

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): January 13, 2020

NeuroBo Pharmaceuticals, Inc.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-37809  
(Commission  
File Number)

47-2389984  
(IRS Employer  
Identification No.)

177 Huntington Avenue, Suite 1700  
Boston, Massachusetts  
(Address of principal executive offices)

02115  
(Zip Code)

Registrant's telephone number, including area code: (617) 313-7331

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 (see General Instruction A.2. below):

- 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 \$0.001 per share	NRBO	The Nasdaq Stock Market, LLC

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 7.01. Regulation FD Disclosure.**

During the week of January 13, 2020, representatives of NeuroBo Pharmaceuticals, Inc. (the “Company”) will be attending meetings with investors, analysts and others at the J.P. Morgan Healthcare Conference in San Francisco, California and these representatives of the Company plan to present the slides attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished pursuant to Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Corporate slide deck, dated January 2020</a>

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**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.

NEUROBO PHARMACEUTICALS, INC.

Date: January 13, 2020

By: /s/ Richard Kang

Richard Kang

*President and Chief Executive Officer*

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## SAFE HARBOR STATEMENT

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Except for statements of historical fact, any information contained in this presentation may be a forward-looking statement that reflects the Company's current views about future events and are subject to risks, uncertainties, assumptions and changes in circumstances that may cause events or the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "could", "would", "should", "plan", "predict", "potential", "project", "promising," "expect," "estimate," "anticipate," "intend," "goal," "strategy," "believe," and similar expressions and variations thereof. Forward-looking statements may include statements regarding the Company's business strategy, market size, potential growth opportunities, capital requirements and use of proceeds, clinical development activities, the timing and results of clinical trials, regulatory submissions, potential regulatory approval and commercialization of the product candidate. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in our filings with the SEC. These forward-looking statements speak only as of the date of this presentation and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market shares and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

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## COMPANY OVERVIEW

Clinical-stage biopharmaceutical company with three drug programs to impact a range of indications in neurodegenerative and cardiometabolic disease

### Multiple Drug Programs; One Phase 3-Ready

#### Multi-modal with potential to be disease-modifying

- **NB-01**: Phase 3 initiation H1 2020; targeting Painful Diabetic Neuropathy (PDN)
- **NB-02**: IND-ready; targeting Alzheimer's Disease (AD) and other dementias
- **Gemcabene**: 25 Phase 1 and Phase 2 trials completed. Awaiting FDA decision to start Phase 3

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### Large Therapeutic Markets with High Unmet Need

- **Painful Diabetic Neuropathy (PDN)**: affects 8.4M\* people globally; current drugs have insufficient efficacy and are poorly tolerated
- **Alzheimer's disease (AD) & other dementias**: AD affects 27.3M\* people globally; with no approved disease modifying therapies
- **Dyslipidemias including orphan and prevalent indications**: HoFH and SHTG globally affect 3,200\* and 12.5M\* respectively

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### Staged Financing Strategy with Experienced Team

- Combination of equity and partnering; **one Asian partnership signed (Beijing SL)**
- Experienced executive team in drug development, innovation, and corporate strategy
- Reverse merger completed with Gemphire Therapeutics (Nasdaq: GEMP) on December 30, 2019; **new NASDAQ listing (NRBO)**

\*Global Data

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## PROVEN LEADERSHIP TEAM

**Richard J. Kang, PhD**  
President & CEO

- Founder of JK BioPharma Solutions and senior management at companies including NeolmmuneTech in immuno-oncology
- Visiting Fellow at NIH and senior research experience in host-disease pathogen interactions

**Mark Versavel, MD, PhD, MBA**  
Chief Medical Officer

- 30 years of drug development experience from Phase 1 to Phase 3 at Pfizer (Lyrica), Bayer, Sunovion (Aptiom, Lunesta)
- Leadership roles at 5 biotech companies
- Founder & President of vZenium LLC
- Drug approvals: 2 NDAs, 1 sNDA

**Nikki Shannon, RegN, BA**  
VP, Clinical Operations

- 26 years of drug development experience from Phase 1 to Phase 4 at Solvay, Sanofi Pasteur, Vertex (Kalydeco), Cubist/Merck, AstraZeneca, Tetrphase (Eravacycline)
- Leadership roles at 4 pharma companies; >55 studies including 14 Phase 3
- Drug approvals: 2 NDAs, 2 MAAs

