Xenon Reports Third Quarter 2025 Financial Results & Business Update

November 3, 2025

– Phase 3 X-TOLE2 FOS topline data on track to read out early 2026 with patient randomization complete

– Phase 3 X-NOVA2 and X-NOVA3 studies in MDD & Phase 3 X-CEED study in BPD continuing to recruit

– Phase 1 Nav1.7 & Kv7 studies underway

– Tucker Kelly appointed as Chief Financial Officer, bringing extensive strategic commercial finance experience in anticipation of the azetukalner launch

– Conference call at 4:30 pm ET today

VANCOUVER, British Columbia and BOSTON, Nov. 03, 2025 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq: XENE), a neuroscience-focused biopharmaceutical company dedicated to drug discovery, clinical development and commercialization of life-changing therapeutics for patients in need, today reported financial results for the third quarter ended September 30, 2025 and provided a business update.

"We are entering an important, catalyst-rich period for Xenon. We recently completed randomization of 380 patients in our Phase 3 X-TOLE2 study of azetukalner in FOS, with topline data expected in early 2026," said Ian Mortimer, President and Chief Executive Officer of Xenon. "We continue to explore broadening the use of azetukalner with our Phase 3 neuropsychiatry studies, including our Phase 3 X-NOVA2 and X-NOVA3 studies in major depressive disorder and the X-CEED study in bipolar depression. With our earlier stage programs, we continue to make good progress in our two first-in-human Phase 1 studies for our lead molecules in our Nav1.7 and Kv7 pain programs."

Business Highlights and Anticipated Milestones

Azetukalner Clinical Development

Azetukalner, a novel, highly potent, selective Kv7 potassium channel opener, represents the most advanced, clinically validated potassium channel modulator in late-stage clinical development for the treatment of multiple indications, including two in epilepsy – focal onset seizures (FOS) and primary generalized tonic-clonic seizures (PGTCS) – as well as neuropsychiatric disorders, including major depressive disorder (MDD) and bipolar depression (BPD).

Epilepsy Programs

- Phase 3 X-TOLE2 study of azetukalner in FOS has completed patient enrollment with 380 patients randomized and topline data anticipated in early 2026.
- Phase 3 X-TOLE3 study of azetukalner in FOS continues patient enrollment.
- Phase 3 X-ACKT study of azetukalner in PGTCS continues to enroll patients and is intended to support regulatory submissions for an additional epilepsy indication.
- Seven abstracts were accepted for presentation at the upcoming American Epilepsy Society (AES) 2025 meeting taking place December 5-9 in Atlanta. The Company plans to showcase new long-term safety and efficacy data from the ongoing X-TOLE open-label extension study of azetukalner in FOS, studies centered around depression and its impact on epilepsy patients, and pre-clinical data from its Nav1.1 program.

Neuropsychiatric Programs

- X-NOVA2 and X-NOVA3, the first two of three planned Phase 3 clinical studies evaluating azetukalner in patients with MDD, are underway.
- X-CEED, the first of two planned Phase 3 clinical studies evaluating azetukalner in patients with BPD I and BPD II, is underway.

Early-Stage Pipeline: Next-Generation Ion Channel Modulators

Xenon continues to expand its portfolio of innovative potential medicines using its expertise in discovering and developing potassium and sodium channel modulators.

- Xenon recently hosted an R&D webinar, *Developing Novel Non-Opioid Treatments for Pain: An Overview of Xenon's Nav1.7 and Kv7 Programs*, focusing on Xenon's approach to treating pain with drug candidates targeting Nav1.7 and Kv7.
- Phase 1 Single Ascending Dose (SAD)/Multiple Ascending Dose (MAD) study is underway for XEN1701, the Company's lead Nav1.7 development candidate for pain. IND-enabling work remains ongoing for additional Nav1.7 candidates. Nav1.7 is an important target for pain based on strong human genetic validation and may represent a new class of pain medicines without the limitations of opioids.
- Phase 1 SAD/MAD study in healthy adult subjects is underway for XEN1120, a Kv7 channel opener in development for pain. Work remains ongoing with additional earlier Kv7 development molecules and chemistries with the hypothesis that Kv7 may have utility in a broad range of therapeutic indications, including seizure disorders, pain, and neuropsychiatric disorders, such as MDD and BPD.
- IND-enabling studies are underway for the Company's lead Nav1.1 candidate. Pre-clinical data suggests that targeting Nav1.1 could potentially address the underlying cause and symptoms of Dravet Syndrome.

