Xenon Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 10, 2022

XEN1101 "End of Phase 2" Meeting with FDA to take Place in Second Quarter and Initiation of Phase 3 in Adult Focal Epilepsy Expected in the Second Half of 2022

Company-sponsored Phase 2 Clinical Trial Initiated to Evaluate XEN1101 for the Treatment of MDD

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, May 10, 2022 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2022 and provided a corporate update.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer stated, "We are excited by the progress across all of our clinical development programs, including screening the first patient in our recently initiated Phase 2 'X-NOVA' clinical trial to evaluate XEN1101 as a potential treatment for major depressive disorder. In addition, we are on track for our end-of-Phase 2 meeting with the FDA this quarter to support the initiation of the Phase 3 development plans for XEN1101 in epilepsy in the second half of this year. The Phase 3 'EPIK' pediatric study evaluating XEN496 as a treatment of KCNQ2-DEE is ongoing with anticipated completion in 2023."

Highlights and Anticipated Milestones

Proprietary Programs

XEN1101 for Epilepsy
XEN1101 is a differentiated Kv7 potassium channel opener being developed for the treatment of epilepsy and major depressive disorder (MDD). In October 2021, Xenon announced positive results from its Phase 2b X-TOLE clinical trial, which evaluated the clinical efficacy, safety and tolerability of XEN1101 administered as an adjunctive treatment for adult patients with focal epilepsy. The topline data showed all primary and secondary seizure reduction endpoints were statistically significant across all dose groups, including the primary endpoint of median reduction from baseline in monthly seizure frequency and in the key secondary endpoint of patients with at least a 50% reduction in monthly focal seizure frequency from baseline, with p-values of <0.001 for both the 20 mg and 25 mg dose groups.

Xenon will participate in an "end-of-Phase 2" meeting with the U.S. Food and Drug Administration (FDA) in the second quarter of this year to support the initiation of its Phase 3 XEN1101 clinical program in adult patients with focal epilepsy, estimated in the second half of the year. The ongoing X-TOLE open-label extension also continues to generate important long-term data for XEN1101. Xenon is also evaluating other potential epilepsy indications for the future development of XEN1101.

XEN1101 for MDD
Based on promising pre-clinical data with XEN1101 and published clinical data generated from both an open-label study and a randomized, placebo-controlled clinical trial that explored the targeting of KCNQ channels as a treatment for MDD using ezogabine, Xenon is evaluating the efficacy, safety and tolerability of XEN1101 for the treatment of MDD in a Phase 2 randomized, double-blind, placebo-controlled, multicenter clinical study – called the "X-NOVA" clinical trial. Following a 4-week screening period, approximately 150 subjects with MDD will be randomized (on a 1:1:1 basis) for once-daily dosing of XEN1101 (10 mg), XEN1101 (20 mg) or placebo for 6 weeks. The primary objective is to assess the efficacy of 10 mg and 20 mg doses 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 (MADRS) score change through week six. Secondary endpoints include improvement of anhedonia symptoms assessed by the Snaith-Hamilton Pleasure Scale (SHAPS) score change through week six, as well as improvement of anxiety symptoms measured by the Beck Anxiety Inventory (BAI) score change through week six. Topline results from the X-NOVA study are anticipated in 2023.

In addition, Xenon is collaborating with the Icahn School of Medicine at Mount Sinai to conduct 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 (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 SHAPS scales.

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 (KCNQ2-DEE). A Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter clinical trial, called the "EPIK" study, 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 2023.

Partnered Programs

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 2023. 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 (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.

PCRX301 (formerly FX301)

In November 2021, Pacira BioSciences, Inc. completed its acquisition of Flexion Therapeutics, Inc., which included Flexion's global rights to develop and commercialize XEN402, a Nav1.7 inhibitor also known as funapide. XEN402 has been formulated for extended release from a thermosensitive hydrogel and is now known as PCRX301 (previously FX301). A Phase 1b proof-of-concept trial is underway evaluating the safety and tolerability of PCRX301 administered as a single-dose, popliteal fossa block in patients undergoing bunionectomy. 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.

