



Aptinyx Reports Third Quarter 2022 Financial Results and Recent Highlights

Company expects to report results from Phase 2 study of NYX-458 in cognitive impairment in 1Q 2023

\$5.6 million NIH grant finalized for research and development of NYX-783 in opioid use disorder

\$67 million cash balance provides operational runway into 2024 and enables readouts from multiple Phase 2 studies

Management to host conference call today at 5:00 p.m. ET

EVANSTON, Ill., November 8, 2022 -- 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 third quarter of 2022 and provided key business updates across the company's clinical-stage pipeline of novel NMDA receptor modulators.

"During the quarter, we took decisive steps to focus our resources on enabling data readouts from our ongoing clinical studies and maintaining cash runway into 2024," said Andy Kidd, M.D., president and chief executive officer of Aptinyx. "Our pipeline continues to progress towards meaningful data catalysts next year, beginning with our Phase 2 study of NYX-458 in cognitive impairment associated with Parkinson's disease. The study is robustly designed to characterize the therapeutic effects of NYX-458 and will measure improvements in cognitive deficits that impact nearly half of all patients with Parkinson's disease. We look forward to reporting data from this study in the first quarter of next year, as well as to data from our Phase 2b study of NYX-783 in PTSD expected later in the year. We are also pleased to be expanding our pipeline through the clinical evaluation of NYX-783 in opioid use disorder, to be conducted by skilled researchers at Yale University School of Medicine and funded by an NIH grant."

Recent Business Highlights

- **Readout of Phase 2 study of NYX-458 in cognitive impairment expected in 1Q 2023.**
 - In August 2022, Aptinyx [announced](#) the completion of enrollment of 99 patients in its ongoing Phase 2 study of NYX-458 in cognitive impairment associated with Parkinson's disease (PD) and dementia with Lewy bodies (DLB).
 - The majority of patients enrolled in the study have a diagnosis of mild cognitive impairment or dementia associated with PD, with fewer patients diagnosed with DLB.
 - The Phase 2 study is a randomized, double-blind, parallel-design, placebo-controlled study to evaluate the efficacy and safety of 12 weeks of daily dosing of NYX-458.
 - The primary endpoint in the study is overall safety and tolerability of NYX-458.
 - Secondary endpoints are evaluated using a battery of six computerized neurocognitive tests (offered by Cogstate, a leading provider of brain health assessments) selected for their relevance to the

specific cognitive domains affected by PD. Improvements relative to baseline and placebo will be measured on:

- A composite score of the Cogstate PD cognitive battery of tests
- Four sub-scores for each of the cognitive domains assessed (Attention, Learning & Memory, Working Memory, and Executive Function), each comprising a subset of the Cogstate PD cognitive battery of tests
- Each of the six individual tests in the Cogstate PD cognitive battery, which include:
 - ✧ Continuous Paired Associate Learning Test
 - ✧ Groton Maze Learning Test
 - ✧ Identification Test
 - ✧ International Shopping List Test
 - ✧ One Back Test
 - ✧ Two Back Test
- Two additional exploratory endpoints evaluate patients' everyday cognitive function:
 - Everyday Cognition-12 (Ecog-12) scale, assessing cognitively relevant functional abilities
 - Penn Parkinson's Daily Activities Questionnaire (PDAQ-15), assessing daily function dependent on cognition
- **Enrollment in Phase 2b study of NYX-783 in post-traumatic stress disorder (PTSD) is progressing.**
 - The company's ongoing Phase 2b study will enroll approximately 300 patients with PTSD, randomized to receive oral doses of NYX-783 50 mg or placebo once daily over a 10-week treatment period.
 - The primary endpoint in the study is the change from baseline in the Clinician-Administered PTSD Scale for the DSM-5 (CAPS-5) total score.
 - Key secondary endpoints include measures of clinicians' and patients' global impressions of severity and improvement (CGI-S, CGI-I, PGI-S, PGI-I).
 - The company expects to report data from the Phase 2b study in the second half of 2023.
- **\$5.6 million NIH grant finalized for research and development of NYX-783 for the treatment of opioid use disorder (OUD).**
 - In November, the company announced the finalization of a grant, issued to researchers at Yale University School of Medicine, funding the research and development of NYX-783 for the treatment of OUD.
 - The \$5.6 million grant was awarded under the National Institutes of Health (NIH) Helping to End Addiction Long-term (HEAL) Initiative, administered by the National Institute on Drug Abuse (NIDA).
 - The first clinical study funded by the grant will be a randomized, double-blind, placebo-controlled, Phase 1 drug-drug interaction study to assess the safety, tolerability, and pharmacokinetics of NYX-783 in combination with oxycodone in individuals who use opioids.
 - The primary outcomes of the study will evaluate a variety of safety-related measures.
 - Secondary outcome measures will evaluate opiate withdrawal and symptom scales.
 - The study will be administered by the Yale Interdisciplinary Stress Center through a research collaboration with Aptinyx.
 - The researchers at Yale University School of Medicine expect to complete the Phase 1 study in the second half of 2023.

