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): March 1, 2023

XENON PHARMACEUTICALS INC.

(Exact name of Registrant as Specified in Its Charter)

Canada	**001-36687**	**98-0661854**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200-3650 Gilmore Way **Burnaby, British Columbia, Canada**	**V5G 4W8**
(Address of Principal Executive Offices)	**(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 March 1, 2023, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the year ended December 31, 2022. 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 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:

Exhibit Number	**Description**
99.1	Press Release issued by Xenon Pharmaceuticals Inc. dated March 1, 2023.
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: March 1, 2023

By: /s/ Sherry Aulin
Sherry Aulin
Chief Financial Officer

Exhibit 99.1

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

XEN1101 Phase 3 epilepsy program continues to advance in focal onset seizures and primary generalized tonic clonic seizures

Topline data from XEN1101 Phase 2 X-NOVA clinical trial in major depressive disorder expected in third quarter

Conference call at 4:30 pm ET today

BURNABY, British Columbia, March 1, 2023 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported financial results for the fourth quarter and full year ended December 31, 2022 and provided a corporate update.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer, stated, "We continue to make progress in the advancement of our robust XEN1101 Phase 3 epilepsy program, including ongoing enrollment in our X-TOLE2 and X-ACKT clinical trials, along with our X-TOLE3 clinical trial, which is on track to initiate in the near term. XEN1101 represents the most advanced potassium channel modulator in clinical development for multiple indications and we continue to build on our leadership position with momentum in our Phase 3 program. We recognize that prescribing physicians are seeking new, differentiated therapeutic options that improve upon existing anti-seizure medications, and we remain committed to improving the lives of patients with epilepsy."

Mr. Mortimer continued, "In addition, we look forward to important clinical milestones this year including the anticipated topline read-out in the third quarter from our XEN1101 Phase 2 X-NOVA study in major depressive disorder as well as an anticipated data read-out from our partners at Neurocrine from their Phase 2 study in adult patients with focal onset seizures in the second half of the year."

Highlights and Anticipated Milestones

XEN1101

XEN1101 is a differentiated Kv7 potassium channel opener being developed for the treatment of epilepsy and other neurological disorders, including major depressive disorder, or MDD.

XEN1101 for Epilepsy (Focal Onset Seizures)

Xenon has initiated its XEN1101 Phase 3 development program, which includes two identical Phase 3 clinical trials to be run in parallel, called X-TOLE2 and X-TOLE3, that are designed closely after the Phase 2b X-TOLE clinical trial. These multicenter, randomized, double-blind, placebo-controlled trials will evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered as adjunctive treatment in approximately 360 patients per study with focal onset seizures, or FOS. The primary efficacy endpoint is the median percent change, or MPC, in monthly seizure frequency from baseline through the double-blind period, or DBP, of XEN1101 compared to placebo.

XEN1101 for Epilepsy (Primary Generalized Tonic Clonic Seizures)

Xenon has initiated a Phase 3 clinical trial, called X-ACKT, to support potential regulatory submissions in an additional epilepsy indication of primary generalized tonic clonic seizures, or PGTCS. This multicenter, randomized, double-blind, placebo-controlled study will evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered as adjunctive treatment in approximately 160 patients with PGTCS. The primary efficacy endpoint is the MPC in monthly PGTCS frequency from baseline through the DBP of XEN1101 compared to placebo.

Upon completion of the DBP in X-TOLE2, X-TOLE3, or X-ACKT, eligible patients may enter an open-label extension, or OLE, study for up to three years. In addition, the ongoing X-TOLE Phase 2b OLE continues to generate important long-term data for XEN1101.

XEN1101 for Major Depressive Disorder

Based on promising pre-clinical data with XEN1101 and published clinical data generated using ezogabine, Xenon is evaluating the clinical efficacy, safety and tolerability of XEN1101 administered as monotherapy in approximately 150 patients with MDD in a Phase 2 clinical trial called X-NOVA. Designed as a randomized, double-blind, placebo-controlled, multicenter clinical study, the primary objective is to assess the efficacy of XEN1101 compared to placebo on improvement of depressive symptoms in subjects diagnosed with moderate to severe MDD, using the Montgomery-Åsberg Depression Rating Scale, or MADRS, score change through week six. Topline results from the X-NOVA study are anticipated in the third quarter of this year.

