
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Act of 1934

Date of Report (Date of earliest event reported): **November 12, 2019**

APTINYX INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-38535
(Commission File Number)

45-4626057
(I.R.S. Employer Identification
Number)

909 Davis Street, Suite 600
Evanston, IL
(Address of principal executive offices)

60201
(Zip Code)

(847) 871-0377
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13d-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	APTX	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On November 12, 2019, Aptinyx Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 12, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aptinyx Inc.

Date: November 12, 2019

By: /s/ Ashish Khanna
Ashish Khanna
Chief Financial Officer and Chief Business Officer



Aptinyx Reports Third Quarter 2019 Financial Results and Highlights

Initiated two Phase 2 studies of NYX-2925 in chronic pain conditions

On track to have four Phase 2 studies ongoing by year end across pipeline of CNS product candidates

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

EVANSTON, Ill., November 12, 2019 — 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 2019 and highlighted recent progress across the company's pipeline of novel NMDA receptor modulators.

"We made significant progress in the third quarter and subsequent period, including the initiation of two Phase 2 studies of NYX-2925 in patients with painful DPN and fibromyalgia," said Norbert Riedel, Ph.D., president and chief executive officer of Aptinyx. "By the end of the year, we will have four Phase 2 studies ongoing, including the pain studies, our study of NYX-783 in PTSD, and a study of NYX-458 in Parkinson's cognitive impairment that we will initiate very soon. We set out to build a transformative neuroscience company, and these pipeline advances are key steps in achieving our goal of bringing novel medicines to patients in need of better therapeutic options."

Third Quarter 2019 and Recent Highlights

- **Initiated a Phase 2 study of NYX-2925 in patients with painful diabetic peripheral neuropathy.** Earlier today, Aptinyx announced the initiation of a Phase 2 study evaluating the effects of NYX-2925 in patients with painful diabetic peripheral neuropathy (DPN). The study is evaluating daily oral dosing of NYX-2925 50 mg compared to placebo. The primary endpoint is the change from baseline in average daily pain score over a 12-week period as reported on the 10-point numeric rating scale (NRS). The company expects to report top-line results from this study in late 2020 or early 2021.
 - **Initiated a Phase 2 study of NYX-2925 in patients with fibromyalgia.** Earlier today, Aptinyx announced the initiation of a Phase 2 study evaluating the effects of NYX-2925 in patients with fibromyalgia. The study is evaluating daily oral dosing of two dose levels of NYX-2925—50 mg and 100 mg—compared to placebo. The primary endpoint is the change from baseline in average daily pain score over a 12-week period as reported on the 10-point numeric rating scale (NRS). The company expects to report top-line results from this study in the first half of 2021.
 - **Results of a Phase 2 fibromyalgia study of NYX-2925 were selected for a late-breaking presentation at the American College of Rheumatology Annual Meeting (ACR/ARP).** In October 2019, Aptinyx announced that data from its Phase 2 neuroimaging study of NYX-2925 in patients with fibromyalgia were selected to be presented in a late-breaking poster presentation at the ACR Annual Meeting. The results of the study show that NYX-2925 had statistically significant effects on neuroimaging biomarkers associated with
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central pain processing and that it significantly improved patient-reported symptoms of fibromyalgia. The ePoster was presented today, November 12, 2019 in Atlanta, Georgia.

- **Presented preclinical data on all three clinical-stage product candidates at the 49th Annual Meeting of the Society for Neuroscience.** In October 2019, Aptinyx announced six presentations at the 49th Annual Meeting of the Society for Neuroscience. The presentations exhibited preclinical data supporting the development of each of the company's three novel NMDA receptor modulators, NYX-2925, NYX-783, and NYX-458, in chronic pain, PTSD, and cognitive impairment, respectively.
- **Three preclinical publications highlighted NMDA receptor activation facilitated by NYX-2925.** In September 2019, Aptinyx announced the publication of three papers in peer-reviewed scientific journals. The publications describe the novel mechanism of action of NYX-2925 and demonstrate that its activation of NMDA receptors leads to enhanced synaptic plasticity, or neuronal communication.
- **Former principal deputy commissioner of the FDA, Rachel Sherman, M.D., joined the company's Board of Directors.** In September 2019, Aptinyx announced that Dr. Sherman joined the company's Board of Directors. She served at the FDA for nearly 30 years, holding roles of increasing responsibility and influence. Dr. Sherman led numerous key initiatives credited with enhancing product development and facilitating patient access to innovative medicines, including expedited drug development and breakthrough therapy designation programs and the Opioid Policy Steering Committee.