## EXPERT SCIENTIFIC ADVISORY BOARDS

### CHAIRMAN

**Roy Freeman, M.D.**  
*Expert in Peripheral Nerve Disorders and Neurodegenerative Diseases*

- Professor of Neurology, Harvard Medical School
- Director of the Center for Autonomic and Peripheral Nerve Disorders

### PAIN

**Robert H. Dworkin, PhD**  
*Leader in Neuropathic Pain Clinical Trials*

- Professor of Anesthesiology, Neurology, Psychiatry, and Experimental Therapeutics at the University of Rochester School of Medicine
- Director of the Anesthesiology Clinical Research Center

**Allan Basbaum, PhD, FRS**  
*Leader in Pain Research*

- Professor and Chair, Department of Anatomy, University of California San Francisco
- Former Editor-in-Chief of PAIN, the journal of the IASP

**Bob Rappaport, M.D.**  
*Regulatory Expert*

- Former Division Director of Anesthesia, Analgesia and Addiction Products at the U.S. Food and Drug Administration
- President and owner of Analgesic Concepts LLC

### ALZHEIMER'S DISEASE & OTHER DEMENTIAS

**Brian Bacskai, PhD**  
*Expert in Alzheimer's Disease Research*

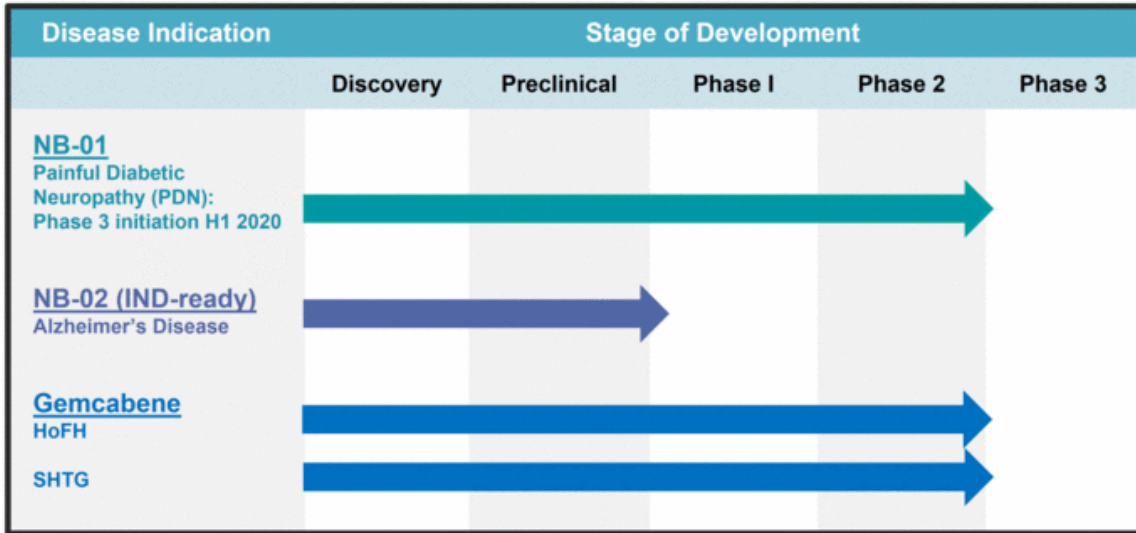
- Professor of Neurology, Harvard Medical School
- Principal Investigator, Neurology, Massachusetts General Hospital

**Pierre N. Tariot, M.D.**  
*Award-Winning Leader in Dementia*

- Director, Banner Alzheimer's Institute, Arizona
- Research Professor of Psychiatry, University of Arizona College of Medicine



# NEUROBO DEVELOPMENT PIPELINE



HoFH = Homozygous Familial Hypercholesterolemia  
 SHTG = Severe Hypertriglyceridemia





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## PAINFUL DIABETIC NEUROPATHY OVERVIEW

