APTINYX INC.

FORM 8-K
(Current report filing)

Filed 10/20/20 for the Period Ending 10/20/20

Address	1801 MAPLE AVENUE SUITE 4300 EVANSTON, IL, 60201
Telephone	847-871-0377
CIK	0001674365
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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 Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): October 20, 2020

APTINYX INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38535**	**47-4626057**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

909 Davis Street, Suite 600
Evanston, IL 60201
(Address of principal executive offices, including zip code)

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

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 240.13e-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 8.01. Other Events.

On October 19, 2020, Aptinyx Inc. (the "Company") announced top-line data from the Company's Phase 2 study of NYX-783 in patients with post-traumatic stress disorder. A copy of the slide presentation relating to these data is being filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Corporate Presentation of Aptinyx Inc., dated October 20, 2020

SIGNATURES

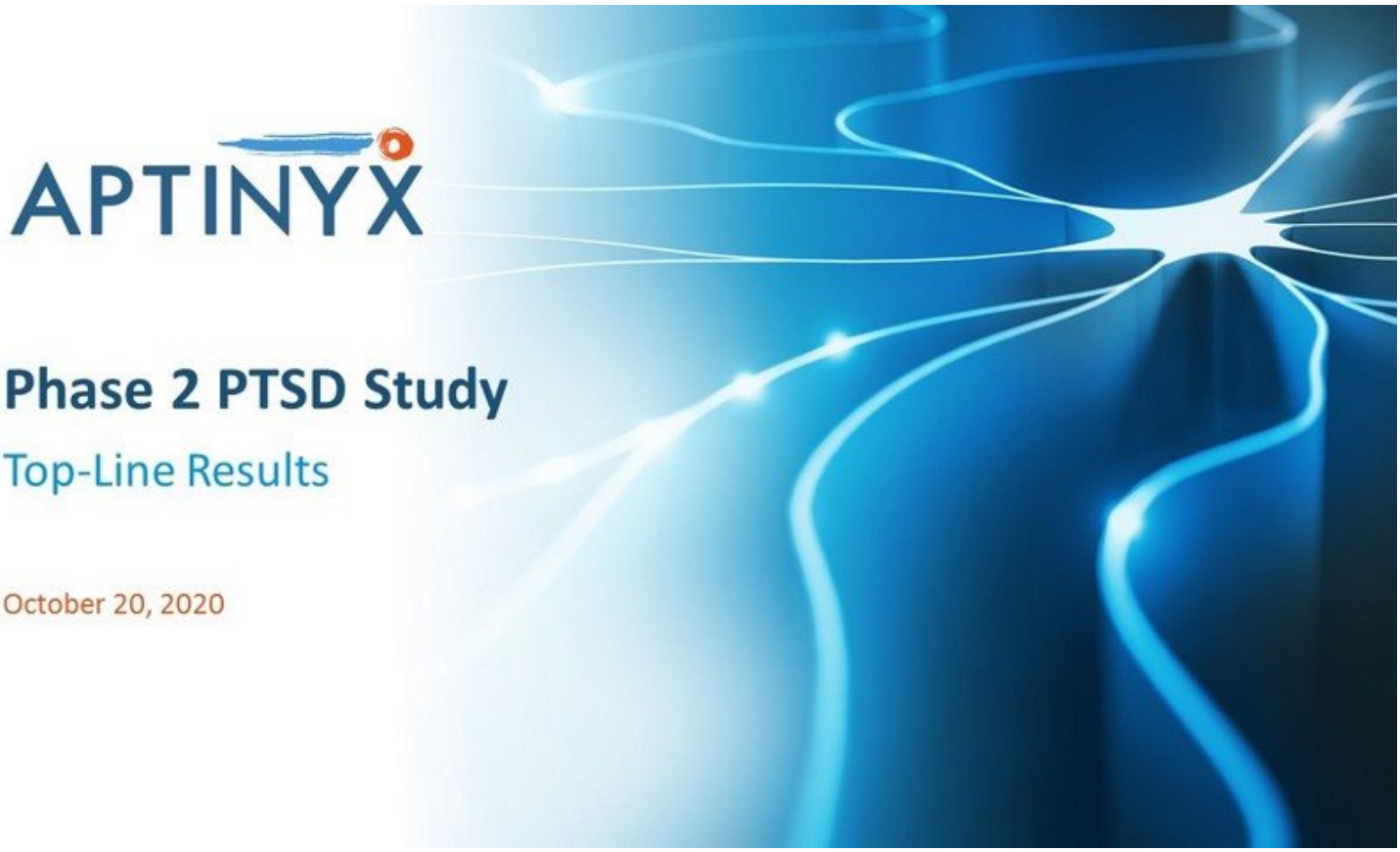
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aptinyx Inc.