Partnered Program

- As part of Xenon's ongoing collaboration with Neurocrine Biosciences, a Phase 1 study is underway for NBI-921355, an investigational, selective inhibitor of voltage-gated sodium channels Nav1.2 and Nav1.6 in development for the potential treatment of certain types of epilepsy.

Corporate

- Appointed Tucker Kelly as Chief Financial Officer. Mr. Kelly brings extensive strategic finance experience to lead finance strategy and forward integration ahead of the anticipated commercialization of azetukalner.

Third Quarter Financial Results

- Cash, cash equivalents and marketable securities were $555.3 million as of September 30, 2025, compared to $754.4 million as of December 31, 2024. Based on current operating plans, including the completion of the azetukalner Phase 3 epilepsy studies and supporting late-stage clinical development of azetukalner in MDD and BPD, Xenon anticipates having sufficient cash to fund operations into 2027. As of September 30, 2025, there were 77,120,168 common shares and 2,173,081 pre-funded warrants outstanding.
- Research and development expenses for the quarter ended September 30, 2025 were $77.1 million, compared to $57.0 million for the same period in 2024. The increase of $20.1 million was primarily attributable to the ongoing azetukalner Phase 3 clinical studies in MDD, start-up costs for the azetukalner Phase 3 BPD program, increased personnel-related costs due to an increase in employee headcount and stock-based compensation expense, and costs associated with pre-clinical, discovery, and other programs.
- General and administrative expenses for the quarter ended September 30, 2025 were $19.3 million, compared to $16.7 million for the same period in 2024. The increase of $2.6 million was primarily attributable to an increase in professional and consulting fees.
- Other income for the quarter ended September 30, 2025 was $6.1 million, compared to $10.6 million for the same period in 2024. The decrease of $4.4 million was primarily attributable to lower interest income.
- Net loss for the quarter ended September 30, 2025 was $90.9 million, compared to $62.8 million for the same period in 2024. The increase in net loss was primarily attributable to higher research and development expenses driven by the azetukalner program, personnel-related costs and pre-clinical, discovery and other programs, higher general and administrative expenses driven by higher professional and consulting fees, and lower interest income.

Conference Call Information

Xenon will host a conference call and webcast today at 4:30 pm Eastern Time (1:30 pm Pacific Time) to discuss its third quarter 2025 results. A listen-only webcast can be accessed on the Investors section of the Xenon website, with a replay available following the event. Participants can access the conference call by dialing (800) 715-9871 or (646) 307-1963 for international callers and referencing conference ID 3971394.

Phase 3 Epilepsy Program

Xenon's Phase 3 epilepsy program includes three Phase 3 clinical studies in focal onset seizures (FOS) and primary generalized tonic-clonic seizures (PGTCS). Designed closely after the Phase 2b X-TOLE clinical study, the Phase 3 X-TOLE clinical studies are multicenter, randomized, double-blind, placebo-controlled studies evaluating the clinical efficacy, safety, and tolerability of 15 mg or 25 mg of azetukalner administered orally with food as adjunctive treatment in approximately 360 patients with FOS per study. The primary efficacy endpoint is the median percent change (MPC) in monthly seizure frequency from baseline through the

12-week double-blind period (DBP) of azetukalner compared to placebo. X-ACKT is a multicenter, randomized, double-blind, placebo-controlled study evaluating the clinical efficacy, safety, and tolerability of 25 mg of azetukalner administered with food as adjunctive treatment in approximately 160 patients with PGTCS. The primary efficacy endpoint is the MPC in monthly PGTCS frequency from baseline through the 12-week DBP of azetukalner compared to placebo. Upon completion of the DBP in the Phase 3 epilepsy studies, eligible patients may enter an open-label extension (OLE) study for up to three years.

Phase 3 MDD Program

Xenon's Phase 3 X-NOVA major depressive disorder (MDD) program includes three multicenter, randomized, double-blind, placebo-controlled clinical studies to evaluate the clinical efficacy, safety, and tolerability of 20 mg of azetukalner administered orally with food over the 6-week double-blind period (DBP) as monotherapy treatment in approximately 450 patients with moderate-to-severe major depressive disorder (MDD) per study. The primary efficacy endpoint is the change from baseline in the HAM-D17 score at week 6 in patients who received azetukalner compared to placebo. Upon completion of the DBP, eligible patients may enter an open-label extension (OLE) study for up to 12 months.