In addition, Xenon is collaborating with the Icahn School of Medicine at Mount Sinai to support an ongoing investigator-sponsored Phase 2 proof-of-concept, randomized, parallel-arm, placebo-controlled multi-site study of XEN1101 for the treatment of MDD in approximately 60 subjects. The primary objective of the study is to investigate the effect of XEN1101 on the brain reward circuit as measured by the change in bilateral ventral striatum activity as assessed by functional MRI, or fMRI. The secondary objectives are to test the effect of XEN1101 compared to placebo on clinical measures of depression and anhedonia using the MADRS and Snaith-Hamilton Pleasure Scale, or SHAPS, respectively.

XEN496

XEN496, a Kv7 potassium channel opener, is a proprietary pediatric formulation of the active ingredient ezogabine being developed for the treatment of KCNQ2 developmental and epileptic encephalopathy, or KCNQ2-DEE. A Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter clinical trial, called EPIK, is ongoing to evaluate the efficacy, safety, and tolerability of XEN496 administered as adjunctive treatment in approximately 40 pediatric patients aged one month to less than six years with KCNQ2-DEE. Xenon anticipates that the EPIK study will be completed in 2024.

NBI-921352

Xenon has an ongoing collaboration with Neurocrine Biosciences to develop treatments for epilepsy. Neurocrine Biosciences has an exclusive license to XEN901, now known as NBI-921352, a selective Nav1.6 sodium channel inhibitor. Neurocrine Biosciences is conducting a Phase 2 clinical trial evaluating NBI-921352 in adult patients with focal onset seizures, with data expected in the second half of this year. In addition, a Phase 2 clinical trial is underway evaluating NBI-921352 in patients aged between 2 and 21 years with SCN8A developmental and epileptic encephalopathy, or SCN8A-DEE. Pursuant to the terms of the agreement, Xenon has the potential to receive certain clinical, regulatory, and commercial milestone payments, as well as future sales royalties.

Fourth Quarter and Full Year 2022 Financial Results

Cash and cash equivalents and marketable securities were $720.8 million as of December 31, 2022, compared to $551.8 million as of December 31, 2021. The increase was primarily the result of the completion of the Company’s public offering in June 2022. Based on current operating plans, including the completion of the XEN1101 Phase 3 epilepsy studies, Xenon anticipates having sufficient cash to fund operations into 2026. As of December 31, 2022, there were 62,587,701 common shares and 3,103,864 pre-funded warrants outstanding.

No revenue was recognized in the fourth quarter of 2022, and $9.4 million for the year ended 2022, compared to $3.7 million and $18.4 million for the same periods in 2021, respectively. For the year, the decrease of $9.0 million was primarily due to the Neurocrine Biosciences collaboration; all performance obligations associated with an upfront payment were completed in March 2022 and the research component of the collaboration ended in June 2022. In addition, a $3.0 million of milestone was recognized under an agreement with Pacira BioSciences in the year ended 2021, whereas no milestones were recognized under this agreement in the year ended 2022.

Research and development expenses were $34.8 million for the fourth quarter of 2022, and $105.8 million for the year ended 2022, compared to $21.9 million and $75.5 million for the same periods in 2021, respectively. For the year, the increase of $30.3 million was primarily attributable to increased expenses related to our XEN1101 program to support the initiation of the Phase 3 epilepsy clinical trials, the ongoing X-TOLE open label extension and the ongoing X-NOVA clinical trial, as well as increased personnel-related costs due to an increase in employee headcount and stock-based compensation expense.