Date: October 20, 2020

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

Exhibit 99.1



Forward-looking Statements

This presentation has been prepared by Aptinyx Inc. ("we," "us," "our," "Aptinyx," or the "Company") and is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this presentation unless stated otherwise, and neither this presentation, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to business, operations, and financial conditions of Aptinyx, including, but not limited to, preclinical and clinical development of Aptinyx's product candidates, including future plans or expectations for NYX-783 and potential therapeutic effects of NYX-783, the timing and reporting of results from preclinical and clinical studies, and the timing and outcome of discussions with FDA and other regulatory agencies, expectations regarding the design, implementation, timing, and success of its future clinical studies of NYX-783, including whether they are pivotal or would support registration, and expectations regarding its other NMDA receptor modulation platform development activities. 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 company's ability to execute on its strategy; that positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; future clinical studies may fail to demonstrate adequate safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization; regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; regulatory developments in the United States and foreign countries; the company's estimates regarding expenses, future revenue, and capital requirements; 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. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements. Although Aptinyx believes the expectations reflected in such forward-looking statements are based upon reasonable assumptions, there can be no assurance that its expectations will be realized. Actual results could differ materially from those projected in Aptinyx's forward-looking statements due to numerous known and unknown risks and uncertainties. All forward-looking statements speak only as of the date of this presentation and are qualified in their entirety by this cautionary statement. Aptinyx undertakes no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

APTINYX

PTSD

~8.5 MILLION **people suffering from PTSD in the U.S.**
with an estimated lifetime prevalence of 6.8%

ONLY 2 APPROVED THERAPIES
both approved **~20+ years ago**

50-66 %
also battle **simultaneous addiction** to alcohol and other drugs

Numerous causes of PTSD

Car accidents
War combat
Criminal assault
Natural disaster
Sexual trauma

Elevated suicide rates among PTSD sufferers

~20 veterans or servicemembers die from suicide daily

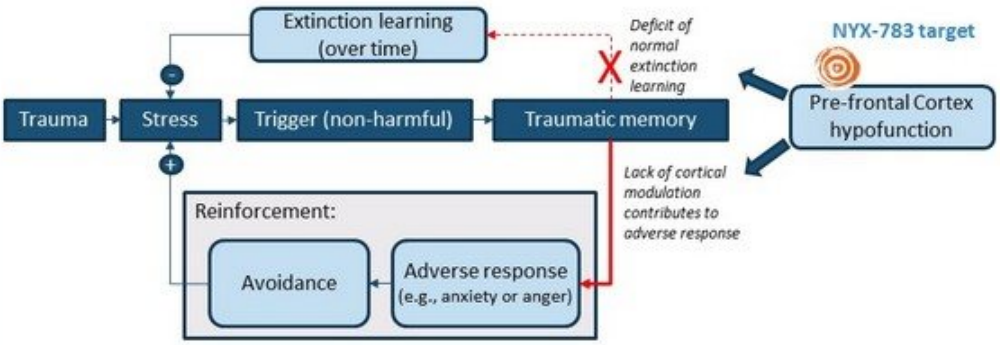
APTINYX

Differentiated Approach to Targeting PTSD: Addressing the Underlying Learning & Memory Dysfunction

CURRENT APPROACHES
Target symptoms

- **ANTIDEPRESSANTS**
  - Mood
- **ANXIOLYTICS**
  - Severe anxiety-related complications
- **HYPNOTICS**
  - Nightmares
  - Sleep disturbances

OUR APPROACH
Targets underlying dysfunction in extinction learning processes



APTINYX

PTSD Symptoms and Diagnosis Characterized by Four Core Symptom Clusters Captured in the CAPS-5

Arousal & Reactivity	Negative Cognitions & Mood	Intrusions	Avoidance
• Jumpiness • Exaggerated startle response • Hypervigilance (always alert, on guard) • Irritability and/or aggressive behavior • Reckless or self-destructive behaviors • Problems with concentration • Sleep disturbances	• Blocking out/not remembering important aspects of trauma • Persistent negative beliefs about oneself, others, the world • Distorted sense of blame • Persistent negative emotions (fear, horror, anger, guilt, shame) • Diminished interest/participation in previously enjoyable activities • Feeling detached or estranged from others • Persistent inability to experience positive emotions	• Recurrent intrusive memories • Negative flashbacks or dissociative reactions • Traumatic nightmares • Intense psychological distress and reminders of trauma • Intense physiological distress	• Withdrawal from situations, thoughts, events, people, conversations, places, objects, etc. that invoke distressing memories, thoughts, or feelings
NYX-783 preclinical data particularly support potential effects across these domains			**Secondary symptoms typically resolved downstream**

