

**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): **September 24, 2019**

**Gemphire Therapeutics 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.)

**P.O. Box 130235, Ann Arbor, MI 48113**  
(Address of principal executive offices) (Zip Code)

**(734) 245-1700**  
(Registrant's telephone number, including area code)

**17199 N. Laurel Park Drive, Suite 401, Livonia, MI 48152**  
(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, \$0.001 par value	GEMP	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 8.01 Other Events.

As Gemphire Therapeutics Inc. ("**Gemphire**") previously disclosed in its current report on Form 8-K filed on July 25, 2019, as amended, Gemphire, GR Merger Sub Inc., a wholly owned subsidiary of Gemphire ("**Merger Sub**"), and NeuroBo Pharmaceuticals, Inc. ("**NeuroBo**"), entered into an Agreement and Plan of Merger and Reorganization (the "**Merger Agreement**") on July 24, 2019, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into NeuroBo, with NeuroBo continuing as a wholly owned subsidiary of Gemphire and the surviving corporation of the merger (the "**Merger**").

On September 24, 2019, NeuroBo presented at the Ladenburg Thalmann 2019 Healthcare Conference in New York, New York. A copy of the presentation is attached as Exhibit 99.1.

### **Forward-Looking Statements**

This communication contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended) concerning Gemphire, NeuroBo, the proposed Merger, the contingent value rights agreement, the license and collaboration agreement with Beijing SL Pharmaceutical Co., