
**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): May 7, 2026

XENON PHARMACEUTICALS INC.

(Exact name of Registrant as Specified in Its Charter)

Canada
(State or Other Jurisdiction
of Incorporation)

001-36687
(Commission File Number)

98-0661854
(IRS Employer
Identification No.)

200-3650 Gilmore Way
Burnaby, British Columbia, Canada
(Address of Principal Executive Offices)

V5G 4W8
(Zip Code)

Registrant's Telephone Number, Including Area Code: (604) 484-3300

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 Shares, without par value	XENE	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

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 May 7, 2026, Xenon Pharmaceuticals Inc. (the “Company”) announced via press release the Company’s financial results for the three months ended March 31, 2026. A copy of the Company’s press release is attached hereto as Exhibit 99.1. The information in Item 2.02 of this Form 8-K and the attached exhibit are furnished to, but not filed with, the Securities and Exchange Commission.

Item 7.01 Regulation FD Disclosure

The Company announces material information to the public through a variety of means, including filings with the Securities and Exchange Commission, press releases, public conference calls, the Company’s website (<https://www.xenon-pharma.com>), its investor relations website (<https://investor.xenon-pharma.com>), and its news site (<https://investor.xenon-pharma.com/news-releases>). The Company uses these channels, as well as social media, including its X (formerly known as Twitter) account (@XenonPharma), LinkedIn account (<https://www.linkedin.com/company/xenonpharma/>), and Facebook page (<https://www.facebook.com/xenonpharma>), to communicate with investors and the public about the Company, its product candidates, and other matters. Therefore, the Company encourages investors, the media, and others interested in the Company to review the information it makes public in these locations, as such information could be deemed to be material information.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Pursuant to the rules and regulations of the Securities and Exchange Commission, the attached exhibit is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission:

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by Xenon Pharmaceuticals Inc. dated May 7, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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.

XENON PHARMACEUTICALS INC.

Date: May 7, 2026

By: /s/ Thomas P. Kelly
Thomas P. Kelly
Chief Financial Officer

Xenon Reports Q1 2026 Financial Results and Provides Business Update

- *Reported positive topline data from Phase 3 X-TOLE2 study of azetukalner in FOS in March and anticipate NDA submission in Q3 2026*
- *Five additional Phase 3 studies of azetukalner continue to enroll in epilepsy and depression indications with Phase 3 X-NOVA2 MDD topline data expected in H1 2027*
- *Phase 1 studies of novel $\text{Na}_v1.7$ (XEN1701) and K_v7 (XEN1120) candidates expected to complete H2 2026 to support Phase 2 proof-of-concept studies in pain*
- *Cash, cash equivalents, and marketable securities of \$1.3 billion extends cash runway into 2029*
- *Conference call at 4:30 pm ET today*

VANCOUVER, British Columbia and BOSTON, MA, May 7, 2026 (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 first quarter ended March 31, 2026 and provided a business update.

“In the first quarter of 2026, we announced positive results from our X-TOLE2 study, which exceeded expectations and reinforced azetukalner’s significant potential to provide a new therapeutic option for FOS patients with uncontrolled seizures. The strong X-TOLE2 results have paved the way for us to submit an NDA to the FDA in the third quarter of 2026 and our commercial preparedness activities are well underway, supported by our strong balance sheet with cash runway into 2029,” said Ian Mortimer, President and Chief Executive Officer of Xenon. “We remain enthusiastic about broadening the opportunity for azetukalner beyond FOS and are making good progress advancing multiple additional Phase 3 studies in epilepsy and neuropsychiatry indications. Additionally, we are looking forward to completing the first-in-human data for our novel programs targeting $\text{Na}_v1.7$ and K_v7 in pain later this year.”