Along with these symptom clusters, a diagnosis of PTSD typically requires:

- Symptoms for ≥ 1 month
- Symptoms cause impairment in important areas of function

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Study Design, Subject Disposition, and Baseline Characteristics

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First-in-Patient Exploratory Phase 2 Study of NYX-783 in PTSD

Important First Step in Evaluating the Efficacy of a Novel Mechanism

- ☑ PRECLINICAL
- ☑ PHASE 1
- ☑ PHASE 2 (FIRST-IN-PATIENT)
- ☐ PHASE 2b/3 STUDIES
- ☐ NDA/REGULATORY APPROVAL

STUDY OBJECTIVE

Inform future development with regard to:

- ☑ Patient inclusion/exclusion criteria
- ☑ Dose level
- ☑ Endpoints
- ☑ Anticipated effect size

Findings from this study inform future development path and pivotal study design

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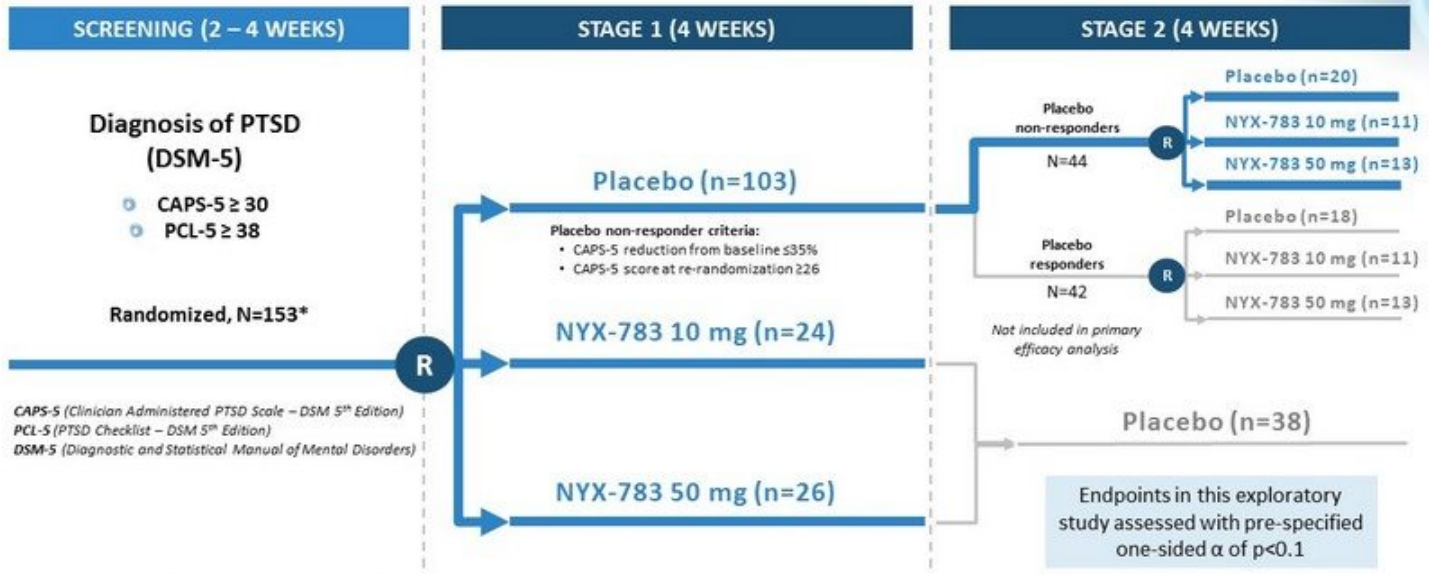
Phase 2 PTSD Study Design

Pre-Specified Primary Objective: To assess efficacy of NYX-783 in a PTSD population using CAPS-5 total score and CAPS-5 symptom cluster scores



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Baseline Demographics

	Stage 1				Stage 2				
Demographic	Placebo (n=103)	10 mg NYX-783 (n=24)	50 mg NYX-783 (n=26)	Total (n=153)	Placebo Only (n=38)	Placebo Stage 2 (n=38)	10 mg NYX-783 (n=22)	50 mg NYX-783 (n=26)	Total (n=124)
Age Mean	40.8	43.4	43.8	41.7	43.6	44.7	37.9	39.8	42.1
Gender, n (%)									
Male	42 (40.8)	7 (29.2)	11 (42.3)	60 (39.2)	18 (47.4)	14 (36.8)	10 (45.5)	7 (26.9)	49 (39.5)
Female	61 (59.2)	17 (70.8)	15 (57.7)	93 (60.8)	20 (52.6)	24 (63.2)	12 (54.5)	19 (73.1)	75 (60.5)
Ethnicity, n (%)									
Hispanic/Latino	13 (12.6)	4 (16.7)	3 (11.5)	20 (13.1)	6 (15.8)	5 (13.2)	6 (27.3)	0	17 (13.7)
Not Hispanic or Latino	90 (87.4)	20 (83.3)	23 (88.5)	133 (86.9)	32 (84.2)	33 (86.8)	16 (72.7)	26 (100)	107 (86.3)
Race, n (%)									
African American	23 (22.3)	6 (25.0)	6 (23.1)	35 (22.9)	7 (18.4)	8 (21.1)	4 (18.2)	8 (30.8)	27 (21.8)
Asian	4 (3.9)	2 (8.3)	0	6 (3.9)	0	2 (5.3)	2 (9.1)	1 (3.8)	5 (4.0)
White	75 (72.8)	16 (66.7)	17 (65.4)	108 (70.6)	31 (81.6)	25 (65.8)	15 (68.2)	17 (65.4)	88 (71.0)
Other	1 (1.0)	0	3 (11.5)	4 (2.6)	0	3 (7.9)	1 (4.5)	0	4 (3.2)

Analysis as of October 17, 2020

APTINYX

Baseline Clinical Characteristics – ITT Primary Efficacy Population

	Stage 1				Stage 2 (PBO Non-Responders)			
Demographic	Placebo (n=103)	10 mg NYX-783 (n=24)	50 mg NYX-783 (n=26)	Total (n=153)	Placebo Stage 2 (n=20)	10 mg NYX-783 (n=11)	50 mg NYX-783 (n=13)	Total (n=44)
Years Since PTSD Dx, mean	5.8	7.2	9.4	6.63	5.40	6.71	6.11	5.94
CAPS-5 Total, mean (SD)	40.6 (7.58)	38.3 (8.26)	36.5 (7.37)	39.6 (7.76)	37.9 (8.29)	33.4 (4.57)	37.0 (6.23)	36.5 (7.04)
PCL-5, mean (SD)	49.9 (10.75)	48.7 (10.65)	48.0 (9.60)	49.4 (10.51)	44.2 (14.72)	38.5 (7.51)	44.1 (11.23)	42.67 (12.40)
HADS-A, mean (SD)	14.3 (3.39)	13.6 (3.43)	12.6 (4.21)	13.9 (3.59)	10.3 (2.83)	11.4 (4.13)	10.4 (3.86)	12.98 (3.13)
Social Circumstances, n (%)*								
Military Service	16 (15.7)	5 (20.8)	8 (30.8)	29 (19.1)				
Victim of Crime	21 (20.6)	3 (12.5)	4 (15.4)	28 (18.4)				
Victim of Sexual Abuse	14 (13.7)	2 (8.3)	2 (7.7)	18 (11.8)				
Death/Suicide of Other	20 (19.4)	2 (8.3)	3 (11.5)	25 (16.4)				
Victim of Other Abuse	8 (7.8)	2 (8.3)	0 (0)	10 (6.5)				

Baseline clinical characteristics are consistent with a moderate to severe PTSD patient population

*Largest categories displayed, does not add to 100%

Analysis as of October 17, 2020

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Efficacy Data

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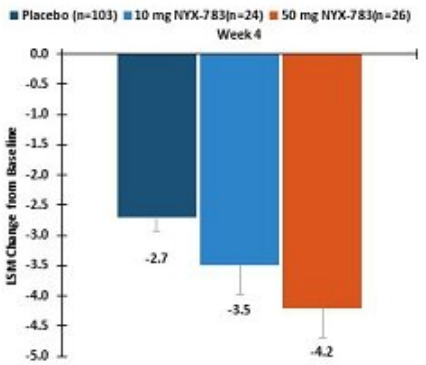
Primary Objectives: CAPS-5 Arousal and Reactivity Score

