Xenon Pharmaceuticals Reports 2021 Financial Results and Provides Corporate Update

March 1, 2022

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, March 01, 2022 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported financial results for the year ended December 31, 2021 and provided a corporate update.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer stated, "We made significant progress in 2021, marked by the positive read-out of strong efficacy data from our XEN1101 Phase 2b X-TOLE clinical trial, which represented a transformative event for Xenon. We have successfully carried this positive momentum into 2022 as we look forward to an end-of-Phase 2 meeting with the FDA in the second quarter and continue to focus on initiation of Phase 3 development for XEN1101 in the second half of 2022. In addition, we have now filed an IND with the FDA to support the initiation of our company-sponsored Phase 2 XEN1101 clinical trial in major depressive disorder, anticipated to commence in the first half of this year."

Mr. Mortimer added, "Patient enrollment is ongoing in our pediatric XEN496 Phase 3 'EPIK' clinical trial, which is expected to be completed in the first half of 2023. Our partnered programs also continue to advance through development with two separate Phase 2 clinical trials underway from Neurocrine Biosciences in adult patients with focal-onset seizures and pediatric patients with SCN8A-related epilepsy."

Highlights and Anticipated Milestones

Proprietary Programs

XEN1101

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 anticipates participating 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 X-TOLE open-label extension, which has been extended to three years, is expected to continue to generate important long-term data for XEN1101. Xenon is also evaluating other potential epilepsy indications for the future development of XEN1101.

Xenon continues to execute on its comprehensive strategy to protect and expand the intellectual property portfolio that covers XEN1101. Importantly, two additional U.S. patents were granted in 2021 with claims related to: (1) compositions-of-matter covering four distinct crystalline forms of XEN1101 drug substance (including the forms used in current and future clinical development); and (2) methods of enhancing the bioavailability of XEN1101 by administration with or close to a meal (consistent with the dosing of XEN1101 in clinical studies). These U.S. patents are expected to expire in 2040 and 2039, respectively, absent any extensions of patent term.

In addition, Xenon is collaborating with the Icahn School of Medicine at Mount Sinai to conduct an investigator-sponsored Phase 2 proof-of-concept, multi-site, randomized, parallel-arm, placebo-controlled clinical trial of XEN1101 for the treatment of MDD, with patient enrollment underway. In addition, an investigational new drug (IND) application has been submitted to the FDA to support its plans for a larger company-sponsored clinical study in MDD with XEN1101, which is expected to be initiated in the first half of 2022.

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 underway 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 the first half of 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, with data now anticipated in the second quarter of this year. 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.

2021 Financial Results

Cash and cash equivalents and marketable securities as of December 31, 2021 were $551.8 million, compared to $177.0 million as of December 31, 2020. As of December 31, 2021 there were 51,634,752 common shares, 2,775,996 pre-funded warrants and 1,016,000 Series 1 Preferred Shares outstanding. The Series 1 Preferred Shares are convertible into common shares on a one-for-one basis at the option of the holder, subject to certain limitations.

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 year ended December 31, 2021, Xenon reported total revenue of $18.4 million, compared to $32.2 million for the same period in 2020. The decrease of $13.7 million was attributable to deferred revenue related to the transfer of exclusive licenses and associated technology and know-how for certain compounds under the license and collaboration agreement with Neurocrine Biosciences being fully recognized by December 2020, partially offset by recognition of $5.3 million of milestone revenue in connection with the license and collaboration agreement with Neurocrine Biosciences, $3.0 million of milestone revenue in connection with the agreement with Pacira BioSciences and an increase in research and development services revenue.

Research and development expenses for the year ended December 31, 2021 were $75.5 million, compared to $50.5 million for the same period in 2020. The increase of $24.9 million was primarily attributable to increased spending on Xenon's clinical development product candidates XEN1101 and XEN496 as well as increased spending on pre-clinical, discovery and other internal programs.

General and administrative expenses for the year ended December 31, 2021 were $22.0 million compared to $12.9 million for the same period in 2020. The increase of $9.0 million was primarily attributable to increased salaries and benefits from additional headcount, stock-based compensation expense, market research costs and legal fees for intellectual property protection.

Other income for the year ended December 31, 2021 was $0.1 million compared to $2.2 million for the same period in 2020. The decrease was primarily attributable to a decrease in interest income and an unrealized loss on fair value of marketable securities recognized for the year ended December 31, 2021 due to fluctuations in market interest yields.

Net loss for the year ended December 31, 2021 was $78.9 million, compared to $28.8 million for the same period in 2020. The change was primarily attributable to higher research and development and general and administrative expenses, and lower revenue as compared to the same period in 2020.

At-the-Market Equity Offering

Xenon also announced today that it has amended its at-the-market equity offering sales agreement dated August 6, 2020, with Jefferies LLC and Stifel, Nicolaus & Company, Incorporated, under which Xenon may sell its common shares from time-to-time. Sales of the common shares, if any, will only be conducted in the United States through the Nasdaq or another exchange at market prices. No sales of common shares will be made in Canada.

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 the year-end 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 (855) 779-9075, or (631) 485-4866 for international callers, and provide conference ID number 7079889.

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; our efforts to enhance our intellectual property portfolio; the timing of potential publication or presentation of future clinical data; and the sale of any common shares pursuant to the at-the-market equity offering, including the price, volume and timing of any distributions. 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: 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" and the Xenon logo are registered trademarks or trademarks of Xenon Pharmaceuticals Inc. in various jurisdictions. All other trademarks belong to their respective owner.

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 551,774	$ 176,997
Other current assets	7,246	4,786
Other assets	12,987	7,403
Total assets	$ 572,007	$ 189,186
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	13,717	10,874
Deferred revenue	-	3,642
Other current liabilities	605	265
Other liabilities	7,652	3,050
Total liabilities	$ 21,974	$ 17,831

Shareholders' equity	$ 550,033	$ 171,355
Total liabilities and shareholders' equity	$ 572,007	$ 189,186

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

	Year Ended December 31,	
	2021	**2020**
Revenue	$ 18,437	$ 32,166
Operating expenses:		
Research and development	75,463	50,523
General and administrative	21,967	12,944
Total operating expenses	97,430	63,467
Loss from operations	(78,993)	(31,301)
Other income	105	2,207
Loss before income taxes	(78,888)	(29,094)
Income tax recovery	6	257
Net loss and comprehensive loss	(78,882)	(28,837)
Net loss attributable to preferred shareholders	(1,795)	(824)
Net loss attributable to common shareholders	$ (77,087)	$ (28,013)
Net loss per common share:		
Basic and diluted	$ (1.77)	$ (0.81)
Weighted-average common shares outstanding:		
Basic and diluted	43,627,452	34,542,213

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