- **Diabetes** is among the leading causes of neuropathic pain
  - A disorder known as painful diabetic neuropathy (PDN)
- PDN affects **8.4M** people worldwide representing global drug sales of **\$3.56B** (2018, *GlobalData*)
- **Pain can be severe** and debilitating, impairing sleep, limiting mobility, and **interfering with quality of life** (*Pop-Busui R et al., 2017*)
- Currently approved therapies have **limited efficacy**
  - **Less than 50%** of treated patients have a 50% response rate
  - **Adverse events** are common
    - Limits tolerability and adherence
  - **Limited success** with first and second-line drugs leading to **high frequency opioid use**
    - 14% and 19% of patient encounters involving gabapentin and pregabalin respectively also involved opioids (*FDA In Brief, 2019*)

# FDA WARNING ON GABAPENTINOIDS FOR SERIOUS BREATHING PROBLEMS

An official website of the United States government [Here's how you know.](#)

FDA U.S. FOOD & DRUG  
ADMINISTRATION

Search

Menu

[Home](#) / [Drugs](#) / [Drug Safety and Availability](#) / [FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin \(Neurontin, Gralise, Horizant\) and pregabalin \(Lyrica, Lyrica CR\)](#)

## FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)

*When used with CNS depressants or in patients with lung problems*

### What is FDA doing?

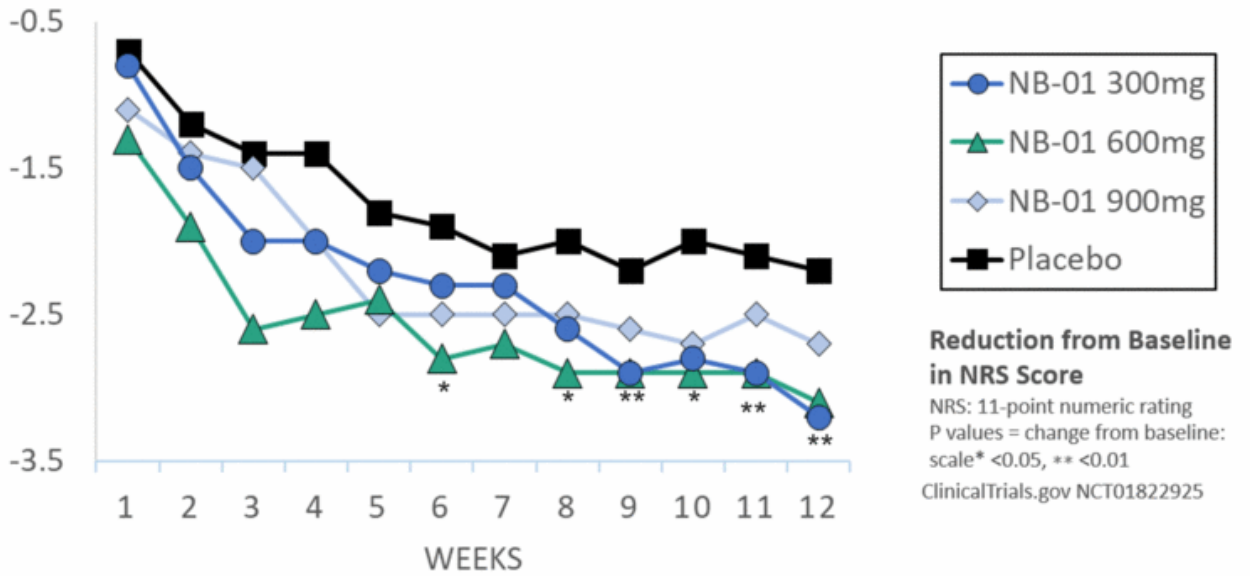


We are requiring new warnings about the risk of respiratory depression to be added to the prescribing information of the gabapentinoids. **We have also required the drug manufacturers to conduct clinical trials to further evaluate their abuse potential, particularly in combination with opioids, because misuse and abuse of these products together is increasing, and co-use may increase the risk of respiratory depression.** Special attention will be paid to the respiratory depressant effects during this abuse potential evaluation.

