



Aptinyx Reports First Quarter 2021 Financial Results and Highlights

Enrollment on track in both Phase 2b studies of NYX-2925 in chronic pain—data readouts expected 1H 2022

Preparing for NYX-783 Phase 2b PTSD study following recent FDA meeting — study initiation expected in 2H 2021

Recommended Phase 2 study of NYX-458 in patients with cognitive impairment—data readout expected 2H 2022

\$146.8 million cash position expected to support operations through multiple Phase 2 readouts and into 2023

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

EVANSTON, Ill., May 13, 2021 -- Aptinyx Inc. (Nasdaq: APTX), a clinical-stage biopharmaceutical company developing transformative therapies for the treatment of nervous system disorders, today reported financial results for the first quarter of 2021 and highlighted recent progress across the company's pipeline of novel, clinical-stage, NMDA receptor modulators.

"We have made excellent progress across our clinical-stage programs over the past few months," said Norbert Riedel, Ph.D., chief executive officer of Aptinyx. "This progress was exemplified by our positive meeting with the FDA regarding our development of NYX-783 in PTSD, and the recommencement of our Phase 2 study of NYX-458 in patients with Parkinson's disease and dementia with Lewy bodies. In conjunction with the continued execution across our two chronic pain studies, in which patient enrollment remains on track, these important milestones position us well to continue advancing our novel therapeutic candidates. We anticipate that our strong financial position will fund the company through multiple Phase 2 clinical study readouts in 2022 and into 2023."

First Quarter 2021 and Recent Clinical Program Highlights

- **Conducted Type C meeting with FDA to discuss future development of NYX-783 in PTSD.** In April, Aptinyx met with the U.S. Food and Drug Administration (FDA) to discuss its development plans for NYX-783 in PTSD, including the design of a planned Phase 2b study. Based on the meeting, the company intends to finalize the design of the planned Phase 2b study such that, if the data are positive, it could be positioned for potential FDA consideration as one of the two well-controlled studies required for registration. Any such consideration would be a matter for review at the FDA's discretion following the completion of the study. The company expects to provide more information regarding the Phase 2b study design at a later date and to initiate the Phase 2b study in the second half of 2021.
- **Presented additional positive data from exploratory Phase 2 study of NYX-783 in PTSD at the SOBP Annual Meeting.** In April, Aptinyx [presented](#) additional data from its completed exploratory Phase 2 study of NYX-783 in patients with PTSD at the Society of Biological Psychiatry Annual Meeting. These additional

data and analyses from Stage 1 of the study had not been previously disclosed:

- A significantly greater proportion ($p < 0.05$) of patients achieved a Clinically Reliable Change (improvement of ≥ 13 points on the CAPS-5 Total score) in the 50 mg treatment group compared to placebo.
- When accounting for baseline imbalances across treatment groups in patients' time since trauma, the percentage improvement on the CAPS-5 Total score for the NYX-783 50 mg group was significantly greater than that in the placebo group ($p < 0.05$).
- **Recommended exploratory Phase 2 study of NYX-458 in patients with cognitive impairment.** In March, Aptinyx [announced](#) the recommencement of its exploratory Phase 2 study of NYX-458 in patients with cognitive impairment associated with Parkinson's disease and dementia with Lewy bodies. Enrollment in this study had previously been suspended due to the escalation of the COVID-19 pandemic. This exploratory Phase 2 study is designed to detect signals of therapeutically relevant activity across various measures of cognitive performance, as well as assess the safety and tolerability profile of NYX-458 in patients. The company expects to enroll approximately 100 patients in the study and anticipates reporting data from the study in the second half of 2022.
- **Announced election of Dr. Joan W. Miller to the Board of Directors.** In May, Aptinyx announced the election of Joan W. Miller, M.D. to its board of directors. Dr. Miller currently serves as the David Glendenning Cogan Professor of Ophthalmology and Chair of the Department of Ophthalmology at Harvard Medical School, as well as Chief of Ophthalmology at both Massachusetts Eye and Ear and Massachusetts General Hospital. Dr. Miller brings extensive experience in academic and medical leadership, clinical development, and clinical research to Aptinyx's board.

