



Aptinyx Reports First Quarter 2019 Financial Results and Provides Corporate Update

May 14, 2019

Four Phase 2 studies expected to be ongoing by year end; multiple data read-outs anticipated in 2019 and 2020

Management to host conference call today at 8:00 a.m. ET

EVANSTON, Ill., May 14, 2019 (GLOBE NEWSWIRE) -- Aptinyx Inc. (Nasdaq: APTX), a clinical-stage biopharmaceutical company developing transformative therapies for the treatment of brain and nervous system disorders, today reported financial results for the first quarter of 2019 and announced recent business highlights.

"So far, 2019 has been marked by the achievement of key milestones and important clinical study results that form the basis for several of our upcoming Phase 2 studies," said Norbert Riedel, Ph.D., president and chief executive officer at Aptinyx. "In the Phase 2 DPN study of NYX-2925, while the primary endpoint was not met in the total study population, importantly, a post-hoc analysis showed significant analgesic effects in subjects with advanced DPN and identified a most appropriate dose level to take forward. This information will be used for a second Phase 2 study in DPN, which we intend to initiate during the second half of the year alongside a Phase 2 study of NYX-2925 we plan to initiate in fibromyalgia. Additionally, we initiated a Phase 2 study of NYX-783 in post-traumatic stress disorder (PTSD) and expect top-line data to be available in the first half of 2020. Further, we reported highly encouraging data from a non-human primate study of NYX-458, in development as a treatment for cognitive impairment associated with Parkinson's disease, showing its ability to reverse cognitive deficits. We also observed a favorable safety, tolerability, and pharmacokinetic profile with NYX-458 in our healthy volunteer Phase 1 study. These accomplishments, combined with our healthy balance sheet, support the four Phase 2 studies across our three clinical programs expected to be ongoing by the end of 2019, setting the stage for a series of potentially catalytic data read-outs within the next 24 months."

First Quarter 2019 and Recent Clinical Program Highlights

- **Reported positive results from Phase 1 study of NYX-458, in development for Parkinson's disease cognitive impairment:** In April 2019, Aptinyx reported [positive results from a Phase 1 clinical study](#) evaluating the safety, tolerability, pharmacokinetics, and CNS penetration of NYX-458 in healthy volunteers. In the study, NYX-458 was safe and well tolerated with no serious adverse events reported. NYX-458 exhibited a dose-proportional and predictable pharmacokinetic profile across a very wide dose range. As evaluated through measurement of concentration in cerebral spinal fluid, NYX-458 readily crosses the blood brain barrier and achieves ample CNS exposure in line with that observed at preclinically efficacious doses. The company expects to initiate a Phase 2 study in the second half of 2019.
- **Reported robust analgesic activity of NYX-2925 in advanced DPN patients:** In April 2019, Aptinyx presented [detailed results from a 300-subject Phase 2 study](#) in patients with painful DPN at the annual meeting of the American Pain Society. While statistically significant separation from placebo was not achieved for the primary endpoint in the total study population, post hoc analysis demonstrated increasing therapeutic benefit of NYX-2925 in patients suffering from DPN for a longer period of time. In particular, the company highlighted results showing that patients in the study who had been diagnosed with DPN for four years or longer (N=127) experienced a clinically meaningful and significant alleviation of their pain with NYX-2925 (p=0.004 vs. placebo). In advanced DPN patients, the 50 mg dose group showed the greatest separation from placebo on the primary efficacy endpoint, and these effects were even more pronounced for patients in this sub-group not taking a concomitant analgesic. These results, which were consistent across the various endpoints in the study, inform the future development of NYX-2925 in chronic pain and the company expects to initiate a Phase 2 study in patients with advanced DPN in the second half of 2019.
- **Presented data showing NYX-458 reversed cognitive deficits in a non-human primate model of Parkinson's disease:** In March 2019, Aptinyx presented findings from two non-human primate studies at the International Conference on Alzheimer's & Parkinson's Diseases (AD/PD™) in Lisbon, Portugal. The results from the first study demonstrated that, in a highly translatable model of Parkinson's disease cognitive impairment, [NYX-458 reversed cognitive deficits](#) in a rapid, robust, and enduring manner. This study employed chronic low doses of MPTP, a neurotoxin, to deplete dopaminergic neurons and induce cognitive deficits similar to those experienced by patients with Parkinson's disease. In the second study, using higher doses of MPTP to induce parkinsonian-like motor symptoms, NYX-458 did not worsen motor symptoms or interfere with the anti-parkinsonian effects of levodopa therapy, the standard of care to treat the motor symptoms of Parkinson's disease.
- **Initiated Phase 2 study of NYX-783 for treatment of PTSD:** In February 2019, [Aptinyx initiated a Phase 2 clinical](#)

[study of NYX-783](#) to characterize its safety, pharmacokinetics, and effects on symptoms in patients with PTSD. Approximately 144 patients will be enrolled and randomly assigned to receive either placebo or NYX-783 over the course of the eight-week study. Multiple efficacy endpoints will be evaluated in the study to assess the impact of NYX-783 across the spectrum of PTSD symptoms. The company expects to report data from this study in the first half of 2020.

Recent Operational Highlight:

- **Announced election of Henry Gosebruch to the Board of Directors:** In early May, Aptinyx announced the [election of industry veteran Henry O. Gosebruch](#) to its board of directors. Mr. Gosebruch is currently executive vice president and chief strategy officer at AbbVie and was formerly co-head of J.P. Morgan's North American M&A Group. His industry expertise and insights will be valuable as the company expands and moves forward with its pipeline of innovative NMDA receptor-modulating therapy candidates.