- **Clinically meaningful and statistically significant improvement on CAPS-5 Arousal and Reactivity Score for 10mg, 50mg, and pooled dose groups**
- **Effect is concordant with fear extinction mechanism of NYX-783**
- Significant improvement on Arousal and Reactivity symptom domain largely drove overall trend on CAPS-5 Total Score and other composite endpoints

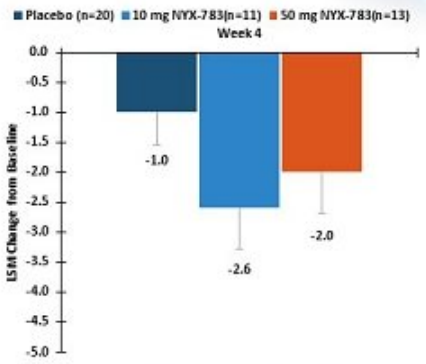
Stage 1 (4 weeks)

MMRM LSM Change from Baseline - ITT



Stage 2 (4 weeks)

MMRM LSM Change from Baseline - ITT
PBO Non-Responders



P-values versus PBO	10mg	50mg	Pooled
Stage 1	0.065	0.004	0.004
Stage 1 + Stage 2 (primary analysis)	**0.049**	**0.040**	**0.027**

P-values versus PBO	10mg	50mg	Pooled
Stage 2	0.037	0.131	0.040

CAPS-5 *(Clinician Administered PTSD Scale – DSM 5th Edition)*
MMRM LSM Change *(Mixed-effects models for repeated measures – Least Squares Means)*
Analysis as of October 17, 2020

Stage 1 baseline mean- *PBO:11.0, 10mg:11.0, 50mg:10.3*

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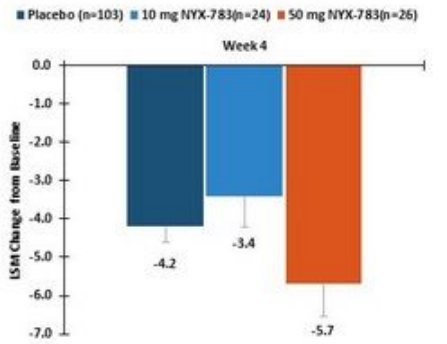
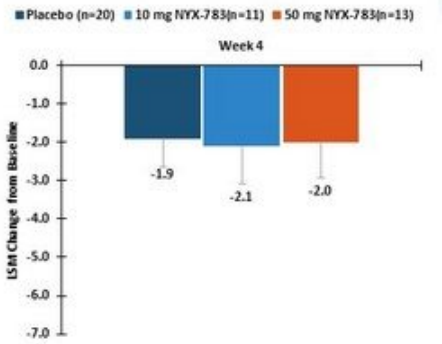
Primary Objectives: CAPS-5 Negative Cognitions and Mood Score

- Trend to significance in combined Stage 1+2 analysis for 50mg dose
- **Statistically significant improvement in Negative Cognitions and Mood Score in Stage 1 with 50mg dose**
- Consistent with pre-clinical data and NYX-783 mechanism of action

Stage 1 (4 weeks)



Stage 2 (4 weeks)



P-values versus PBO	10mg	50mg	Pooled
Stage 1	NS	0.049	NS
Stage 1 + Stage 2 (primary analysis)	**NS**	**0.138**	**NS**

P-values versus PBO	10mg	50mg	Pooled
Stage 2	NS	NS	NS

CAPS-5 *(Clinician Administered PTSD Scale – DSM 5th Edition)*
MMRM LSM Change *(Mixed-effects models for repeated measures – Least Squares Means)*
Analysis as of October 17, 2020

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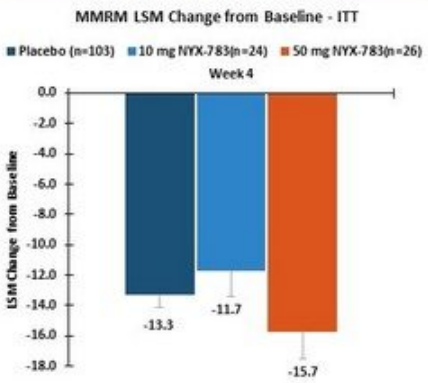
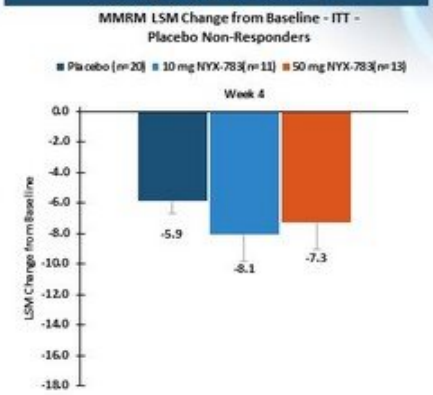
Primary Objectives: CAPS-5 Total Score

