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): November 3, 2020

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 November 5, 2020, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three and nine month periods ended September 30, 2020. 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 3, 2020, the Company's board of directors (the "Board"), based upon a recommendation from the Nominating and Corporate Governance Committee of the Board, voted to appoint Mr. Patrick Machado as a director of the Company, effective as of November 5, 2020.

There are no transactions and no proposed transactions between Mr. Machado (or any member of his immediate family) and the Company (or its subsidiary), and there is no arrangement or understanding between Mr. Machado and any other person or entity pursuant to which Mr. Machado was appointed as a director of the Company.

Mr. Machado will participate in the Company's standard compensation plan for non-employee directors, including an initial stock option grant, which will be granted to Mr. Machado on November 5, 2020. The standard compensation plan for non-employee directors is described in the section titled "Director Compensation Policy" of the Company's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 28, 2020.

The Board has not yet determined the committee(s) of the Board, if any, to which Mr. Machado will be named.

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 November 5, 2020.
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: November 5, 2020

By: /s/ Ian Mortimer
Ian Mortimer
President & Chief Financial Officer

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports Third Quarter 2020 Financial Results and Provides Corporate Update

Experienced Biotech Executive, Patrick Machado, Joins Xenon's Board of Directors

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, November 5, 2020 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported financial results for its third quarter ended September 30, 2020 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "We continue to make good progress as we advance our proprietary neurology product candidates into mid- to late-stage clinical development despite the ongoing COVID-19 pandemic. We continue to manage our business prudently and are in a very sound financial position with cash, cash equivalents and marketable securities of approximately $191 million and today extend our cash runway guidance into 2023. Within our ongoing XEN1101 Phase 2b X-TOLE study, we experienced a significant decrease in patient screening and randomization during the early stages of the COVID-19 pandemic. In response, we implemented several risk mitigation strategies that resulted more recently in a positive uptick in patient screening and randomization, although rates have yet to return to pre-COVID levels. We remain confident in the conduct of the study and integrity of the data as captured by electronic diary. We believe the positive effects of these additional measures will continue to materialize over the coming months and expect to complete all patient randomization for the X-TOLE trial in the first half of 2021, with topline data now expected in the third quarter of 2021."

Dr. Pimstone continued, "In our XEN496 program, we also continued to make significant progress this past quarter. With the FDA having completed its review of our clinical trial protocol, we remain on track to initiate our Phase 3 EPIK clinical trial studying XEN496 in pediatric patients with KCNQ2-DEE prior to year-end. To support the upcoming EPIK study, we continue to work closely with the medical community, genetic testing companies, and patient advocacy groups to identify potential patients. While some factors, such as the impact of the COVID-19 pandemic, are outside of our direct control, we are committed to driving our proprietary neurology programs forward, with important milestone events anticipated in 2021."

Dr. Pimstone added, "Today, we are also pleased to welcome Patrick Machado to our Board of Directors. Pat brings to Xenon a depth of biotech experience and track record of strong business leadership, having overseen finance, business development and legal functions over more than 20 years of an impressive career. I believe Pat will add tremendous value to our Board as we continue to advance multiple mid- to late-stage neurology-focused clinical development programs."

Highlights and Anticipated Milestones

Proprietary Programs

- XEN1101 is a differentiated Kv7 potassium channel modulator being developed for the treatment of epilepsy and potentially other neurological disorders. Designed as a randomized, double-blind, placebo-controlled, multicenter study, Xenon's "X-TOLE" study is an ongoing Phase 2b clinical trial to evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered as adjunctive treatment in approximately 300 adult patients with focal epilepsy. The primary endpoint is the median percent change in monthly focal seizure frequency from baseline compared to treatment period of active versus placebo. Xenon is in close collaboration with each of the XEN1101 clinical sites in North America and Europe, taking specific direction from their respective clinical guidelines as they relate to new patient screening and randomization in the context of the COVID-19 pandemic. Xenon has expanded the X-TOLE clinical trial to include new sites in both existing and new jurisdictions to support increased patient screening. Xenon is updating its guidance to reflect the impact of COVID-19 on patient enrollment rates, and now anticipates that patient randomization will be completed in the first half of 2021, with topline data anticipated in the third quarter of 2021, dependent upon ongoing patient enrollment rates.

- XEN496, a Kv7 potassium channel modulator, is a proprietary pediatric formulation of the active ingredient ezogabine being developed for the treatment of epilepsy. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for XEN496 for the treatment of seizures associated with KCNQ2 developmental and epileptic encephalopathy (KCNQ2-DEE) and Orphan Drug Designation (ODD) for the treatment of KCNQ2-DEE. In addition, Xenon has received a positive opinion from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA), which recommends the granting of an orphan medicinal product designation for XEN496 for the treatment of KCNQ2-DEE. The FDA has completed its review of the clinical trial protocol, and Xenon expects to initiate its XEN496 Phase 3 “EPIK” clinical trial in pediatric patients with KCNQ2-DEE before year-end. This study is designed as a randomized, double-blind, placebo-controlled, parallel group, multicenter clinical trial to evaluate the efficacy, safety and tolerability of XEN496 administered as adjunctive treatment in approximately 40 pediatric patients aged one month to less than 6 years with KCNQ2-DEE. After screening, patients will enter a baseline period to assess the frequency of seizures. Eligible subjects will be randomized on a 1:1 basis to receive either XEN496 or placebo for approximately 15 weeks (titration and a 12-week maintenance period). At the end of treatment, there will be a period of tapering off of study drug, followed by a 28-day safety monitoring period. Patients may be considered for an open-label extension if they meet all requirements. The primary endpoint is the percent change from baseline in monthly countable motor seizure frequency during the blinded treatment period, as recorded by caregivers in a daily seizure diary. Key secondary endpoints include the proportion of patients experiencing greater than or equal to 50 percent reduction in monthly seizure frequency from baseline, caregiver global impression of change (CaGI-C) scores, and caregiver global impression of severity (CaGI-S) scores.

- XEN007 (active ingredient flunarizine) is a CNS-acting calcium channel modulator that modulates Cav2.1 and T-type calcium channels. Other reported mechanisms include dopamine, histamine, and serotonin inhibition. A physician-led, Phase 2 proof-of-concept study is examining the potential clinical efficacy, safety, and tolerability of XEN007 as an adjunctive treatment in pediatric patients diagnosed with treatment-resistant childhood absence epilepsy, or CAE. A presentation of interim data collected from a small number of patients is expected to be presented in a poster presentation at “AES2020,” the virtual annual meeting of the American Epilepsy Society to be held in December 2020. Xenon continues to work with its collaborators and expects that topline results from a larger data set will be available by the middle of next year. Depending on the final results, CAE may represent a potential orphan indication for future development of XEN007.

Partnered Programs

- 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 clinical stage selective Nav1.6 sodium channel inhibitor with potential in SCN8A developmental and epileptic encephalopathy (SCN8A-DEE) and other forms of epilepsy. The FDA has provided feedback on an Investigational New Drug (IND) application submitted by Neurocrine Biosciences in support of a Phase 2 clinical trial in pediatric SCN8A-DEE patients. As part of its review of the IND, the FDA is requesting additional non-clinical data to support dose justification in this pediatric study. Neurocrine Biosciences and Xenon will engage with the FDA to address the feedback received with the goal of initiating a Phase 2 clinical trial in 2021. In parallel with this interaction, Neurocrine Biosciences is advancing clinical plans to develop NBI-921352 for the treatment of adult focal epilepsy. Pursuant to the collaboration agreement, upon FDA acceptance of an IND for NBI-921352 in either SCN8A-DEE or a major indication, Xenon is eligible to receive a milestone payment of either $25 million or $10 million, respectively, with 55% of the amount in the form of an equity investment in Xenon at a 15% premium to Xenon’s 30-day trailing volume weighted average price at that time.

