Aktis Oncology Reports Third-Quarter Financial Results and Highlights Clinical Trial Progress

11/12/2026

- Initiated the Company's third Phase 1b clinical trial, BActinium-2, broadening the evaluation of AKY-2519 to lung cancer and other B7-H3 expressing tumors
- Started first backfill cohorts in the ongoing Phase 1b NECTINIUM-2 clinical trial of AKY-1189 and Phase 1b BActinium-1 clinical trial of AKY-2519
- On track to present preliminary data for AKY-1189 in first quarter of 2027 and AKY-2519 in 2027

BOSTON, Nov. 12, 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, today reported financial results for the third quarter ended September 30, 2026, and provided a business update, including progress with the Company's two clinical-stage programs.

"Aktis is on a trajectory to redefine radiopharmaceuticals as a major pillar of cancer treatment by expanding the modality to more targets, broader indications, and larger patient populations. In the third quarter, we continued to make tremendous progress operationalizing this vision," said Matthew Roden, Ph.D., President and Chief Executive Officer at Aktis Oncology. "With the initiation of the BActinium-2 trial of AKY-2519, we now have three clinical trials underway in the U.S. across two novel targets, Nectin-4 and B7-H3, which are both implicated in a range of solid tumor types. We also opened the first backfill cohorts in our ongoing NECTINIUM-2 and BActinium-1 trials to further characterize safety and preliminary antitumor activity at the selected doses, while dose escalation continues in both studies. This substantial clinical progress is a testament to our ability to execute rapidly with quality across multiple clinical trials and positions Aktis for a data-rich 2027."

Third quarter 2026 and recent business highlights

AKY-1189

AKY-1189 is a novel, clinical-stage miniprotein radioconjugate designed to selectively deliver actinium-225 (^{225}Ac) to tumors expressing Nectin-4, a clinically and commercially validated target expressed in several tumor types, including locally advanced or metastatic urothelial cancer (mUC) and breast cancer.

- Dose escalation is ongoing in the Phase 1b NECTINIUM-2 trial evaluating AKY-1189 in patients with locally advanced or mUC and other Nectin-4 expressing solid tumors.
- Aktis initiated backfill at the 6 MBq dose level to further characterize safety and preliminary antitumor activity in up to 30 patients. This is the first of up to two dose levels planned to be selected for backfill.

AKY-2519

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

- Aktis initiated the Phase 1b BActinium-2 trial evaluating AKY-2519 in patients with non-small cell lung cancer (NSCLC) and other B7-H3 expressing solid tumors.
- Dose escalation is ongoing in the Phase 1b BActinium-1 trial evaluating AKY-2519 in patients with metastatic castration-resistant prostate cancer (mCRPC), including PLUVICTO®-naïve and PLUVICTO-experienced patients.
- In the Phase 1b BActinium-1 trial, Aktis initiated backfill at the 9 MBq dose level for both the PLUVICTO-naïve and PLUVICTO-experienced cohorts to further characterize safety and preliminary antitumor activity in up to 30 patients per cohort. This is the first of up to two planned dose levels that will be backfilled in each of the mCRPC patient populations.

Dr. Roden added, "With our robust end-to-end supply chain supported by multiple contract manufacturing organizations and isotope suppliers, we are successfully delivering clinical supply for our clinical trials nationally. In the quarter, we operationalized our in-house GMP facility at 17 Drydock in Boston, where we expect to begin supplying drug product for our clinical trials in the first half of 2027, further expanding manufacturing capacity for clinical supply. The 17 Drydock facility progresses our strategy to build capabilities to support potential Phase 3 trials and commercial product supply in a capital-efficient manner."

Manufacturing

- Aktis began manufacturing drug product in its in-house GMP facility, as part of the Company's hybrid sourcing manufacturing strategy. Aktis intends to amend the INDs for AKY-2519 and AKY-1189 to include the in-house facility as a manufacturer of clinical supply for its ongoing clinical trials.

Anticipated milestones for the next 12 months

- **AKY-1189:** Expect preliminary data from the ongoing Phase 1b NECTINIUM-2 trial in the first quarter of 2027.
- **AKY-2519:** Expect preliminary data from the ongoing Phase 1b BActinium-1 trial in 2027.
- **Early pipeline:** Two programs tracking toward development candidate nomination and commencement of IND-enabling activities in the first quarter of 2027.
- **Corporate:** Expect to expand drug supply to include our in-house GMP facility to support ongoing clinical trials in the first half of 2027.