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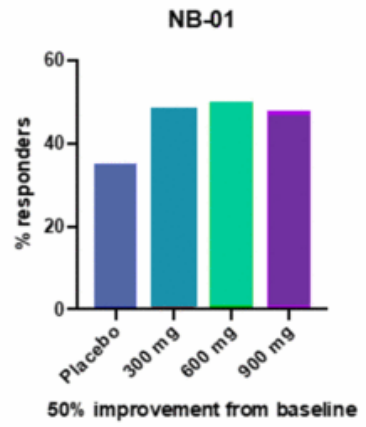
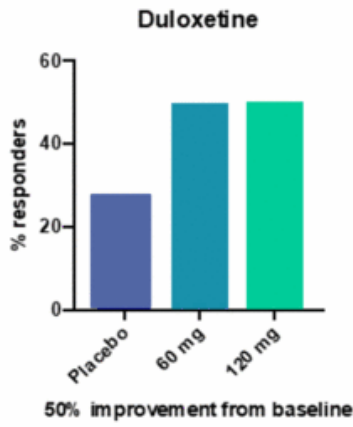
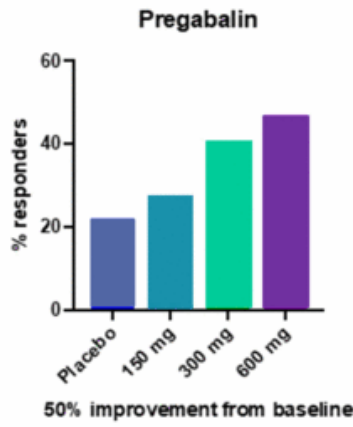


# NB-01 DEMONSTRATED PAIN REDUCTION IN US PHASE 2 STUDY



14 US sites, 128 subjects, 3 doses vs. placebo

# 50% RESPONSE RATES - COMPARISON OF NB-01 TO APPROVED THERAPIES



Freedman, Diabetes Care 22008;31  
Pritchett, Pain Med 2007;8:397-409

# ADVERSE EVENTS WITH NB-01 TREATMENT WERE SIMILAR TO PLACEBO

## TEAEs with a $\geq 2\%$ Difference (Safety Population)

	Incident on NB-01 N=96	Incident on Placebo N=32	Difference in Incident NB-01 from Placebo
Constipation	5.2%	0.0%	5.2%
Sinusitis	5.2%	0.0%	5.2%
Back pain	6.3%	3.1%	3.1%
Myalgia	3.1%	0.0%	3.1%
Pain in extremity	3.1%	0.0%	3.1%
Arthralgia	5.2%	3.1%	2.1%
Musculoskeletal pain	2.1%	0.0%	2.1%
Nasopharyngitis	2.1%	0.0%	2.1%
Pneumonia	2.1%	0.0%	2.1%

### Duloxetine\*

(Placebo vs 60mg QD/BID)

- Nausea: 8% vs 24-27%
- Somnolence: 4% vs 15-20%
- Dizziness: 5% vs 10-13%

### Pregabalin\*\*

(Placebo vs 300/600mg QD)

- Dizziness: 5% vs 23-28%
- Peripheral Edema: 7% vs 10-16%
- Somnolence: 3% vs 13-14%

Source: DA9801-DN-001 (USA) Table 14.3.1.1A

\*Pritchett, Pain Medicine, v8, 2007  
\*\*Freeman, Diabetes Care, v31 2008

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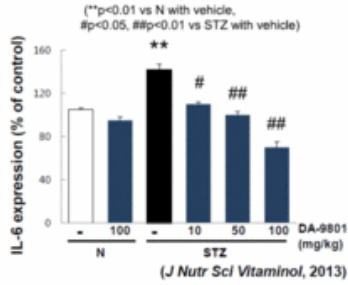
# DISTINCT MULTI-TARGET APPROACH: PRE-CLINICAL DATA