- Flexion Therapeutics, Inc. acquired the global rights to develop and commercialize XEN402, a Nav1.7 inhibitor also known as funapide. Flexion’s pre-clinical FX301 consists of XEN402 formulated for extended release from a thermosensitive hydrogel. The initial development of FX301 is intended to support administration as a peripheral nerve block for control of post-operative pain. Flexion anticipates filing an IND application in the first half of 2021 to support a proof-of-concept clinical trial of popliteal fossa block with FX301 in patients undergoing bunionectomy. Results from that trial could potentially be available in late 2021.

Corporate Highlights

- Subsequent to quarter end, Xenon appointed Patrick Machado to its Board of Directors. Mr. Machado co-founded and served as Chief Financial Officer and Chief Business Officer at Medivation, Inc. until his retirement in 2014 and served as a member of Medivation's Board of Directors from 2014 until its acquisition for approximately $14 billion by Pfizer in 2016. During his tenure at Medivation, Mr. Machado helped lead the company through substantial growth and challenges, providing strong leadership during the clinical development and successful commercial launch of XTANDI®. Mr. Machado serves on multiple public company Boards, including as Chair of the Board of Directors of Adverum Biotechnologies, Inc., and as member of the Board of Directors of Arcus Biosciences, Inc., Turning Point Therapeutics and Chimerix, Inc. Additionally, Mr. Machado is a member of the Board of Directors of Armaron Bio Pty Ltd., Roivant Sciences Ltd., and Turnstone Biologics, all private companies. Earlier in his career, from 1998 to 2001, Mr. Machado worked with ProDuct Health, Inc., a medical device company as Senior Vice President, Chief Financial Officer, and earlier as General Counsel. Previously, Mr. Machado worked for Morrison & Foerster LLP, a leading international law firm, and for the Massachusetts Supreme Judicial Court. Mr. Machado received his J.D. degree from Harvard Law School and holds both a Bachelor of Science degree in Economics and a Bachelor of Arts degree in German from Santa Clara University in California.

Third Quarter 2020 Financial Results

Cash and cash equivalents and marketable securities as of September 30, 2020 were $190.9 million, compared to $141.4 million as of December 31, 2019. There were 34,994,946 common shares and 1,016,000 Series 1 Preferred Shares, which are convertible into common shares on a one-for-one basis at the option of the holder, subject to certain limitations, outstanding as of September 30, 2020.

Based on current assumptions, which include fully supporting the planned clinical development of XEN1101, XEN496 and XEN007, Xenon anticipates having sufficient cash to fund operations into 2023, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

For the quarter ended September 30, 2020, Xenon reported total revenue of $6.6 million, compared to $3.5 million for the same period in 2019. The increase of $3.1 million was attributable to the recognition of $5.2 million of deferred revenue as well as $1.3 million for research and development services from the license and collaboration agreement with Neurocrine Biosciences, compared to $3.5 million recognized in the comparative quarter in connection with the agreement entered into in September 2019 with Flexion.

Research and development expenses for the quarter ended September 30, 2020 were $13.0 million, compared to $9.8 million for the same period in 2019. The increase was primarily attributable to increased spending on Xenon's clinical development product candidates XEN496 and XEN1101, and, to a lesser extent, increased spending on pre-clinical, discovery and other internal programs. This was partially offset by decreased spending on XEN901, now known as NBI-921352, as clinical development costs are borne by Neurocrine Biosciences.

General and administrative expenses for the quarter ended September 30, 2020 were $3.2 million compared to $2.7 million for the same period in 2019. The increase of $0.5 million was primarily attributable to increased stock-based compensation expense, insurance premiums and salaries and benefits, partially offset by a decrease in legal fees for intellectual property protection.

Other income for the quarter ended September 30, 2020 was $0.6 million compared to $0.1 million for the same period in 2019. The increase was primarily attributable to an increase in foreign exchange gains largely from the translation of cash and cash equivalents and marketable securities denominated in Canadian dollars to U.S. dollars and a decrease in interest expense due to the repayment of a term loan in May 2020, partially offset by a decrease in interest income.