General and administrative expenses were $8.5 million for the fourth quarter of 2022, and $32.8 million for the year ended 2022, compared to $6.7 million and $22.0 million for the same periods in 2021, respectively. For the year, the increase of $10.8 million was primarily attributable to personnel-related costs due to an increase in employee headcount and stock-based compensation expense, recruitment fees, insurance premiums, expenses supporting intellectual property protection and professional fees.

Net loss was $37.4 million for the fourth quarter of 2022, and $125.4 million for the year ended 2022, compared to $25.6 million and $78.9 million for the same periods in 2021, respectively. For the year, the increase in net loss of $46.5 million was primarily attributable to higher operating expenses, driven by research and development expenses related to the Company's initiation of the XEN1101 Phase 3 epilepsy clinical trials, increased employee headcount and higher stock-based compensation expense across the organization as well as lower revenue from the collaboration with Neurocrine Biosciences.

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 fourth quarter and full year 2022 results. The audio webcast can be accessed on the Investors section of the Xenon website. Participants can access the live conference call by dialing (800) 715-9871, or (646) 307-1963 for international callers, and provide conference ID number 5740430. A replay of the webcast will be available on the website approximately one hour after the conclusion of the event and will be archived for approximately one month.

About Xenon Pharmaceuticals Inc.

Xenon Pharmaceuticals (NASDAQ:XENE) is a clinical stage biopharmaceutical company committed to developing innovative therapeutics to improve the lives of patients with neurological disorders. We are advancing a novel product pipeline of neurology therapies to address areas of high unmet medical need, with a focus on epilepsy. For more information, please visit www.xenon-pharma.com.

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 trials; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of our and our partners' product candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in our XEN1101 and other development programs; the timing and results of our interactions with regulators; our ability to successfully develop and obtain regulatory approval of XEN1101 and our other product candidates; anticipated enrollment in our clinical trials and the timing thereof; and our expectation that we will have sufficient cash to fund operations into 2026. 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 trials 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 trial results may not be replicated in later clinical trials; 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 XEN1101, 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 of clinical trials; 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 the ongoing COVID-19 pandemic on our research and clinical development plans and timelines and results of operations, including impact on our clinical trial sites, collaborators, regulatory agencies and related review times, and contractors who act for or on our behalf, may be more severe and more prolonged than currently anticipated; the impact of the COVID-19 pandemic on our business; 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 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.

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 592,087	$ 551,774
Other current assets	8,211	7,246
Marketable securities, long-term	128,682	—
Other long-term assets	25,166	12,987
Total assets	$ 754,146	$ 572,007
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,214	$ 13,717
Other current liabilities	488	605
Other long-term liabilities	9,947	7,652
Total liabilities	$ 32,649	$ 21,974
Shareholders' equity	$ 721,497	$ 550,033
Total liabilities and shareholders' equity	$ 754,146	$ 572,007

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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenue	$ —	$ 3,737	$ 9,434	$ 18,437
Operating expenses:				
Research and development	34,830	21,887	105,767	75,463
General and administrative	8,501	6,688	32,810	21,967
Total operating expenses	43,331	28,575	138,577	97,430
Loss from operations	(43,331)	(24,838)	(129,143)	(78,993)
Other income (loss)	7,075	(242)	3,888	105
Loss before income taxes	(36,256)	(25,080)	(125,255)	(78,888)
Income tax (expense) recovery	(1,139)	(484)	(118)	6
Net loss	(37,395)	(25,564)	(125,373)	(78,882)
Net loss attributable to preferred shareholders	—	(478)	(437)	(1,795)
Net loss attributable to common shareholders	$ (37,395)	$ (25,086)	$ (124,936)	$ (77,087)
Other comprehensive loss:				
Unrealized losses on available-for-sale securities	$ (45)	$ —	$ (2,010)	$ —
Comprehensive loss	$ (37,440)	$ (25,564)	$ (127,383)	$ (78,882)
Net loss per common share:				
Basic and diluted	$ (0.57)	$ (0.47)	$ (2.06)	$ (1.77)
Weighted-average common shares outstanding:				
Basic and diluted	65,657,784	53,320,634	60,542,142	43,627,452

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