



Aptinyx Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

March 30, 2020

Initiated four Phase 2 clinical studies based on compelling prior data

Actions taken on ongoing clinical studies due to COVID-19 pandemic

Strong cash position following recently completed common stock offering provides runway into 2022

Conference call today at 5:00 p.m. EDT

EVANSTON, Ill., March 30, 2020 (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 fourth quarter and full year 2019 and provided updates across the company's pipeline of novel NMDA receptor modulators. Aptinyx has three distinct product candidates in Phase 2 clinical development across three primary therapeutic areas: chronic pain, post-traumatic stress disorder (PTSD), and cognitive impairment.

"We made great progress in 2019 across our programs in chronic pain, PTSD, and cognitive impairment, highlighted by the initiation of four Phase 2 studies and positive clinical read-outs on NYX-2925 and NYX-458," said Norbert Riedel, Ph.D., president and chief executive officer of Aptinyx. "Like other life sciences companies, we have had to assess the impact of the evolving COVID-19 pandemic on the enrollment and conduct of our ongoing Phase 2 studies. The health and safety of the patients, clinicians, and colleagues involved in our studies are of the utmost importance to Aptinyx. Under these unprecedented circumstances, we are taking actions to address and react to operational challenges and reduce the risk of viral infection. We are fortunate to have a strong balance sheet and we currently expect our cash on hand, including the approximately \$33 million in net proceeds from our January financing, to support our operations into 2022."

Actions Taken on Ongoing Clinical Studies Due to COVID-19 Pandemic

The company has worked closely with the clinicians and study personnel involved in each of its ongoing studies to evaluate the impacts of the COVID-19 pandemic and identify the most appropriate measures to ensure patient safety and data integrity.

- **NYX-783 exploratory Phase 2 study in PTSD.** This study is approximately 80% enrolled to date. At present, Aptinyx has been able to mitigate and manage the impacts of COVID-19 on the study through measures such as home delivery of study drug and virtual participant follow-up. While monitoring the impacts of COVID-19 continuously, the company intends to continue enrollment of patients as long as it is responsible and practical to do so. Aptinyx anticipates providing updated guidance on the expected timing of study completion and reporting of data at a future date.
- **NYX-2925 Phase 2b studies in painful diabetic peripheral neuropathy (DPN) and fibromyalgia.** On March 27, 2020, Aptinyx temporarily suspended enrollment of new patients in these studies. Aptinyx has instituted certain measures to support the continuity of patients currently enrolled, but the challenges posed by the COVID-19 pandemic to patient recruitment, screening, and randomization limit the feasibility of enrolling new patients at the present time. Aptinyx anticipates updating guidance around the expected timing of reporting top-line data from these studies at a future date following the recommencement of enrollment.
- **NYX-458 exploratory Phase 2 study in Parkinson's disease cognitive impairment.** On March 27, 2020, Aptinyx temporarily suspended enrollment of new patients in this study. The elevated risk of the COVID-19 pandemic to the relatively elderly patient population in this study, as well as the challenges of administering cognitive assessments remotely, limit the feasibility of enrolling new patients in this study at the present time. Aptinyx anticipates updating guidance around the expected timing of reporting data from this study at a future date following the recommencement of enrollment.

Pipeline and Corporate Updates

Chronic Pain Franchise – NYX-2925:

Aptinyx is developing NYX-2925 for the treatment of chronic centralized pain conditions. To date, NYX-2925 has been studied in more than 400 human subjects, including three Phase 1 studies in healthy volunteers and two completed Phase 2 studies in patients with chronic pain. Across all of these studies, NYX-2925 has been well tolerated with no drug-related serious adverse events reported.

- **Development in painful DPN:** In January 2019, Aptinyx reported results from a 300-patient Phase 2 study in patients with painful DPN.