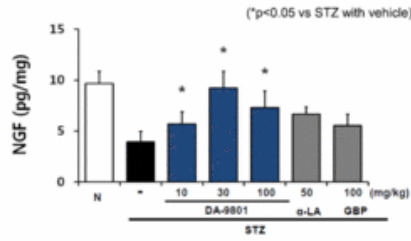
## Nerve growth and repair

## Reducing cell damage

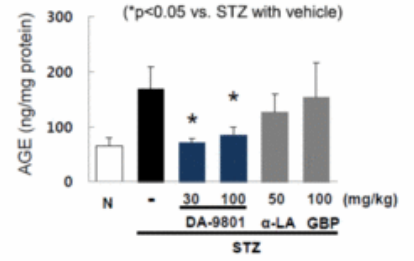
Reduction IL-6 Expression in STZ model



NGF restored to normal endogenous levels in STZ model



AGE Reduction in STZ model



\* Preclinical rodent models have also shown improved nerve conduction velocity (NCV), neurite outgrowth, and reduction of thermal and mechanical hyperalgesia

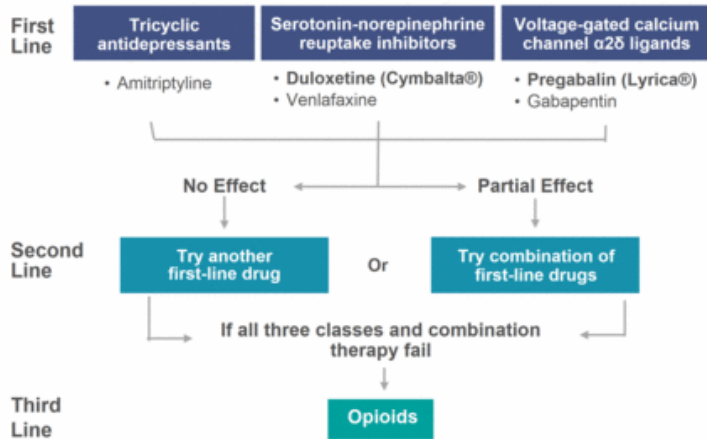
Note: DA-9801 is now NB-01  
\* Data on file NeuroBo



## PDN TREATMENT PARADIGM



### Confirmed painful diabetic neuropathy



Source: Adapted from Callahan et al., 2012

\*Source: GlobalData

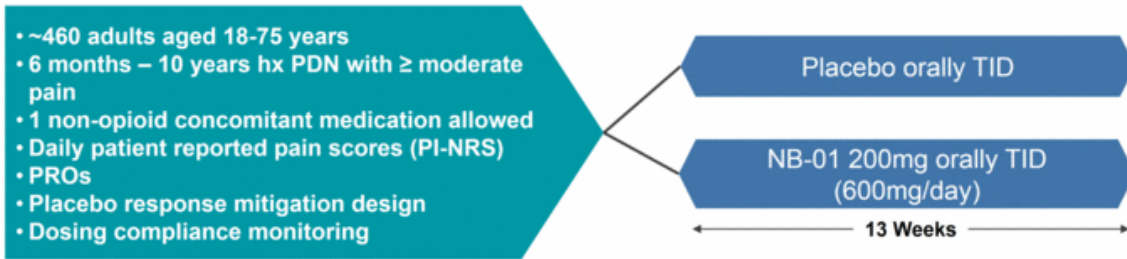
- PDN is a **multi-billion-dollar market** in U.S.
  - 2018 Lyrica® sales for PDN were \$1.87B\*
- Available treatments **do not provide adequate relief** and have serious side effects
- Many **PDN patients resort to opioids** for pain management, which creates unwanted risk for addiction while treating a chronic condition
- In Phase 2 trials, **NB-01** demonstrated efficacy similar to results seen in studies of best-in-class approved drugs with **substantially fewer side effects**
- NB-01 may potentially demonstrate **disease-modifying properties**





# PHASE 3 PDN TRIAL

## Double-Blind, Placebo-Controlled; Safety, Efficacy, & Tolerability



### Primary Endpoint:

- Change from baseline in weekly mean of daily average pain score

### Secondary Endpoints:

- Responders on Patient Global Impression of Change
- Responders on PI-NRS
- Change from baseline in weekly mean of Daily Sleep Interference Scale

Conducted in U.S. only



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## ALZHEIMER'S DISEASE & OTHER DEMENTIAS

### Alzheimer's disease

- Alzheimer's disease (AD) affects **27.3M people** globally (2018, Global Data)
- Approved treatments **focus on symptomatic** management and largely on acetylcholinesterase (AChE) inhibition