Third quarter 2026 financial results

- **Cash position:** Cash, cash equivalents, and marketable securities were $492.9 million as of September 30, 2026, compared with $226.8 million as of December 31, 2025. The increase in cash, cash equivalents, and marketable securities 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 September 30, 2026, are expected to fund the Company's operating plan into 2029.
- **Collaboration revenue:** Collaboration revenue was $3.9 million for the quarter ended September 30, 2026, compared with $1.6 million for the comparable prior-year period. The increase of $2.3 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 $32.1 million for the quarter ended September 30, 2026, compared with $16.5 million for the comparable prior-year period. The increase of $15.6 million was primarily driven by the advancement of clinical trials for AKY-1189 and AKY-2519 and increased headcount primarily in clinical development and manufacturing to support the advancement of the clinical pipeline.
- **G&A expenses:** General and administrative expenses were $6.5 million for the quarter ended September 30, 2026, compared with $3.3 million for the comparable prior-year period. The increase of $3.2 million was primarily due to increased headcount to support company growth and increased activities associated with operating as a public company.
- **Net loss:** Net loss was $29.9 million for the quarter ended September 30, 2026, compared with $15.5 million for the comparable prior-year period. The increase of $14.4 million was primarily driven by higher operating expenses, partially offset by increased collaboration revenue recognized and interest income, net.

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is a registered trademark of Novartis Pharmaceuticals Corporation.

About NECTINIUM-2
The Phase 1b multicenter, open-label clinical trial is evaluating AKY-1189 in patients with locally advanced or mUC, breast cancer and other Nectin-4 expressing tumors. The trial will explore up to 5 dose levels in the dose escalation. Per protocol, Aktis has the ability to expand enrollment in backfill cohorts at selected dose levels and tumor types to generate additional clinical data while dose escalation continues. The trial is being conducted in the U.S. Additional information about the trial is available at clinicaltrials.gov using the identifier NCT07020117.

About BActinium-1
The Phase 1b multicenter, open-label clinical trial is evaluating AKY-2519 in patients with mCRPC, including PLUVICTO-naïve and PLUVICTO-experienced cohorts. The study will explore up to 3 dose levels in the dose escalation. Per protocol, Aktis has the ability to expand enrollment in backfill cohorts at selected dose levels to generate additional clinical data while dose escalation continues. The trial is being conducted in the U.S. Additional information about the trial is available at clinicaltrials.gov using the identifier NCT07581184.

About BActinium-2
The Phase 1b multicenter, open-label trial is evaluating AKY-2519 in patients with NSCLC and other B7-H3 expressing solid tumors. The study will explore up to 3 dose levels in the dose escalation. Per protocol, Aktis has the ability to expand enrollment at selected dose levels and tumor types to generate additional clinical data while dose escalation continues. The trial is being conducted in the U.S. Additional information about the trial is available at clinicaltrials.gov using the identifier NCT07887971.

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 anticancer 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 clinical supply chain built for resiliency and scalability, 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, and other solid tumor cancers. Aktis' second clinical-stage pipeline program, AKY-2519, is a miniprotein radioconjugate targeting B7-H3 expressing tumors, including prostate, lung, 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 and results of ongoing and planned clinical trials and regulatory filings, goals to develop and commercialize its product candidates, 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 commencement and completion of the Company's ongoing and planned clinical trials, the Company's limited operating history, 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, 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)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Collaboration revenue	$ 3,905	$ 1,579	$ 10,516	$ 4,627
Operating expenses:				
Research and development	32,125	16,467	77,441	50,958
General and administrative	6,527	3,315	19,427	10,978
Total operating expenses	38,652	19,782	96,868	61,936
Loss from operations	(34,747)	(18,203)	(86,352)	(57,309)
Other income (expense):				
Interest income	4,822	2,682	13,971	8,761
Other expense, net	(14)	(12)	(27)	(45)
Total other income, net	4,808	2,670	13,944	8,716
Net loss	$ (29,939)	$ (15,533)	$ (72,408)	$ (48,593)

AKTIS ONCOLOGY, INC.
BALANCE SHEET DATA
(In thousands)
(Unaudited)

	September 30, 2026	December 31, 2025

Cash, cash equivalents, and marketable securities	$	492,929	$	226,787
Total assets		532,484		264,885
Total liabilities		73,612		77,625
Total stockholders' equity and redeemable convertible preferred stock	$	458,872	$	187,260

Media contact:
Melone Communications, LLC
Liz Melone
617-256-6622
liz@melonecomm.com

Investor contact:
Precision AQ
Alex Lobo
212-698-8802
Alex.lobo@precisionaq.com