Upcoming Milestones

- Initiation of Phase 2b study of NYX-783 in patients with PTSD – 2H 2021
- Data readout from Phase 2b study of NYX-2925 in patients with fibromyalgia – 1H 2022
- Data readout from Phase 2b study of NYX-2925 in patients with painful DPN – 1H 2022
- Data readout from exploratory Phase 2 study of NYX-458 in cognitive impairment – 2H 2022

First Quarter 2021 Financial Results

Cash Position: Cash and cash equivalents were \$146.8 million at March 31, 2021 compared to \$141.0 million at December 31, 2020. Aptinyx expects its current cash balance to support anticipated operations into 2023.

Collaboration Revenue: Revenue was \$1.0 million for the first quarter of 2021 compared to \$0.8 million for same period in 2020. Aptinyx's revenue was derived from its research collaboration agreement with Allergan, a subsidiary of AbbVie. The company does not rely on these revenues to fund its operations.

Research and Development (R&D) Expenses: R&D expenses were \$10.3 million for the first quarter of 2021 as compared to \$11.1 million for the same period in 2020. The decrease in R&D expenses was primarily driven by the completion of the exploratory Phase 2 study of NYX-783 in PTSD in October 2020 and the temporary suspension of enrollment in the exploratory Phase 2 study of NYX-458 in cognitive impairment—the latter of which recommenced in March. The decrease was partially offset by increased costs related to the recommencement of the company's two Phase 2b studies of NYX-2925 in chronic pain.

General and Administrative (G&A) Expenses: G&A expenses were \$5.0 million for the first quarter of 2021 as compared to \$4.9 million for the same period in 2020.

Net Loss: For the first quarter of 2021, net loss was \$14.2 million compared to a net loss of \$14.7 million for the first quarter 2020.

Conference Call

The Aptinyx management team will host a conference call and webcast today at 5:00 p.m. ET to review its financial results and highlights for the first quarter of 2021 and subsequent period. To access the call, please dial (833) 772-0394 (domestic) or (236) 738-2205 (international) and refer to conference ID 3628539. 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. 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 or follow Aptinyx on Twitter [@Aptinyx](https://twitter.com/Aptinyx).

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, or NYX-458, including 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, effects of the COVID-19 pandemic on patient enrollment and the expected timing of study completion, and data reporting, 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, including the operational runway of its current cash balance, and the effect of the COVID-19 pandemic on the foregoing. Risks that contribute to the uncertain nature of the forward-looking statements include: the effect of the COVID-19 pandemic on our business and financial results, including with respect to disruptions to our clinical studies, 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 into 2023; 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, 2021. 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, 2021	December 31, 2020
Current Assets:		
Cash and cash equivalents	\$ 146,810	\$ 141,028
Restricted cash	179	179
Accounts receivable	0	257
Prepaid expenses and other current assets	5,421	8,140
Total current assets	152,410	149,604
Property and equipment, net and other long-term assets	480	1,002
Total assets	\$ 152,890	\$ 150,606
 Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable	\$ 1,674	\$ 1,209
Accrued expenses and other current liabilities	2,204	3,374
Total current liabilities	3,878	4,583
Other long-term liabilities	71	114
Total liabilities	3,949	4,697
Stockholders' equity	148,941	145,909
Total liabilities and stockholders' equity	\$ 152,890	\$ 150,606

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

	Three Months Ended March 31,	
	2021	2020
Revenues		
Collaboration revenue	\$ 1,000	\$ 818
Operating expenses		
Research and development	10,314	11,055
General and administrative	4,976	4,899
Total operating expenses	15,290	15,954
Loss from operations	(14,290)	(15,136)
Other income	64	426
Net loss and comprehensive loss	\$ (14,226)	\$ (14,710)
Net loss per share - basic and diluted	\$ (0.22)	\$ (0.34)
Weighted average shares outstanding - basic and diluted	66,043	43,835

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Source: Aptinyx Inc.