- **Results:**

- On the primary endpoint, change in average daily pain score at week four, statistically significant separation from placebo was not observed for the total study population (N=300); however, a clinically meaningful reduction in pain scores from baseline was observed with a numeric separation from placebo.
- In a pre-specified analysis, patients not taking a concomitant analgesic (N=147) showed even greater separation from placebo at week 4 compared to the overall population.
- A retrospective analysis demonstrated that, consistent with the mechanism of NYX-2925 targeting the centralized pain processing that manifests over time, as duration of DPN increased, a greater benefit with NYX-2925 was observed. In advanced DPN patients—patients with DPN for four years or longer (N=127)—NYX-2925 demonstrated clinically meaningful and statistically significant separation from placebo on the change in average daily pain score and other patient-reported symptoms.
- The 50 mg dose demonstrated the largest and most consistent separation from placebo within the study.
- Aptinix presented the detailed findings from this study at the American Pain Society Annual Meeting in April 2019.
- Next steps:
 - The signal observed in the first Phase 2 study informed Aptinix's initiation of a follow-up Phase 2b study in patients with painful DPN. This study is a randomized, double-blind, parallel-design, placebo-controlled study to evaluate daily oral dosing of 50 mg of NYX-2925 compared to placebo in approximately 200 patients with advanced DPN. The primary endpoint is the change in average daily pain score over a 12-week period as reported on the 10-point numeric rating scale (NRS).
 - Due to screening and enrollment challenges introduced by the COVID-19 pandemic, on March 27, 2020, Aptinix temporarily suspended enrollment of new patients in this Phase 2b study. Patients already enrolled may continue in the study as per protocol and based on medical guidance.
 - Aptinix anticipates updating guidance around the expected timing of reporting top-line data from this Phase 2b study at a future date following the recommencement of enrollment.

• **Development in fibromyalgia:** In June 2019, Aptinix reported results from a 22-patient Phase 2 neuroimaging biomarker study in patients with fibromyalgia.

- Results:
 - NYX-2925 met the primary endpoint in the study, exhibiting statistically significant effects on validated neuroimaging biomarkers in certain pre-specified brain regions known to be involved in centralized pain processing.
 - NYX-2925 also demonstrated corresponding statistically significant improvements on key secondary endpoints—measures of patient-reported symptoms, including pain scores, overall fibromyalgia impact, and fatigue.
 - The results from this study were presented at the American College of Rheumatology Annual Meeting in November 2019 as a late-breaking presentation.
- Next steps:
 - Based on the positive results and activity observed in the initial Phase 2 biomarker study, Aptinix initiated a follow-up Phase 2b study in patients with fibromyalgia. The study is a randomized, double-blind, parallel-design, placebo-controlled study to evaluate daily oral dosing of two dose levels of NYX-2925 (50 mg and 100 mg) compared to placebo in approximately 300 patients with fibromyalgia. The primary endpoint is the change in average daily pain score over a 12-week period as reported on the 10-point NRS.
 - Due to screening and enrollment challenges introduced by the COVID-19 pandemic, on March 27, 2020, Aptinix temporarily suspended enrollment of new patients in this study. Patients already enrolled in the Phase 2 study may continue in the study as per protocol and based on medical guidance.
 - Aptinix anticipates updating guidance around the expected timing of reporting top-line data from this Phase 2b study at a future date following the recommencement of enrollment.

Psychiatry Franchise – NYX-783:

Aptinix is developing NYX-783 for the treatment of post-traumatic stress disorder. In a Phase 1 study conducted in healthy volunteers, NYX-783 was well tolerated with no drug-related serious adverse events reported.

• **Development in post-traumatic stress disorder (PTSD):** In February 2019, Aptinix initiated a first-in-patient Phase 2 exploratory study of NYX-783 in patients with PTSD.

- Phase 2 study:
 - The study is a double-blind, placebo-controlled, sequential parallel comparison design (SPCD) study in approximately 150 patients with PTSD. The study consists of two four-week stages in which patients are randomly assigned to receive once-daily doses of either placebo, 10 mg of NYX-783, or 50 mg NYX-783.
 - This first Phase 2 study in PTSD patients evaluates whether NYX-783 exhibits a signal of efficacy on the CAPS-5 composite endpoint of PTSD symptoms as well as its sub-scores.
 - Multiple other efficacy endpoints are under evaluation in the study to assess the impact of NYX-783 across a

spectrum of PTSD symptoms.