Expected Near-Term Milestones

- Completion of, and reporting data from, NYX-2925 exploratory Phase 2 study in fibromyalgia in 1H 2019.
- Completion of, and reporting top-line data from, Phase 2 first-in-patient study of NYX-783 in PTSD in 1H 2020.

First Quarter 2019 Financial Results

Cash Position: Cash and cash equivalents were \$136.6 million at March 31, 2019 compared to \$150.6 million at December 31, 2018.

Collaboration and Grant Revenue: Revenue was \$0.9 million for the first quarter of 2019 compared to \$2.5 million for same period in 2018. Aptinyx's revenue was primarily derived from its research collaboration agreement with Allergan and government grants. The decrease was primarily driven by the completion of work related to all outstanding grants in the first half of 2018. The company does not rely on these revenues to fund its operations.

Research and Development (R&D) Expenses: R&D expenses were \$12.5 million for the first quarter of 2019 as compared to \$12.2 million for the same period in 2018. The increase in R&D expenses was primarily driven by support of the company's ongoing development of NYX-2925, NYX-783, and NYX-458.

General and Administrative (G&A) Expenses: G&A expenses were \$5.7 million for the first quarter of 2019 as compared to \$2.0 million for the same period in 2018. The increase in G&A expenses was primarily driven by increased costs related to employee compensation, patent-related matters, and professional fees to support ongoing business operations and compliance with obligations associated with being a publicly traded company.

Net Loss: For the first quarter of 2019, net loss was \$16.7 million compared to a net loss of \$11.7 million for the first quarter 2018.

Conference Call

The Aptinyx management team will host a conference call and webcast today at 8:00 a.m. ET to review its financial results for the first quarter of 2019 and provide a corporate update. To access the call please dial 1-866-930-5579 (domestic) or 1-409-216-0606 (international) and refer to conference ID 8758664. A live webcast of the call will be available on the Investors & Media section of Aptinyx's website at <https://ir.aptinyx.com>. The archived webcast will be available approximately two hours after the conference call and for 30 days thereafter.

About Aptinyx

Aptinyx Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of proprietary synthetic small molecules for the treatment of brain and nervous system disorders. Aptinyx has a platform for discovery of novel compounds that work through a unique mechanism to modulate—rather than block or over-activate—NMDA receptors and enhance synaptic plasticity, the foundation of neural cell communication. The company has three product candidates in clinical development in central nervous system indications, including chronic pain, post-traumatic stress disorder, and cognitive impairment associated with Parkinson's disease. Aptinyx is also advancing additional compounds from its proprietary discovery platform, which continues to generate a rich and diverse pipeline of small-molecule NMDA receptor modulators with the potential to treat an array of neurologic disorders. For more information, visit www.aptinyx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the company's business plans and objectives, including future plans or expectations for the company's product candidates, therapeutic effects of the company's product candidates, expectations regarding the design, implementation, timing, and success of its current and planned clinical studies, the timing for the company's receipt of data from its clinical studies, expectations regarding its preclinical development activities, and expectations regarding its uses and sufficiency of capital. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the company's product candidate development activities and planned clinical studies; the company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; the company's estimates regarding expenses, future revenue, and capital requirements, and other financial results; the company's ability to fund operations through 2020; as well as those risks and uncertainties set forth in the company's most recent Annual Report on Form 10-K and subsequent filings with the Securities and Exchange Commission, including our upcoming quarterly report on Form 10-Q for the period ended March 31, 2019. All forward-looking statements contained in this press release speak only as of the date on which they were made. Aptinyx undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

APTINYX INC.
CONDENSED BALANCE SHEETS
(in thousands)
(Unaudited)

Assets	March 31, 2019	December 31, 2018
Current Assets:		
Cash and cash equivalents	\$ 136,580	\$ 150,637
Restricted cash	252	252
Accounts receivable	415	578
Prepaid expenses and other current assets	1,518	1,784
Total current assets	138,765	153,251
Property and equipment and other long-term assets	2,228	2,363
Total assets	<u>\$ 140,993</u>	<u>\$ 155,614</u>
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable	\$ 1,337	\$ 1,889
Accrued expenses and other current liabilities	4,586	3,996
Total current liabilities	5,923	5,885
Other long-term liabilities	384	418
Total liabilities	6,307	6,303
Stockholders' equity (deficit)	134,686	149,311
Total liabilities and stockholders' equity (deficit)	<u>\$ 140,993</u>	<u>\$ 155,614</u>

APTINYX INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(Unaudited)

	Three Months Ended	
	March 31,	
	2019	2018
Revenues		
Collaboration revenue	\$ 890	\$ 934
Grant revenue	-	1,530
Total Revenues	890	2,464
Operating expenses		
Research and development	12,490	12,224
General and administrative	5,725	2,049
Total operating expenses	18,215	14,273
Loss from operations	(17,325)	(11,809)
Other income	614	137
Net loss and comprehensive loss	<u>\$ (16,711)</u>	<u>\$ (11,672)</u>
Net loss per share - basic and diluted	<u>\$ (0.50)</u>	<u>\$ (2.17)</u>
Weighted average shares outstanding - basic and diluted	<u>33,390</u>	<u>5,378</u>

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