Phase 3 BPD Program

Xenon's Phase 3 X-CEED Bipolar Depression **(**BPD) program includes two multicenter, randomized, double-blind, placebo-controlled clinical studies to evaluate the clinical efficacy, safety, and tolerability of 20 mg of azetukalner administered orally with food over the 6-week double-blind period (DBP) as monotherapy treatment in approximately 400 patients per study with BPD I or II. The primary efficacy endpoint is the change from baseline in the MADRS score at week 6 in patients who received azetukalner compared to placebo. Upon completion of the DBP, eligible patients may enter an open-label extension (OLE) study for up to 12 months.

About Xenon Pharmaceuticals Inc.
Xenon Pharmaceuticals (Nasdaq: XENE) is a neuroscience-focused biopharmaceutical company dedicated to drug discovery, clinical development, and commercialization of life-changing therapeutics for patients in need. Xenon's lead molecule, azetukalner, is a novel, potent, selective Kv7 potassium channel opener in Phase 3 clinical studies for the treatment of epilepsy, major depressive disorder (MDD) and bipolar depression (BPD). Xenon is also advancing an early-stage portfolio of multiple promising potassium and sodium channel modulators, including Nav1.7 and Kv7 programs in Phase 1 development for the potential treatment of pain. Xenon has offices in Vancouver, British Columbia, and Boston, Massachusetts. For more information, visit www.xenon-pharma.com and follow us on LinkedIn and X.

Safe Harbor Statement

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, and the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. These forward-looking statements are not based on historical fact, and include statements regarding the timing of and potential results from clinical studies; the potential efficacy, safety profile, future development plans in current and anticipated indications, addressable market, regulatory success and commercial potential of our and our partners' product candidates; the efficacy of our clinical study designs; our ability to successfully develop and achieve milestones in our azetukalner and other pipeline and development programs, including the anticipated filing of INDs and NDAs; the timing and results of our interactions with regulators; our ability to successfully develop and obtain regulatory approval of azetukalner and our other product candidates; and anticipated timing of topline data readout from our clinical studies of azetukalner. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events, or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical studies may not demonstrate safety and efficacy of any of our or our collaborators' product candidates; promising results from pre-clinical development activities or early clinical study results may not be replicated in later clinical studies; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our ongoing discovery and pre-clinical efforts may not yield additional product candidates; any of our or our collaborators' product candidates, including azetukalner, may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones in our proprietary or partnered programs; regulatory agencies may impose additional requirements or delay the initiation or completion of clinical studies; the impact of market, industry, and regulatory conditions on clinical study enrollment; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; the impact of new or changing laws and regulations; the impact of unstable economic conditions in the general domestic and global economic markets; adverse conditions from geopolitical events; as well as the other risks identified in our filings with the U.S. Securities and Exchange Commission and the securities commissions in British Columbia, Alberta, and Ontario. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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XENON PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheets
(Expressed in thousands of U.S. dollars)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 462,268	$ 626,905
Other current assets	17,869	8,359
Marketable securities, long-term	92,988	127,496
Other long-term assets	34,711	35,379
Total assets	$ 607,836	$ 798,139
Liabilities		
Current liabilities:		
Accounts payable and accrued liabilities	$ 36,840	$ 34,221
Other current liabilities	1,495	1,369
Other long-term liabilities	9,990	7,646
Total liabilities	$ 48,325	$ 43,236
Shareholders' equity	$ 559,511	$ 754,903
Total liabilities and shareholders' equity	$ 607,836	$ 798,139

XENON PHARMACEUTICALS INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Expressed in thousands of U.S. dollars except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	$ —	$ —	$ 7,500	$ —
Operating expenses:				
Research and development	77,054	56,970	213,239	150,922
General and administrative	19,282	16,706	57,564	50,899
Total operating expenses	96,336	73,676	270,803	201,821
Loss from operations	(96,336)	(73,676)	(263,303)	(201,821)
Other income	6,117	10,566	23,132	32,935
Loss before income taxes	(90,219)	(63,110)	(240,171)	(168,886)
Income tax recovery (expense)	(677)	320	(478)	241
Net loss	$ (90,896)	$ (62,790)	$ (240,649)	$ (168,645)
Other comprehensive income:				
Unrealized gain on available-for-sale securities	364	3,548	2,089	1,413
Comprehensive loss	$ (90,532)	$ (59,242)	$ (238,560)	$ (167,232)
Net loss per common share:				
Basic and diluted	$ (1.15)	$ (0.81)	$ (3.05)	$ (2.17)
Weighted average common shares outstanding:				
Basic and diluted	79,247,976	77,926,205	78,962,975	77,730,644



Source: Xenon Pharmaceuticals Inc.