Pipeline Updates

- **NYX-2925 Phase 2b fibromyalgia study results reported.**
 - In August 2022, Aptinyx announced that the primary endpoint was not achieved in its Phase 2b study

- of NYX-2925 in patients with fibromyalgia.
- NYX-2925 was well tolerated in the study, with no concerning safety issues observed.
- The company does not intend to dedicate additional resources to the development of NYX-2925 for chronic pain.

Third Quarter 2022 Financial Results

Cash Position: Cash and cash equivalents were \$66.5 million as of September 30, 2022, compared to \$106.1 million as of December 31, 2021. Aptinyx expects its current cash balance to fund readouts from each of the company's Phase 2 clinical development programs and support anticipated operations into 2024.

Research and Development (R&D) Expenses: Research and development expenses were \$10.0 million for the three months ended September 30, 2022, compared to \$16.2 million for the three months ended September 30, 2021. The decrease in R&D expenses was primarily driven by the completion of the company's Phase 2b studies of NYX-2925 in patients with painful diabetic peripheral neuropathy in April 2022 and in patients with fibromyalgia in August 2022.

General and Administrative (G&A) Expenses: General and administrative expenses were \$4.6 million for the three months ended September 30, 2022, compared to \$4.9 million for the same period in 2021.

Net Loss: Net loss was \$15.3 million for the third quarter of 2022, compared to a net loss of \$21.2 million for the third quarter of 2021.

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 third quarter of 2022 and subsequent period. To access the live conference call, please dial 844-200-6205 (domestic) or 929-526-1599 (international) and refer to conference ID 141144. A live audio webcast of the event will be available on the Investors & Media section of Aptinyx's website at <https://ir.aptinyx.com>. A replay of the webcast will be archived on Aptinyx's website for 30 days following the event.

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 multiple product candidates in clinical development in central nervous system indications, including cognitive impairment, post-traumatic stress disorder, and opioid use disorder. 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-783 or NYX-458, the potential 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, the timing for the company's receipt and announcement of data from its clinical studies, and the company's expectations regarding its uses and sufficiency of capital, including the operational runway of its current cash balance. Risks that contribute to the uncertain nature of the forward-looking statements include: the effect of the COVID-19 pandemic on the company's business and financial results, including with respect to disruptions to the company's 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 2024 and the company's ability to raise additional capital; 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 the company's upcoming Quarterly Report on Form 10-Q for the period ended September 30, 2022. 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	September 30, 2022	December 31, 2021
Current Assets:		
Cash and cash equivalents	\$ 66,584	\$ 106,124
Restricted cash	179	197
Prepaid expenses and other current assets	7,187	8,422
Total current assets	73,950	114,743
Property and equipment, net and other long-term assets	2,255	185
Total assets	\$ 76,205	\$ 114,928
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable	\$ 474	\$ 622
Accrued expenses and other current liabilities	2,220	5,064
Total current liabilities	2,694	5,686
Term loan, non-current	24,709	14,155
Other long-term liabilities	10	331
Total liabilities	27,413	20,172
Stockholders' equity	48,792	94,756
Total liabilities and stockholders' equity	\$ 76,205	\$ 114,928

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues				
Collaboration revenue	\$ —	\$ —	\$ —	\$ 1,000
Operating expenses				
Research and development	10,008	16,278	35,519	41,388
General and administrative	4,649	4,928	15,622	14,974
Total operating expenses	14,657	21,206	51,141	56,362
Loss from operations	(14,657)	(21,206)	(51,141)	(55,362)
Other (income) expense, net	(208)	(47)	(432)	(158)
Interest Expense	854	72	2,088	72
Net loss and comprehensive loss	\$ (15,303)	\$ (21,231)	\$ (52,797)	\$ (55,276)
Net loss per share - basic and diluted	\$ (0.23)	\$ (0.31)	\$ (0.78)	\$ (0.82)
Weighted average shares outstanding - basic and diluted	67,716	67,716	67,716	67,053

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Source: Aptinyx Inc.