### Other Dementias

- **>20 diseases** that result from **tau protein aggregation** in the brain; progressive supranuclear palsy (PSP) is a key focus
- **No approved therapies** for patients with tauopathies

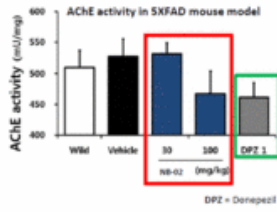
**Significant opportunity for safe, disease-modifying therapies that restore cognitive function**



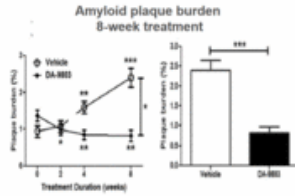
## NB-02: OUR DISTINCT, MULTIPLE PATHWAY APPROACH

- Alzheimer's disease is a multi-mechanism disease with a complex pathophysiology
- NB-02 has effects on multiple pathways shown in pre-clinical models

**Inhibits  
Acetylcholinesterase  
(AChE)**

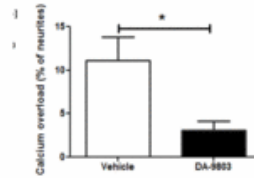


**Prevents Amyloid- $\beta$   
Plaque Deposition**



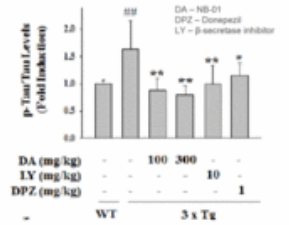
DA-9803 is NB-02  
Pagnier et al., 2018  
Alzheimer Research  
& Therapy

**Restores Disrupted  
Ca<sup>++</sup> Homeostasis**



DA-9803 is NB-02  
Pagnier et al., 2018  
Alzheimer Research  
& Therapy

**Inhibits  
Tau Phosphorylation**



DA (mg/kg)	-	-	100	300	-
LY (mg/kg)	-	-	-	-	10
DPZ (mg/kg)	-	-	-	-	1



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## IND-READY: EXTENSIVE PRECLINICAL STUDIES



**NB-02 impacts multiple pathways implicated in neurodegenerative disease**



**Efficacy demonstrated in extensive cognitive and behavioral studies**

Y-Maze, Morris Water Maze, and Novel Object Recognition studies show improved cognitive endpoints in transgenic mouse models



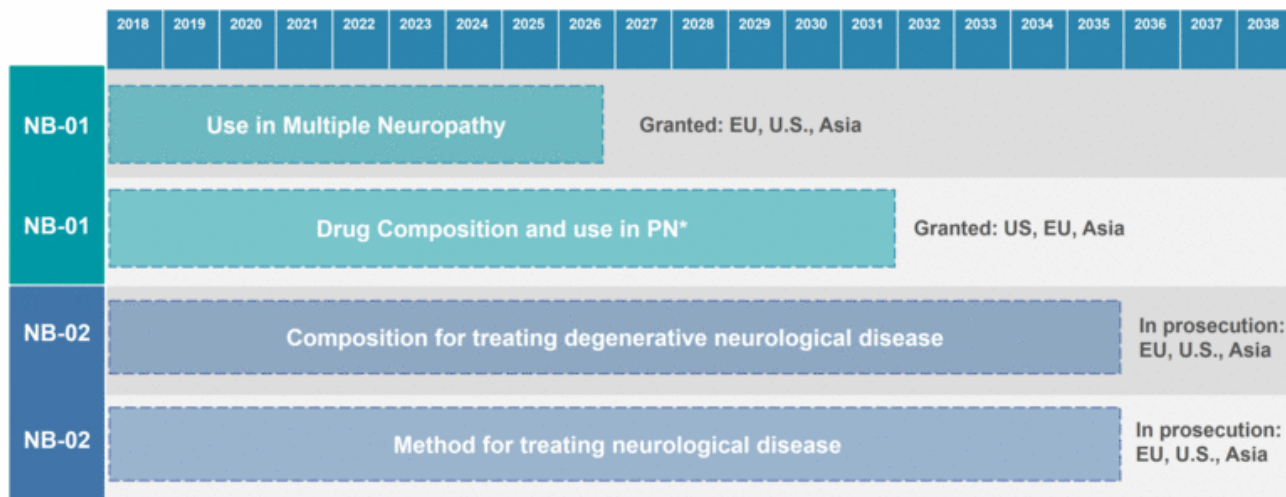
**IND-enabling toxicology studies completed**

