Xenon Pharmaceuticals Reports 2017 Financial Results and Provides Corporate Update

March 7, 2018

Two novel anti-epileptic drugs advancing in clinical development;

Interim XEN1101 Phase 1 data expected to be released in May 2018 at scientific symposium;

Xenon announces new clinical stage ion channel product to expand its neurology pipeline

BURNABY, British Columbia, March 07, 2018 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today reported its financial results for the year ended December 31, 2017 and provided a corporate update.

Dr. Simon Pimstone, Xenon's President and Chief Executive Officer, said, "In 2017, we concentrated our efforts on developing novel ion channel modulators to address central nervous system (CNS) disorders, and our product candidates are advancing as planned. We believe that XEN1101 and XEN901, our two proprietary epilepsy products that are currently in clinical development, have unique mechanisms of action and other attractive properties that could differentiate them from existing anti-epileptic drugs presently available to prescribing physicians."

Dr. Pimstone continued, "Xenon is poised to reach key milestone events within the next 6 to 12 months. We look forward to presenting interim Phase 1 data from our ongoing XEN1101 Phase 1 clinical trial, including results from a pilot transcranial magnetic stimulation (TMS) pharmacodynamic study, at the 14th EILAT Conference on New Antiepileptic Drugs and Devices to be held in Madrid, Spain in May 2018. We believe these interim results – which build upon the existing pre-clinical data and relevant benchmarks from ezogabine, an earlier generation Kv7 opener – could validate the activity of XEN1101 on CNS cortical hyperexcitability and support planning for the next stages of clinical development."

Dr. Pimstone added, "Additionally, we are excited to announce a new ion channel product candidate, XEN007, a CNS acting calcium channel modulator (active ingredient flunarizine). We have received FDA orphan drug designation for XEN007 for the treatment of hemiplegic migraine, a rare and severe form of migraine with a strong heritable component. To potentially expedite the development of XEN007, we have entered into key agreements that provide us with access to regulatory data and manufacturing support, which may allow us to advance this product candidate – either on our own or in partnership – directly into a Phase 2 clinical trial."

Achievements and Anticipated Milestones

- XEN1101 is a Kv7 potassium channel opener being developed by Xenon for the treatment of epilepsy including: treatment-resistant adult and pediatric focal seizures; rare, pediatric forms of epilepsy, such as EIEE7, an early infantile epileptic encephalopathy associated with mutations in the KCNQ2 gene that cause loss-of-function in the Kv7.2 potassium channel; and potentially other neurological disorders.

  In October 2017, Xenon initiated a randomized, double-blind, placebo-controlled Phase 1 clinical trial to evaluate the safety, tolerability and pharmacokinetics of both single ascending doses (SAD) and multiple ascending doses (MAD) of XEN1101 in healthy subjects. The XEN1101 Phase 1 clinical trial includes a pharmacodynamic biomarker read-out from a transcranial magnetic stimulation (TMS) study, designed to assess XEN1101's ability and potency to modulate cortical excitability, thereby demonstrating activity in the target CNS tissue. Xenon has completed a Phase 1a pilot TMS study in 8 healthy subjects and has now begun a double-blind, placebo-controlled, randomized cross-over Phase 1b TMS study in 15 healthy subjects.

  Xenon expects to present interim Phase 1 results – including preliminary pharmacokinetic, tolerability and safety data from 42 subjects, along with a read-out from the Phase 1a pilot TMS study – at the 14th EILAT Conference on New Antiepileptic Drugs and Devices to be held in Madrid, Spain in May 2018. The release of the complete Phase 1 results, including the Phase 1b TMS data, is anticipated in the second half of 2018. Xenon anticipates initiating a Phase 2 proof-of-concept trial evaluating XEN1101's efficacy as a treatment for adult focal seizures by year end. Xenon also intends to explore a parallel plan to advance XEN1101 into rare, pediatric forms of epilepsy as soon as feasible thereafter.

- XEN901 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed by Xenon for the treatment of epilepsy including treatment resistant adult and pediatric focal seizures, as well as rare, pediatric forms of epilepsy, such as EIEE13, an early infantile epileptic encephalopathy due to gain-of-function mutations in the SCN8A gene that encodes the Nav1.6 sodium channel.