- Next steps:
 - Aptinyx is currently enrolling patients in this Phase 2 exploratory study and approximately 80% of the target enrollment has been achieved to date.
 - The COVID-19 pandemic has resulted in some disruptions at the site level in this Phase 2 study, which Aptinyx has been able to mitigate and manage to date. Notwithstanding, Aptinyx is actively and continuously monitoring any further impacts the COVID-19 pandemic may have on this study and anticipates providing updated guidance on the expected timing of its completion and reporting of data at a future date.

Neurology Franchise – NYX-458:

Aptinyx is developing NYX-458 for the treatment of cognitive impairment associated with Parkinson's disease. In a Phase 1 study conducted in healthy volunteers, NYX-458 was well tolerated with no drug-related serious adverse events reported.

• **Development in Parkinson's disease cognitive impairment** : In December 2019, based on compelling preclinical data including those from a highly translatable model in non-human primates, Aptinyx initiated a first-in-patient Phase 2 exploratory study of NYX-458 in patients with mild cognitive impairment associated with Parkinson's disease (Parkinson's MCI).

- Phase 2 study:
 - The Phase 2 study is a randomized, double-blind, parallel-design, placebo-controlled study to evaluate the safety and potential cognitive benefits of daily oral dosing of three dose levels of NYX-458 (10 mg, 30 mg, and 100 mg) compared to placebo in approximately 135 patients with Parkinson's MCI over a 12-week period.
 - This exploratory study evaluates the safety of NYX-458 in patients with Parkinson's MCI, as well as its effects on cognitive performance using multiple measures across various cognitive domains.
- Next steps:
 - Due to clinical study conduct challenges introduced by the COVID-19 pandemic, on March 27, 2020, Aptinyx temporarily suspended enrollment of new patients in this study. Patients already enrolled in the Phase 2 study may continue in the study as per protocol and based on medical guidance.
 - Aptinyx anticipates updating guidance around the expected timing of reporting data from this Phase 2 exploratory study at a future date following the recommencement of enrollment.

• **Publication of data in *Movement Disorders* demonstrating reversal of cognitive deficits with NYX-458 in primate model of Parkinson's disease.** In January 2020, Aptinyx announced a publication in *Movement Disorders* highlighting the results of a preclinical study of NYX-458 in a validated and translatable model of Parkinson's disease in non-human primates. In the study, administration of NYX-458 resulted in a robust and enduring reversal of MPTP-induced cognitive deficits. The data were published in the January 2020 issue of *Movement Disorders*, the official journal of the International Parkinson and Movement Disorder Society.

Corporate Updates:

• **Strengthened the company's financial position through the completion of a \$35 million common stock offering.** In early January 2020, Aptinyx announced the closing of a public offering of common stock with gross proceeds totaling \$35.1 million, inclusive of the full exercise of the underwriters' option to purchase additional shares and before deducting underwriting discounts and commissions and offering expenses. The offering included participation from new and existing investors. The company's current cash balance, inclusive of the proceeds from the offering, is expected to provide financial support into 2022.

• **Key strategic and regulatory expertise added to Aptinyx's Board of Directors.** In 2019, Aptinyx appointed two new members to its Board of Directors. Henry Gosebruch, chief strategy officer at AbbVie and former co-head of J.P. Morgan's North American M&A group, joined the company's Board in May 2019. Additionally, Rachel Sherman, M.D., M.P.H., former principal deputy commissioner of the U.S. Food and Drug Administration (FDA), joined the company's Board in September 2019.

Fourth Quarter and Full Year 2019 Financial Results

Cash Position: Cash and cash equivalents were \$98.8 million at December 31, 2019, compared to \$150.6 million at December 31, 2018. Subsequently, Aptinyx completed a follow-on public offering of common stock in January 2020 with net proceeds of approximately \$33.3 million.

Collaboration and Grant Revenue: Revenue was \$0.9 million and \$3.7 million for the fourth quarter and full year 2019, respectively, as compared to \$1.0 million and \$6.6 million for same periods in 2018. Aptinyx's revenue was primarily derived from its research collaboration agreement with Allergan. The company does not rely on these revenues to fund its operations. The decrease in collaboration and grant revenue compared to 2018 was primarily driven by the receipt of a \$1.0 million option exercise fee from Allergan in 2018, as well as the completion of grant-related activities in 2018.