26-week rat toxicity, 39-week dog toxicity, and other IND requirements done



# PATENT PROTECTION FOR NB-01 AND NB-02

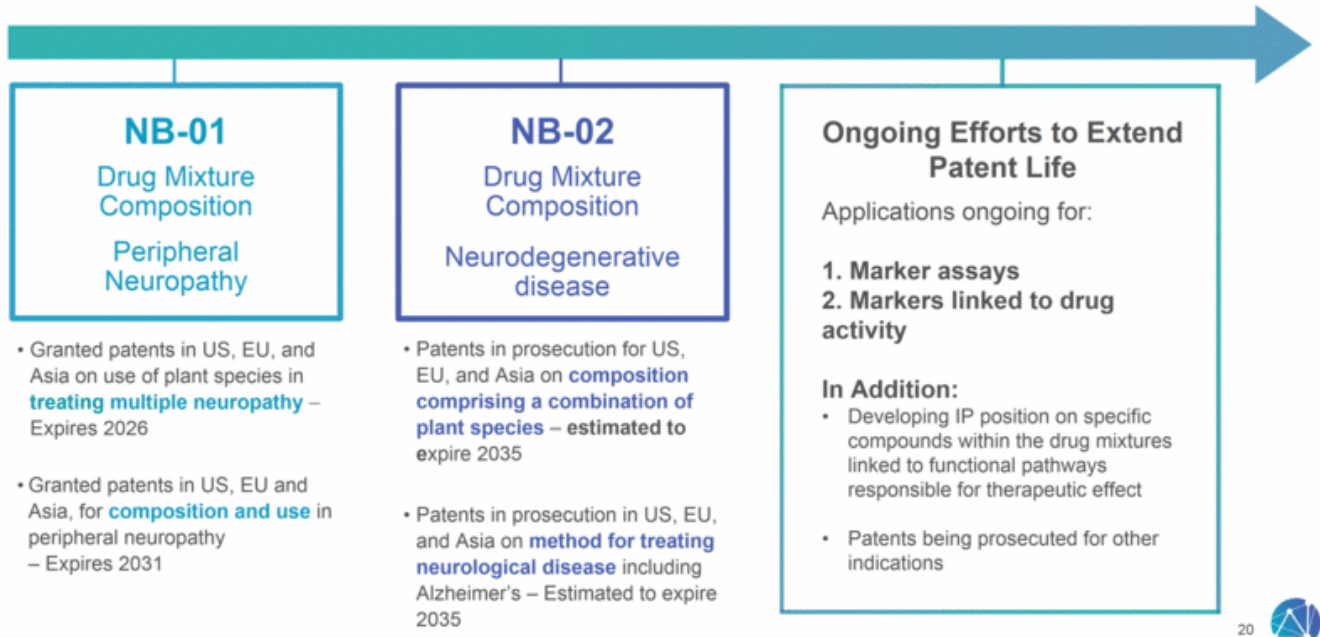
IP Protection for Indications and Long-Term Runway for Commercialization



\*PN= Painful Neuropathy



# INTELLECTUAL PROPERTY PORTFOLIO & FUTURE EXPANSION PLANS







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## GEMCABENE: NEAR-TERM CATALYST MAY PROVIDE FINANCIAL UPSIDE

- **Gemcabene**: a Phase 2b asset acquired in the reverse merger
  - Provides **potential financial upside** (subject to contingent rights[CVR] payments to pre-merger Gemphire stockholders)
  - PPAR (peroxisome proliferation activated receptor) agonist in development by Gemphire for the treatment of dyslipidemia
- FDA requires the completion of **two-year rat and mouse carcinogenicity** trials before conducting clinical trials of longer than six months.
- Submission of **request to lift partial clinical hold for gemcabene to the FDA is expected to occur in H1 2020**

**We have taken the following actions in response to the clinical hold:**

- Submitted a **2-year rodent carcinogenicity study** in 2018
- **Completed additional in-vitro PPAR- $\alpha$  transactivation study** in dog and monkey, per FDA request
- **Completed** a 13-week PPAR- $\alpha$  **knockout mouse study**, requested by FDA