In February 2018, Xenon initiated a randomized, double-blind, placebo-controlled Phase 1 clinical trial to evaluate XEN901's safety, tolerability and pharmacokinetics in both SAD and MAD cohorts of approximately 64 healthy subjects in total. Upon completion of the Phase 1 clinical trial, a read-out of results is anticipated in the second half of 2018, followed by a Phase 2 proof-of-concept trial evaluating XEN901's efficacy as a treatment for adult focal seizures. Xenon also intends to pursue a parallel plan to advance XEN901 into rare, pediatric forms of epilepsy as soon as feasible thereafter.

- Xenon has identified an additional clinical stage, ion channel program, XEN007 (active ingredient flunarizine), to complement its existing neurology-focused product pipeline. XEN007 is a CNS-acting calcium channel inhibitor that directly modulates Cav2.1, which is a critical calcium channel implicated in the pathophysiology of hemiplegic migraine (HM), a rare and debilitating neurological disorder afflicting approximately 60,000 people in the U.S. Flunarizine has been used outside of the U.S. in the prevention of chronic migraine and has been reported to have clinical benefit in HM case studies. Xenon's clinical development plans include a proposed strategy to develop XEN007 as the first treatment specifically approved for HM anywhere in the world. Xenon has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for XEN007 for the treatment of HM. In addition, Xenon has entered into key agreements in order to access regulatory files and manufacturing support to potentially enable the accelerated clinical development of XEN007 directly into a Phase 2 clinical trial. Xenon is currently examining various development strategies for XEN007 with key opinion leaders and leading clinicians, as well as exploring options for potential partnerships for this program.

  Xenon believes that there is strong human genetic validation supporting the use of XEN007 for the treatment of HM. At least three different genes have been implicated in HM, all of which can promote excessive glutamatergic (excitatory) neurotransmission leading to cortical spreading depression which mediates the progressive symptoms characteristic of HM. HM patients may have mutations in one of these three causal ion channel genes. In particular, gain-of-function mutations in CACNA1A, the gene that encodes for Cav2.1, have been shown to increase the activity of Cav2.1 and thereby enhance excitatory neurotransmission. This increase in Cav2.1 activity is therefore thought to play an important causal role in HM. In contrast, the suppression of the channel activity by XEN007, both in HM patients with or without mutant Cav2.1, has the potential to dampen the excessive excitatory neurotransmission, thereby mediating a beneficial effect in HM. These genetic causes of HM suggest that XEN007 may be well suited for the treatment of HM, which has been supported by case study reports. Other neurological disorders are also being considered for future development of XEN007, in both adult and pediatric populations.

- Xenon has an ongoing collaboration with Genentech, a member of the Roche Group, which is focused on developing novel inhibitors of Nav1.7 for the treatment of pain. Genentech has completed a Phase 1 clinical trial for GDC-0310, which is an oral, selective Nav1.7 small-molecule inhibitor developed for the potential treatment of pain. Guidance around the future clinical development of GDC-0310 will be updated once ongoing pre-clinical studies are completed and the final results are analyzed by Genentech.

- On March 7, 2018, Xenon and Teva Pharmaceuticals International GmbH, along with Teva Canada Limited (Teva) entered into an agreement terminating by mutual agreement the collaborative development and license agreement dated December 7, 2012, as amended. Teva and Xenon agreed to terminate the collaborative development and license agreement after Teva informed Xenon that it no longer intends to further develop TV-45070.

  Pursuant to the termination agreement and subject to receipt by Xenon of an order from the Ontario Securities Commission (OSC), Teva has agreed to transfer and assign 1,000,000 common shares of Xenon held by Teva Canada Limited to Xenon for cancellation. Teva will also return, license or assign to Xenon certain intellectual property including certain patent rights. The termination agreement requires Xenon to pay a low single-digit percentage royalty to Teva based on net sales of approved products, if any, resulting from any continued development and commercialization of TV-45070 by Xenon. Teva will also transfer regulatory filings related to TV-45070 to Xenon.

  The termination agreement will become effective on the date specified by Xenon in a written notice to Teva. The effective date will be after the date that Xenon receives an order from the OSC granting Xenon exemptive relief from the requirements related to issuer bids under applicable Canadian securities laws in connection with the transfer and assignment to Xenon by Teva Canada Limited of the common shares. Xenon has made an application to the OSC for exemptive relief and expects the effective date to be on or about March 22, 2018.