Business Highlights and Anticipated Milestones

Azetukalner Clinical Development

Azetukalner is a novel, potent K_v7 potassium channel opener in Phase 3 clinical development for 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

- Xenon announced positive topline data from the Phase 3 X-TOLE2 study in March 2026. The study met its primary endpoint of median percent change (MPC) in monthly FOS frequency from baseline to week 12 in both the 25 mg and 15 mg azetukalner dose groups compared to placebo (MPC of -53.2%, -34.5% and -10.4%, respectively; $p < 0.0001$ for both 25 and 15 mg vs. placebo). The placebo-adjusted MPC in the 25 mg group was -42.7%, outperforming the previously completed Phase 2b X-TOLE study and demonstrating the highest placebo-adjusted efficacy ever observed in a pivotal FOS study, to the company’s knowledge. The safety and tolerability profile of azetukalner was consistent with the previously disclosed data from the Phase 2b X-TOLE study. Based on the positive results from X-TOLE2 and X-TOLE, Xenon anticipates submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2026.
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- X-TOLE2 topline efficacy and safety results were featured as a Late Breaking Science oral and poster presentation at the American Academy of Neurology (AAN) Annual Meeting in Chicago, Illinois, April 18-22. Also at AAN, Xenon presented 48-month data from the ongoing X-TOLE open-label extension study, which demonstrated continued reductions in monthly FOS frequency with longer azetukalner treatment, greater seizure reductions in less refractory patients, and sustained periods of seizure freedom. Xenon also presented real-world data regarding unmet needs in epilepsy, including the need for no-titration options.
- The Phase 3 X-TOLE3 study of azetukalner in FOS continues to enroll and is intended to support regulatory submissions outside the United States. X-TOLE3 enrollment outside of Japan is expected to complete in 2026.
- The Phase 3 X-ACKT study of azetukalner in PGTCs continues to enroll and is intended to support regulatory submissions for an additional epilepsy indication.

Depression Programs

- Enrollment is ongoing for the Phase 3 X-NOVA2 and X-NOVA3 studies evaluating azetukalner in patients with MDD, with topline data from X-NOVA2 expected in H1 2027.
- Enrollment is ongoing in the Phase 3 X-CEED study evaluating azetukalner in patients with BPD I or II.

Early-Stage R&D

Xenon continues to expand its portfolio of potent, selective ion channel modulators using the Company's strong heritage in human genetics, deep understanding of ion channel biology, and expertise in novel chemistries. This includes clinical-stage candidates targeting $Na_v1.7$ and K_v7 , which are important targets for pain.

$Na_v1.7$ and K_v7 in Pain

- The Phase 1 Single Ascending Dose (SAD)/Multiple Ascending Dose (MAD) study in healthy adult participants is ongoing for XEN1701 targeting $Na_v1.7$. Study completion is expected in H2 2026 to support initiating a Phase 2 proof-of-concept study in acute pain.
- The Phase 1 SAD/MAD study in healthy adult participants is ongoing for XEN1120 targeting K_v7 . Study completion is expected in H2 2026 to support initiating a Phase 2 proof-of-concept study in acute pain.

$Na_v1.1$ in Epilepsy

- IND-enabling studies are ongoing for the Company's $Na_v1.1$ program. Pre-clinical data suggest that targeting $Na_v1.1$ could potentially address the underlying cause and symptoms of Dravet syndrome.
- The Company presented pre-clinical data for its $Na_v1.1$ program in an oral session at the AAN meeting, demonstrating that selective potentiation of $Na_v1.1$ channels in Dravet mice improves motor performance, suppresses spontaneous seizures, prevents Sudden Unexpected Death in Epilepsy (SUDEP), increases long-term potentiation (a potential cellular correlate of learning and memory), and produces more mature dendritic spine morphology.

Partnered Program

- In collaboration with Neurocrine Biosciences, a Phase 1b study is ongoing for NBI-921355, an investigational, selective inhibitor of voltage-gated sodium channels $Na_v1.2$ and $Na_v1.6$ in development for the potential treatment of certain types of epilepsy. Data from the Phase 1b study are expected in 2027.

Upcoming Investor Conferences

- Xenon will present at three upcoming investor conferences in the second quarter of 2026, including the Bank of America Global Healthcare Conference on Thursday, May 14, the RBC Capital Markets Global Healthcare Conference on May 19, and the Jefferies Global Healthcare Conference on June 4. Details about the presentations, including webcast information, can be found on the Investors section of Xenon's website.