Research and Development (R&D) Expenses: R&D expenses were \$10.6 million and \$44.3 million for the fourth quarter and full year 2019, respectively, as compared to \$10.9 million and \$48.8 million for same periods in 2018. The decrease in R&D expenses during 2019 was primarily driven by a reduction in product and clinical development spend related to NYX-2925 and a decrease in costs associated with our preclinical research efforts with external research organizations.

General and Administrative (G&A) Expenses: G&A expenses were \$4.5 million and \$19.0 million for the fourth quarter and full year 2019, respectively, as compared to \$4.8 million and \$12.7 million for the same periods in 2018. The increase in G&A expenses was primarily driven by increased costs related to employee compensation, including a \$4.1 million increase in non-cash stock-compensation expense for the full year 2019,

increased professional fees and insurance costs to support ongoing business operations, and patent-related costs associated with developing a robust patent estate covering the company's novel product candidates.

Net Loss: Net loss was \$13.8 million for the fourth quarter of 2019 compared to a net loss of \$14.1 million for the same period in 2018. For the year ended December 31, 2019, net loss was \$57.4 million, or basic and diluted net loss per share attributable to common stockholders of \$1.71, compared to a net loss \$53.3 million, or basic and diluted net loss per share attributable to common stockholders of \$2.64, for the year ended December 31, 2018.

Financial Guidance: Aptinyx expects that current cash, inclusive of the \$33.3 million in net proceeds from the common stock offering in January 2020, will be sufficient to fund the company's planned operations into 2022.

Conference Call

The Aptinyx management team will host a conference call and webcast today at 5:00 p.m. EDT to review its financial results and highlights for the full year 2019 and to provide other business updates. To access the call, please dial 1-866-930-5579 (domestic) or 1-409-216-0606 (international) and refer to conference ID 3837499. 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 NYX-2925, NYX-783, and NYX-458, therapeutic effects of the company's product candidates and discovery platform, expectations regarding the design, implementation, timing, and success of its current and planned clinical studies, including providing updated guidance with respect thereto, the timing for the company's receipt and announcement of data from its clinical studies, expectations regarding its preclinical development activities, expectations regarding its uses and sufficiency of capital and the effect of COVID-19 on the foregoing. Risks that contribute to the uncertain nature of the forward-looking statements include: the effect of COVID-19 on our business and financial results, including with respect to disruptions to our clinical trials, business operations, and ability to raise additional capital; 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; the company's ability to fund operations through 2021; as well as those risks and uncertainties set forth in the company's most recent quarterly report on Form 10-Q and subsequent filings with the Securities and Exchange Commission, including our upcoming Annual Report on Form 10-K for the year ended December 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)

	December 31, 2019	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	\$ 98,849	\$ 150,637
Restricted cash	179	252
Accounts receivable	444	578
Prepaid expenses and other current assets	5,637	1,784
Total current assets	105,109	153,251
Property and equipment and other long-term assets	1,370	2,363
Total assets	\$ 106,479	\$ 155,614
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable	\$ 1,555	\$ 1,889
Accrued expenses and other current liabilities	3,341	3,996
Total current liabilities	4,896	5,885

Other long-term liabilities	272	418
Total liabilities	5,168	6,303
Convertible preferred stock	—	—
Stockholders' equity (deficit)	101,311	149,311
Total liabilities and stockholders' equity (deficit)	<u>\$ 106,479</u>	<u>\$ 155,614</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Collaboration and grant revenue	\$ 918	\$ 1,039	\$ 3,669	\$ 6,574
Operating expenses				
Research and development	10,598	10,928	44,330	48,788
General and administrative	4,533	4,822	18,952	12,674
Total operating expenses	<u>15,131</u>	<u>15,750</u>	<u>63,282</u>	<u>61,462</u>
Loss from operations	(14,213)	(14,711)	(59,613)	(54,888)
Other income	435	618	2,203	1,607
Net loss and comprehensive loss	<u>\$ (13,778)</u>	<u>\$ (14,093)</u>	<u>\$ (57,410)</u>	<u>\$ (53,281)</u>
Net loss per share - basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.42)</u>	<u>\$ (1.71)</u>	<u>\$ (2.64)</u>
Weighted average shares outstanding - basic and diluted	<u>33,692</u>	<u>33,286</u>	<u>33,556</u>	<u>20,199</u>

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