2017 Financial Results

Cash and cash equivalents and marketable securities as of December 31, 2017 were $43.7 million, compared to $64.1 million as of December 31, 2016. There were 17,998,420 common shares outstanding as of December 31, 2017. Based on current assumptions, which include fully supporting the planned clinical development of XEN1101 and XEN901, Xenon anticipates having sufficient cash to fund operations into mid-2019, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

For the year ended December 31, 2017, Xenon reported total revenue of $0.3 million, compared to $1.8 million for the same period in 2016. The decrease of $1.5 million was primarily attributable to revenue recognized related to the upfront payment from the March 2014 genetics collaborative agreement with Genentech, which was fully recognized by March 2016, partially offset by a $0.25 million milestone payment recognized in July 2017 under the same collaborative agreement. The remaining decrease was due to less full-time equivalent funding from collaborative partners as resources were shifted from supporting collaborations to

Xenon's proprietary programs.

Research and development expenses for the year ended December 31, 2017 were $25.6 million, compared to $19.8 million for the same period in 2016. The increase of $5.7 million was primarily attributable to spending on XEN1101 which was acquired in April 2017 and increased spending on pre-clinical, discovery and other internal programs as well as on XEN901, partially offset by a decrease in XEN801 expenses, a product candidate that is no longer being developed, and a decrease in collaboration expenses.

General and administrative expenses for the year ended December 31, 2017 were $7.3 million, compared to $6.8 million for the same period in 2016. The increase of $0.5 million was primarily attributable to increased costs for business development activities and salaries and benefits.

Other income for the year ended December 31, 2017 was $1.9 million and did not change significantly as compared to $1.8 million for the same period in 2016.

Net loss for the year ended December 31, 2017 was $30.7 million, compared to $23.0 million for the same period in 2016. The change was primarily attributable to lower revenue and higher research and development expenses and general and administrative expenses.

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 2017 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 5578516. 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 focused on developing innovative therapeutics to improve the lives of patients with neurological disorders. Building upon our extensive knowledge of human genetics and diseases caused by mutations in ion channels, known as channelopathies, we are advancing – both independently and with our collaborators – a novel product pipeline of central nervous system, or CNS, therapies to address areas of high unmet medical need, such as epilepsy and pain. 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 and Section 21E of the Securities Exchange Act of 1934 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 our expectations regarding the sufficiency of our cash to fund operations into mid-2019, the timing of and results from clinical trials and pre-clinical development activities, including those related to XEN901, XEN1101 and our other product candidates, the plans of our collaboration partners, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN901, XEN1101 and our other product candidates, the anticipated timing of IND, or IND equivalent, submissions and the initiation of future clinical trials for XEN901, XEN1101 and our other product candidates, the efficacy of our clinical trial designs, our ability to successfully develop and achieve milestones in the XEN901, XEN1101 and other development programs, the potential to advance XEN007 directly into a Phase 2 clinical trial, the anticipated benefits of the unique mechanisms of action of XEN901 and XEN1101, the design of our clinical trials and anticipated enrollment, the progress and potential of our other ongoing development programs, the anticipated termination of our collaboration agreement with Teva, and anticipated receipt of the OSC exemptive relief order and the effectiveness of the transfer and assignment of 1,000,000 common shares to us by Teva. 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; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our efforts to expand our current pipeline may not be successful; 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 not permit XEN007 to advance directly into a Phase 2 clinical trial; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; 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.

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XENON PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheets

(Expressed in thousands of U.S. dollars)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 43,667	$ 64,146
Other current assets	1,154	1,529
Other assets	1,300	1,812
Total assets	$ 46,121	$ 67,487
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	3,383	3,586
Loan payable, current portion	700	—
Loan payable, long-term	6,104	—
Total liabilities	$ 10,187	$ 3,586
Shareholders' equity	$ 35,934	$ 63,901
Total liabilities and shareholders' equity	$ 46,121	$ 67,487

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,		
	2017	2016	2015
Revenue:			
Collaboration revenue	$ 309	$ 1,767	$ 15,573
Royalties	2	36	4
	311	1,803	15,577
Operating expenses:			
Research and development	25,573	19,828	15,152
General and administrative	7,313	6,792	9,786
Total operating expenses	32,886	26,620	24,938
Loss from operations	(32,575)	(24,817)	(9,361)
Other income	1,871	1,820	(6,391)
Net loss	(30,704)	(22,997)	(15,752)
Net loss per common share:			
Basic	$ (1.71)	$ (1.48)	$ (1.10)
Diluted	$ (1.72)	$ (1.48)	$ (1.10)
Weighted-average common shares outstanding:			
Basic	17,985,061	15,493,474	14,281,837
Diluted	18,001,759	15,493,474	14,281,837

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