Q1 2026 Financial Results

- Cash and cash equivalents and marketable securities were \$1,339.6 million as of March 31, 2026, compared to \$586.0 million as of December 31, 2025. During the quarter ended March 31, 2026, \$130.0 million of net proceeds was raised under the Company's ATM and \$707.6 million of net proceeds was raised through a public offering. Based on current operating plans, Xenon anticipates having sufficient cash to fund operations into 2029. As of March 31, 2026, there were 96,624,123 common shares and 2,931,293 pre-funded warrants outstanding.
- Research and development expenses were \$88.5 million for the quarter ended March 31, 2026, compared to \$61.2 million for the same period in 2025. The increase in research and development expenses for the period was primarily attributable to the ongoing azetukalner Phase 3 clinical studies in the MDD and BPD programs, ongoing Phase 1 clinical studies of XEN1701 and XEN1120, as well as increased personnel-related costs due to an increase in employee headcount and stock-based compensation expense.
- General and administrative expenses were \$23.8 million for the quarter ended March 31, 2026, compared to \$19.0 million for the same period in 2025. The increase in general and administrative expenses for the period was primarily attributable to personnel-related costs due to an increase in employee headcount and an increase in professional and consulting fees.
- Other income was \$7.5 million for the quarter ended March 31, 2026, compared to \$8.1 million for the same period in 2025. The decrease in other income for the period was primarily attributable to lower interest income.
- Net loss was \$102.3 million for the quarter ended March 31, 2026, compared to \$65.0 million for the same period in 2025. The increase in net loss for the period was primarily attributable to lower revenue from the collaboration with Neurocrine Biosciences, higher research and development expenses driven by the azetukalner and pain programs and higher personnel-related costs, higher general and administrative expenses driven by higher personnel-related costs and 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 first quarter 2026 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 7898598.

About Azetukalner

Azetukalner is a novel, potent K_v7 potassium channel opener currently in Phase 3 clinical trials for the treatment of epilepsy, major depressive disorder (MDD) and bipolar depression (BPD). It represents the most advanced, clinically validated potassium channel modulator in late-stage clinical development. Azetukalner is designed to open potassium channels in the central nervous system, allowing potassium ions to flow and hyperpolarizing neurons. This process helps reduce excessive neuronal firing, which is a key contributor to several neurologic and psychiatric disorders. It is the only K_v7 potassium channel opener in development for multiple indications that is backed by long-term efficacy and safety data in epilepsy patients and proof-of-concept data in MDD patients.

Phase 3 Epilepsy Studies

Xenon's clinical development program for azetukalner in epilepsy includes three Phase 3 clinical studies in focal onset seizures (FOS) and primary generalized tonic-clonic seizures (PGTCS). The completed X-TOLE2 study and the ongoing X-TOLE3 study were both designed as multicenter, randomized, double-blind, placebo-controlled studies to evaluate 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-ACT 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 six years.

Phase 3 MDD Studies

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 Studies

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 K_v7 potassium channel opener in Phase 3 clinical trials 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 K_v7 and $Na_v1.7$ 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.

Xenon and the Xenon logo are registered trademarks or trademarks of Xenon Pharmaceuticals Inc. in the US, Canada, and elsewhere. All other trademarks belong to their respective owner.

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 potential timing of trial enrollment completion and the anticipated filing of INDs and NDAs; the timing and results of our interactions with regulators, including the timing of any NDA submission; and our ability to successfully develop and obtain regulatory approval of azetukalner and our other product candidates. 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.

Contacts

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

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 1,094,747	\$ 548,886
Other current assets	11,885	11,763
Marketable securities, long-term	244,874	37,152
Other long-term assets	35,304	35,362
Total assets	\$ 1,386,810	\$ 633,163
Liabilities		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 38,254	\$ 40,260
Other current liabilities	1,561	1,532
Other long-term liabilities	9,176	9,611
Total liabilities	\$ 48,991	\$ 51,403
Shareholders' equity	\$ 1,337,819	\$ 581,760
Total liabilities and shareholders' equity	\$ 1,386,810	\$ 633,163

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 March 31,	
	2026	2025
Revenue	\$ —	\$ 7,500
Operating expenses:		
Research and development	88,508	61,200
General and administrative	23,820	19,038
Total operating expenses	112,328	80,238
Loss from operations	(112,328)	(72,738)
Other income	7,455	8,118
Loss before income taxes	(104,873)	(64,620)
Income tax recovery (expense)	2,571	(427)
Net loss	\$ (102,302)	\$ (65,047)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	(1,546)	776
Comprehensive loss	\$ (103,848)	\$ (64,271)
Net loss per common share:		
Basic and diluted	\$ (1.17)	\$ (0.83)
Weighted average common shares outstanding:		
Basic and diluted	87,345,717	78,687,503