- Trend to significance in combined Stage 1+2 analysis for 50mg dose
- **Robust and clinically meaningful reduction in CAPS-5 Total Score from baseline during Stage 1 for 50mg dose – trend to significance despite strong placebo effect**
- Reduction in CAPS-5 Total Score during Stage 2 for 10mg and 50mg
- Strong signal despite high placebo response in Stage 1

Stage 1 (4 weeks)



Stage 2 (4 weeks)



P-values versus PBO	10mg	50mg	Pooled	P-values versus PBO	10mg	50mg	Pooled
Stage 1	NS	0.119	NS	Stage 2	NS	NS	NS
Stage 1 + Stage 2 (primary analysis)	**NS**	**0.161**	**NS**				

CAPS-5 *(Clinician Administered PTSD Scale – DSM 5th Edition)*
MMRM LSM Change *(Mixed-effects models for repeated measures – Least Squares Means)*
Analysis as of October 17, 2020

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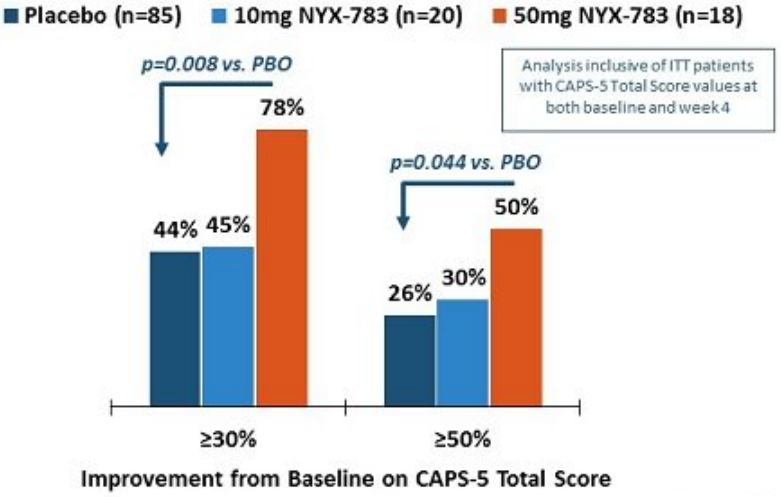
Primary Objectives: CAPS-5 Total Score – Responder Analysis

- **Consistent, dose-dependent efficacy signal in CAPS-5 Total Score in patient responder analysis**
- For 50mg dose in Stage 1, 78% of patients achieved 30% reduction in CAPS-5 Total Score, and 50% of patients achieved 50% reduction

Stage 1 (Week 4) – ITT Completers

Proportion of Patients Achieving Key Response Thresholds @ Week 4



Analysis as of October 17, 2020

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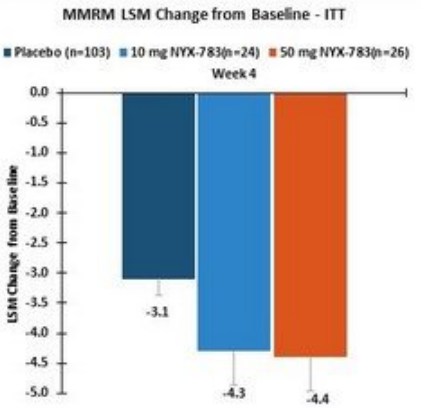
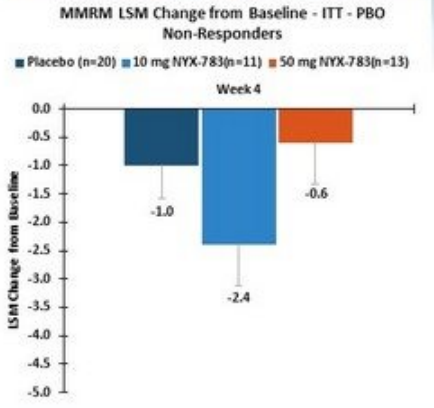
Additional Pre-Specified Endpoints: HADS-Anxiety

