced

patients with mCRPC.
- Plan to initiate a Phase 1b basket trial in patients with lung, colorectal, and other B7-H3 expressing solid tumors in the second half of 2026. The protocol for this trial has been finalized and is currently under regulatory review.
- Announced clinical imaging and dosimetry data for AKY-2519 has been accepted for presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting being held May 29 – June 2, 2026, in Chicago. The data facilitate initial understanding of AKY-2519 biodistribution and predicted absorbed doses in tumors and normal tissues in patients with B7-H3 expressing solid tumors.

[1] IND applications were cleared for [^{64}Cu]Cu-AKY-2519 for imaging and [^{225}Ac]Ac-AKY-2519 for therapeutic use.

General corporate highlights

- Appointed industry veteran Glenn Gormley, MD, PhD as an independent director to the Company's Board of Directors (Board) and as co-chair of the Board's newly established Science and Technology Committee.
- In January 2026, completed an initial public offering of 20,297,500 shares of common stock, including the exercise in full by the underwriters of their option to purchase an additional 2,647,500 shares of common stock, at $18.00 per share, resulting in gross proceeds of approximately $365.4 million, before deducting underwriting discounts and commissions and other offering expenses.

Anticipated pipeline and corporate milestones for the next 12 months

- **AKY-1189:** Expect preliminary data from the ongoing Phase 1b clinical trial in the first quarter of 2027.
- **AKY-2519:**
  - Will present clinical imaging and dosimetry data of AKY-2519 in patients with mCRPC and various solid tumors at the upcoming ASCO Annual Meeting.
  - Expect to commence Phase 1b basket trial in lung, colorectal, and other solid tumor cancers in the second half of 2026.
  - Expect preliminary data from the Phase 1b mCRPC clinical trial in 2027.
- **Early pipeline:** Two programs are tracking toward development candidate nomination and commencement of IND-enabling activities in the first quarter of 2027.
- **Corporate:** In-house Good Manufacturing Practices (GMP) facility expected to be operational in the second half of 2026 as part of the Company's hybrid manufacturing strategy to expand capabilities and support clinical supply demand.

First quarter 2026 financial results

- **Cash position:** Cash, cash equivalents and marketable securities were $538.5 million as of March 31, 2026, compared to $226.8 million as of December 31, 2025. The increase of $311.7 million primarily reflects net proceeds from the Company's initial public offering in January 2026, primarily offset by cash used in operations. The Company's cash, cash equivalents and marketable securities as of March 31, 2026 are expected to fund its operations into 2029.
- **Collaboration revenue:** Collaboration revenue was $3.2 million for the quarter ended March 31, 2026, compared to $1.4 million for the comparable prior year period. The increase of $1.8 million was attributable to continued advancement of the Company's research collaboration with Eli Lilly and Company, with revenue recognized over time using the cost incurred input method.
- **R&D expenses:** Research and development expenses were $20.0 million for the quarter ended March 31, 2026, compared to $15.9 million for the comparable prior year period. The increase of $4.1 million was primarily driven by Phase 1b clinical trial expenses for AKY-1189, which initiated in the second quarter of 2025, increased expenses with advancing AKY-2519 through IND-enabling studies, and increased employee-related costs (including stock-based compensation) associated with increased hiring to support the advancing clinical pipeline.
- **G&A expenses:** General and administrative expenses were $5.9 million for the quarter ended March 31, 2026, compared to $3.7 million for the comparable prior year period. The increase of $2.2 million was primarily due to higher employee-related costs (including stock-based compensation) related to increased hiring to support the Company's growth, and increased expenses associated with operating as a public company.
- **Net loss:** Net loss was $18.3 million for the quarter ended March 31, 2026, compared to $15.0 million for the comparable prior year period. The increase in net loss of $3.3 million was primarily driven by increased operating expenses.

About Aktis' miniprotein radioconjugate platform

Aktis has developed a proprietary, isotope-agnostic miniprotein radioconjugate platform to selectively deliver the tumor-killing properties of radioisotopes to targeted tumors. Aktis' therapeutic miniprotein radioconjugates are designed to maximize anti-cancer activity through high tumor penetration coupled with internalization and retention in cancer cells, while rapidly clearing from normal organs and tissues. The Aktis platform further enables clinicians to visualize and verify target engagement with imaging isotopes prior to exposure to therapeutic radioisotopes. Leveraging this platform, and its patient-first end-to-end supply chain, Aktis is advancing a pipeline of next-generation targeted radiopharmaceuticals to address the unmet needs of patients across a broad spectrum of solid tumors.

About Aktis Oncology

Aktis Oncology, Inc. is a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large patient populations, including those not addressed by existing platform technologies. Aktis' most advanced clinical-stage pipeline program, AKY-1189, is a miniprotein radioconjugate targeting Nectin-4, with multi-indication potential across multiple tumor types, including locally advanced or metastatic urothelial cancer, breast cancer, non-small cell lung cancer, colorectal cancer, cervical cancer, and head and neck cancer. Aktis' second clinical-stage pipeline program, AKY-2519, is a miniprotein radioconjugate targeting B7-H3 expressing tumors, including prostate, lung, colorectal, and other solid tumors. Aktis has a discovery collaboration with Eli Lilly and Company to leverage Aktis' miniprotein platform to develop novel radioconjugates outside of its proprietary pipeline. For more information, please visit www.aktisoncology.com.

Forward-looking statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the Company's expectations about the timing of ongoing and planned clinical trials and regulatory filings, goals to develop and commercialize its product candidates, its liquidity and capital resources, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond the Company's control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to the Company's limited operating history, its ability to obtain necessary funding, its ability to generate positive clinical trial results for its product candidates and other risks inherent in clinical development, the timing and scope of regulatory approvals, changes in laws and regulations to which the Company is subject, competitive pressures, its ability to identify additional product candidates, risks relating to business interruptions, and other risks set forth under the heading "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2025 and in subsequent filings with the Securities and Exchange Commission. The Company's actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, the Company undertakes no obligation to update or revise these forward-looking statements.

AKTIS ONCOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(In thousands, except shares and par value data)
(Unaudited)

	Three Months Ended March 31,	
	2026	**2025**
Revenue:		
Collaboration revenue	$ 3,227	$ 1,447
Operating expenses:		
Research and development	20,036	15,863
General and administrative	5,897	3,727
Total operating expenses	25,933	19,590
Loss from operations	(22,706)	(18,143)
Other income (expense):		
Interest income	4,384	3,171
Other expense, net	(3)	(13)
Total other income, net	4,381	3,158
Net loss	$ (18,325)	$ (14,985)

AKTIS ONCOLOGY, INC.
BALANCE SHEET DATA
(In thousands, except shares and par value data)
(Unaudited)

	March 31,	December 31,
	2026	**2025**
Cash, cash equivalents and marketable securities	$ 538,484	$ 226,787
Total assets	576,801	264,885
Total liabilities	70,693	77,625
Total stockholders' equity (deficit) and redeemable convertible preferred stock	$ 506,108	$ 187,260

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