Net loss for the quarter ended September 30, 2020 was $8.9 million, consistent with $8.9 million for the same period in 2019.

Conference Call Information

Xenon will host a conference call and live audio webcast today at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss its third quarter 2020 financial results and to provide a business update. To participate in the call, please dial (855) 779-9075, or (631) 485-4866 for international callers, and provide conference ID number 8125409. The webcast will be broadcast live on the “Investors” section of Xenon's website at www.xenon-pharma.com and will be available for replay following the call for 30 days.

About Xenon Pharmaceuticals Inc.

We are 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 anticipated impact and timing of the COVID-19 pandemic on our business, research and clinical development plans and timelines and results of operations; the timing of and results from clinical trials and pre-clinical development activities, including those related to XEN496, XEN1101, XEN007, and other proprietary products, and those related to NBI-921352, FX301, and other partnered product candidates; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN1101, XEN007 and other proprietary and partnered product candidates; the anticipated timing of IND, or IND-equivalent, submissions and the initiation of future clinical trials for XEN496, XEN1101, XEN007, and other proprietary products, and those related to NBI-921352, FX301, and other partnered candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in the XEN496, XEN1101, XEN007 and other proprietary development programs; the timing and results of our interactions with regulators; the potential to advance certain of our product candidates directly into Phase 2 or later stage clinical trials; anticipated enrollment in our clinical trials and the timing thereof; the expansion of the X-TOLE clinical trial and the anticipated timing of the topline data therefrom; the progress and potential of our other ongoing development programs; the potential receipt of milestone payments and royalties from our collaborators; our expectation of having sufficient cash to fund operations into 2023; and the timing of potential publication or presentation of future clinical data. 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: the impact of the COVID-19 pandemic on our business, research and clinical development plans and timelines and results of operations, including impact on our clinical trial sites, collaborators, and contractors who act for or on our behalf, may be more severe and more prolonged than currently anticipated; clinical trials may not demonstrate safety and efficacy of any of our or our collaborators’ product candidates; 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 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; regulatory agencies may be delayed in reviewing, commenting on or approving any of our or our collaborators’ clinical development plans as a result of the COVID-19 pandemic, which could further delay development timelines; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; impact of new or changing laws and regulations; adverse conditions in the general domestic and global economic markets; 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)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 190,927	$ 141,358
Other current assets	3,883	3,508
Other assets	4,318	2,831
Total assets	$ 199,128	$ 147,697
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	8,875	8,818
Deferred revenue	7,446	29,743
Term loan	—	4,650
Other current liabilities	596	168
Other liabilities	188	12,341
Total liabilities	$ 17,105	$ 55,720
Shareholders' equity	$ 182,023	$ 91,977
Total liabilities and shareholders' equity	$ 199,128	$ 147,697

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	$ 6,554	$ 3,500	$ 27,016	$ 3,500
Operating expenses:				
Research and development	13,045	9,751	35,556	27,093
General and administrative	3,208	2,700	9,838	7,628
Total operating expenses	16,253	12,451	45,394	34,721
Loss from operations	(9,699)	(8,951)	(18,378)	(31,221)
Other income	641	85	1,621	1,015
Loss before income taxes	(9,058)	(8,866)	(16,757)	(30,206)
Income tax (expense) recovery	203	(5)	243	(13)
Net loss and comprehensive loss	(8,855)	(8,871)	(16,514)	(30,219)
Net loss attributable to preferred shareholders	(250)	(336)	(474)	(1,146)
Net loss attributable to common shareholders	$ (8,605)	$ (8,535)	$ (16,040)	$ (29,073)
Net loss per common share:				
Basic and diluted	$ (0.25)	$ (0.33)	$ (0.47)	$ (1.13)
Weighted-average common shares outstanding:				
Basic and diluted	34,994,944	25,793,482	34,387,986	25,773,732

Investor/Media Contact:
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