First Quarter 2022 Financial Results

Cash and cash equivalents and marketable securities were $537.9 million as of March 31, 2022, compared to $551.8 million as of December 31, 2021. As of March 31, 2022, there were 53,059,049 common shares and 2,775,996 pre-funded warrants outstanding.

Based on current assumptions, which include fully supporting the planned XEN1101 clinical development program, XEN496, and pre-clinical and discovery programs, Xenon anticipates having sufficient cash to fund operations into at least 2024, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

For the quarter ended March 31, 2022, Xenon reported total revenue of $8.8 million, compared to $4.4 million for the same period in 2021. The increase was primarily attributable to recognition of $7.1 million of milestone revenue in connection with the license and collaboration agreement with Neurocrine Biosciences, partially offset by $3.0 million of milestone revenue recognized in the quarter ended March 31, 2021 in connection with the agreement with Pacira BioSciences.

Research and development expenses for the quarter ended March 31, 2022 were $19.4 million, compared to $16.3 million for the same period in 2021. The increase of $3.1 million was primarily attributable to increased spending on pre-clinical, discovery and other internal programs as well as increased spending on XEN1101.

General and administrative expenses for the quarter ended March 31, 2022 were $6.8 million compared to $4.1 million for the same period in 2021. The increase of $2.7 million was primarily attributable to increased stock-based compensation expense, salaries and benefits from additional headcount, recruitment fees and market research costs.

Other expense for the quarter ended March 31, 2022 was $2.7 million compared to other income of $0.2 million for the same period in 2021. The change was primarily attributable to an unrealized loss on fair value of marketable securities for the quarter ended March 31, 2022 due to fluctuations in market yields, partially offset by higher interest income due to an increase in marketable securities.

Net loss for the quarter ended March 31, 2022 was $19.7 million, compared to $15.8 million for the same period in 2021. The change was primarily attributable to higher unrealized fair value loss on marketable securities, an increase in research and development and general and administrative expenses, partially offset by higher revenue as compared to the same period in 2021.

Conference Call Information

Xenon will host a conference call and live audio webcast today at 4:30 pm Eastern Time (1:30 pm Pacific Time) to discuss its first quarter results and to provide a corporate update. The webcast will be broadcast live on the Investors section of the Xenon website. To participate in the call, please dial 1-855-779-9075, or 1-631-485-4866 for international callers, and provide conference ID number 2263884.

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 results from clinical trials and pre-clinical development activities, including those related to XEN496, XEN1101, and other proprietary products, and those related to NBI-921352, PCRX301, and other partnered product candidates; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN1101 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, and other proprietary products, and those related to NBI-921352, PCRX301, and other partnered candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in the XEN496, XEN1101, and other proprietary development programs; the timing and results of our interactions with regulators; anticipated enrollment in our clinical trials and the timing thereof; 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 at least 2024; 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 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, 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; the impact of the COVID-19 pandemic on our business, 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)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 537,940	$ 551,774
Other current assets	7,676	7,246
Other assets	12,443	12,987
Total assets	$ 558,059	$ 572,007
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,982	$ 13,717
Other current liabilities	-	605
Other liabilities	8,224	7,652
Total liabilities	$ 16,206	$ 21,974
Shareholders' equity	$ 541,853	$ 550,033
Total liabilities and shareholders' equity	$ 558,059	$ 572,007

XENON PHARMACEUTICALS INC.
Condensed Consolidated Statements of Operations

(Expressed in thousands of U.S. dollars except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Revenue	$ 8,766	$ 4,358
Operating expenses:		
Research and development	19,360	16,308
General and administrative	6,775	4,109
Total operating expenses	26,135	20,417
Loss from operations	(17,369)	(16,059)
Other (expense) income	(2,695)	227
Loss before income taxes	(20,064)	(15,832)
Income tax recovery	394	68
Net loss and comprehensive loss	(19,670)	(15,764)
Net loss attributable to preferred shareholders	(299)	(423)
Net loss attributable to common shareholders	$ (19,371)	$ (15,341)
Net loss per common share:		
Basic and diluted	$ (0.35)	$ (0.42)
Weighted-average common shares outstanding:		
Basic and diluted	54,852,792	36,824,619

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