Upcoming Milestones

- Initiation of Phase 2 study of NYX-458 in patients with mild cognitive impairment in Parkinson's disease in 4Q 2019.
- Completion of, and reporting data from, Phase 2 first-in-patient study of NYX-783 in PTSD in 2H 2020.
- Completion of, and reporting top-line data from, Phase 2 study of NYX-2925 in painful DPN in late 2020 or early 2021.
- Completion of, and reporting top-line data from, Phase 2 study of NYX-2925 in fibromyalgia in 1H 2021.

Third Quarter 2019 Financial Results

Cash Position: Cash and cash equivalents were \$114.2 million at September 30, 2019, compared to \$150.6 million at December 31, 2018. The company expects this cash balance to be sufficient to fund anticipated operations into 2021.

Collaboration and Grant Revenue: Revenue was \$0.9 million for the third quarter of 2019 compared to \$0.9 million for same period 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.

Research and Development (R&D) Expenses: R&D expenses were \$11.8 million for the third quarter of 2019 compared to \$12.0 million for the same period in 2018. The decrease in R&D expenses was primarily driven by a decrease of \$2.2 million related to the completion of two Phase 2 studies of NYX-2925, partially offset by a \$2.0 million increase in spending related to NYX-783 and NYX-458.

General and Administrative (G&A) Expenses: G&A expenses were \$4.5 million for the third quarter of 2019 compared to \$3.8 million for the same period in 2018. The increase in G&A expenses was primarily driven by \$0.7 million in increased expenses related to employee compensation, as well as professional fees and insurance costs to support ongoing business operations.

Net Loss: Net loss was \$14.8 million for the third quarter of 2019 compared to a net loss of \$14.2 million for the same period in 2018.

Conference Call

The Aptinyx management team will host a conference call and webcast today at 5:00 p.m. EST to review its financial results and highlights for the third quarter of 2019 and subsequent period. To access the call, please dial 1-866-930-5579 (domestic) or 1-409-216-0606 (international) and refer to conference ID 4280058. 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 into 2021; 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 September 30, 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)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 114,214	\$ 150,637
Restricted cash	179	252
Accounts receivable	461	578
Prepaid expenses and other current assets	3,980	1,784
Total current assets	<u>118,834</u>	<u>153,251</u>
Property and equipment, net and other long-term assets	1,496	2,363
Total assets	<u>\$ 120,330</u>	<u>\$ 155,614</u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable	\$ 1,750	\$ 1,889
Accrued expenses and other current liabilities	5,344	3,996
Total current liabilities	<u>7,094</u>	<u>5,885</u>
Other long-term liabilities	309	418
Total liabilities	<u>7,403</u>	<u>6,303</u>
Stockholders' equity	112,927	149,311
Total liabilities and stockholders' equity	<u>\$ 120,330</u>	<u>\$ 155,614</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues				
Collaboration revenue	\$ 936	\$ 943	\$ 2,751	\$ 3,893
Grant revenue	—	—	—	1,642
Total revenues	936	\$ 943	2,751	5,535
Operating expenses				
Research and development	11,761	11,950	33,732	37,860
General and administrative	4,523	3,782	14,419	7,853
Total operating expenses	16,284	15,732	48,151	45,713
Loss from operations	(15,348)	(14,789)	(45,400)	(40,178)
Other income	558	608	1,768	990
Net loss and comprehensive loss	\$ (14,790)	\$ (14,181)	\$ (43,632)	\$ (39,188)
Net loss per share - basic and diluted	\$ (0.44)	\$ (0.43)	\$ (1.30)	\$ (2.48)
Weighted average shares outstanding - basic and diluted	33,646	33,191	33,510	15,789

Investor & Media Contact:

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Source: Aptinix Inc.