- **Strong effect on HADS-Anxiety scale – statistically significant for 10mg and pooled doses, trending for 50mg**
- HADS-Anxiety reduction consistent with reduction in CAPS-5 Arousal and Reactivity Score and NYX-783 mechanism of fear extinction

Stage 1 (4 weeks)



Stage 2 (4 weeks)



P-values versus PBO	10mg	50mg	Pooled
Stage 1	0.024	0.018	0.004
Stage 1 + Stage 2 (primary analysis)	**0.045**	**0.166**	**0.056**

P-values versus PBO	10mg	50mg	Pooled
Stage 2	0.067	NS	NS

CAPS-5 *(Clinician Administered PTSD Scale – DSM 5th Edition)*
MMRM LSM Change *(Mixed-effects models for repeated measures – Least Squares Means)*
HADS-A *(Hospital Anxiety and Depression Scale – Anxiety)*
Analysis as of October 17, 2020

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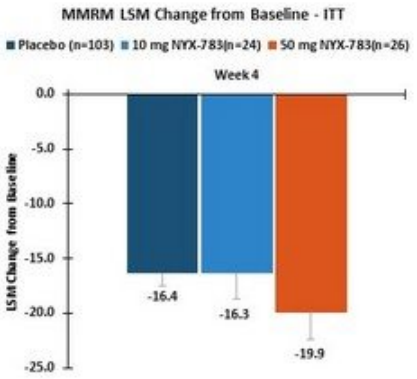
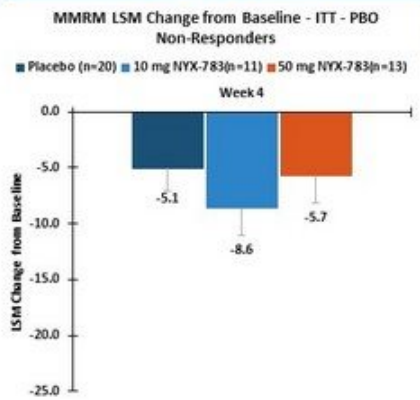
Additional Pre-Specified Endpoints: PCL-5 (Patient Reported)

- PCL-5 is a patient response endpoint with symptom questions identical to CAPS-5
- **Trend to significance for 50mg and pooled doses in Stage 1+2 analysis**
- **Statistically significant reduction in Stage 1 for 50mg**
- Trend to significance in Stage 2 for 10mg

Stage 1 (4 weeks)



Stage 2 (4 weeks)



P-values versus PBO	10mg	50mg	Pooled
Stage 1	NS	0.0987	NS
Stage 1 + Stage 2 (primary analysis)	**NS**	**0.170**	**0.180**

P-values versus PBO	10mg	50mg	Pooled
Stage 2	0.138	NS	NS

CAPS-5 *(Clinician Administered PTSD Scale – DSM 5th Edition)*
PCL-5 *(PTSD Checklist - DSM 5th Edition)*
MMRM LSM Change *(Mixed-effects models for repeated measures – Least Squares Means)*
Analysis as of October 17, 2020

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Tolerability and Adverse Event Data

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Favorable Tolerability and Adverse Event Profile Observed

Safety Population

Treatment Emergent Adverse Events (TEAE)	Stage 1				Stage 2				
	Placebo Only (N=102) n (%)	NYX-783 10 mg (N=24) n (%)	NYX-783 50 mg (N=26) n (%)	Total (N=152) n (%)	Placebo Only (N=38) n (%)	Placebo Stage 2 (N=36) n (%)	NYX-783 10 mg (N=21) n (%)	NYX-783 50 mg (N=27) n (%)	Total (N=122) n (%)
Subjects with at least 1 TEAE	38 (37.3)	9 (37.5)	9 (34.6)	56 (36.8)	8 (21.1)	6 (16.7)	7 (33.3)	9 (33.3)	30 (24.6)
Subjects with at least 1 *related* TEAE	22 (21.6)	6 (25.0)	7 (26.9)	35 (23.0)	4 (10.5)	1 (2.8)	1 (4.8)	2 (7.4)	8 (6.6)
Subjects with a TEAE leading to discontinuation	4 (3.9)	1 (4.2)	3 (11.5)	8 (5.3)	1 (2.6)	-	-	-	1 (0.8)
TEAEs at ≥ 5% Frequency or 2x Placebo									
Headache	4 (3.9)	2 (8.3)	1 (3.8)	7 (4.6)	3 (7.9)	-	-	1 (3.7)	4 (3.3)