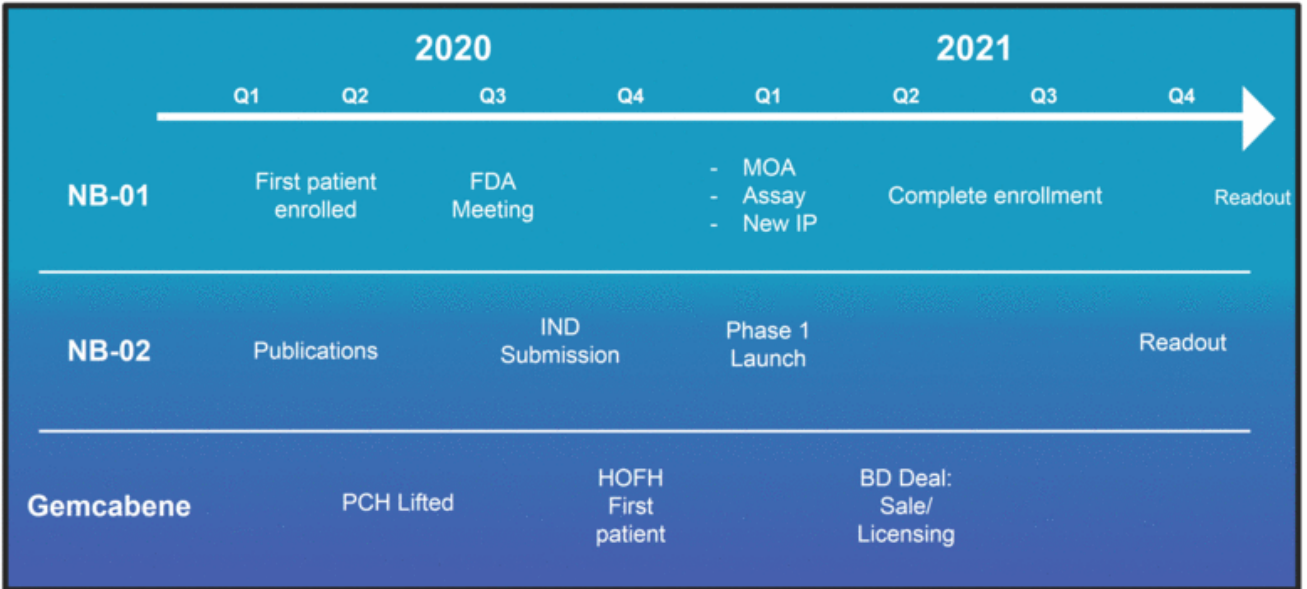
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## GEMCABENE: PHASE 2B ASSET WITH SIGNED PARTNERSHIP

- 25 completed Phase 1 and Phase 2 studies and **> 1,110 subjects treated with gemcabene** with multiple cardiometabolic indications studied, including Severe Hypertriglyceridemia ASCVD, Hypercholesterolemia, and Familial Partial Lipodystrophy, with promising results
- Gemphire signed an **out-licensing partnership with Beijing SL Pharmaceutical Co. Ltd.** to advance gemcabene, into the **Chinese market**
  - Provides **back end milestone and royalty payments** to NeuroBo if certain development and commercialization milestones are met
- **Pre-merger Gemphire stockholders received contingent value rights (CVRs)** entitling them to certain cash payments in the event the gemcabene assets are sold or licensed during the 10-year period following the closing of the merger or pursuant to the license agreement with Beijing SL



## PIPELINE AND POTENTIAL MILESTONES WITH ADDITIONAL ASSETS



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## NEUROBO CAPITALIZATION TABLE

NASDAQ GLOBAL MARKET	
Symbol	NRBO
Market Cap <sup>1</sup>	\$140M
Price Per Share <sup>1</sup>	\$9.00
Shares Outstanding <sup>2</sup>	15.6M
Combined Cash at 6/30/19	\$28.2M

1. 01/08/2020

2. Fully diluted shares outstanding = 16.6M as of 12/30/19