Observed tolerability and adverse events similar to placebo

Tolerability is an especially important factor for this population

Analysis as of October 17, 2020

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Other Adverse Event and Tolerability Observations

- No fatal adverse events
- No life-threatening adverse events
- No drug-related serious adverse events
  - 3 reports of suicidal ideation in the study
    - 2 on placebo
    - 1 on NYX-783 – deemed by investigator to be unrelated to study drug
- No drug-related severe adverse events
- No signal of clinically meaningful changes in lab values

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Clinician's Perspective: PTSD

Murray Stein, MD, MPH

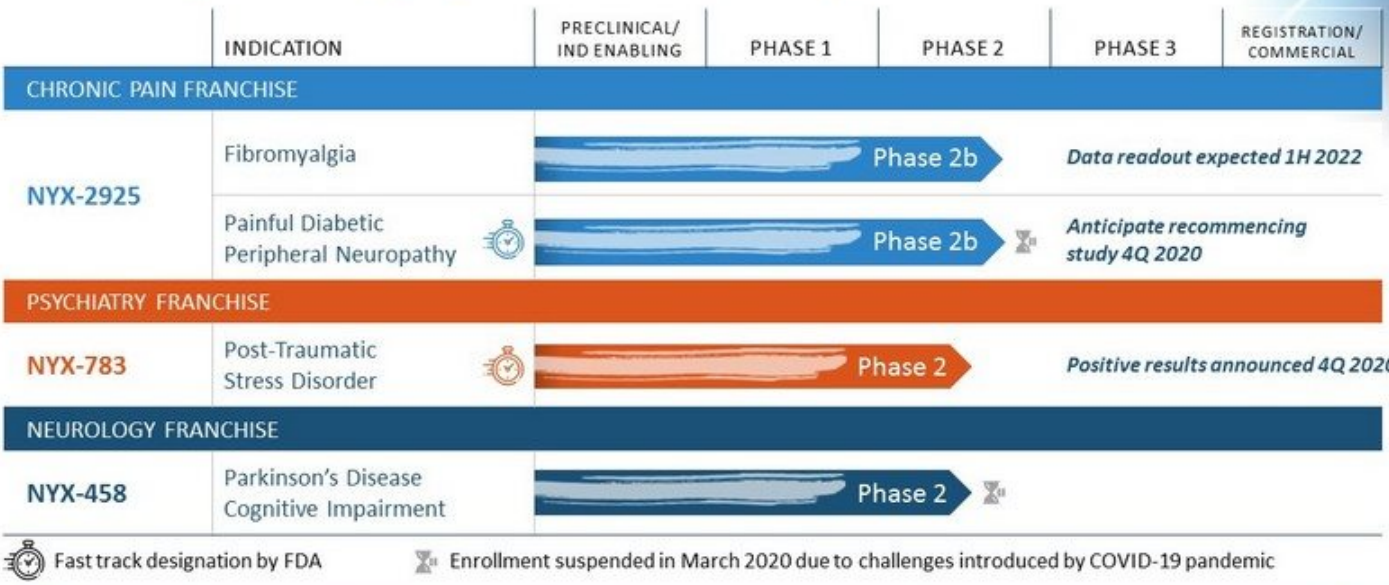
Distinguished Professor of Psychiatry and Public Health
University of California San Diego

Staff Psychiatrist at the VA San Diego Healthcare System

DSM-5 Anxiety, Obsessive-Compulsive Spectrum, Posttraumatic, and Dissociative Disorders Work Group

APTINYX

Advancing a Leading Pipeline of CNS Therapies



Approximate cash balance of $116 mm as of June 30, 2020, is expected to provide operational runway into 2022

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Q&A

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Summary of Top-line Results

Met primary objective – positive results across numerous efficacy endpoints with favorable tolerability and adverse event profile

- Robust, statistically significant, clinically meaningful, mechanistically relevant effects observed on numerous efficacy endpoints with **only 4 weeks of treatment**
- Clear dose response: 50mg dose demonstrated better effect than 10mg dose
- Majority of patients in the 50mg group demonstrated clinically meaningful response on key endpoints
- Overall effects in-line with effects observed with approved therapies at 8 or 12 weeks
- Well tolerated with overall tolerability profile comparable to placebo
- Demonstrates clear potential for NYX-783 to be a meaningful therapy in an extremely underserved patient population
- **Study supports advancing NYX-783 into pivotal studies in PTSD**

Third Phase 2 study demonstrating therapeutic potential of Aptinyx's novel NMDAr modulator platform

APTINYX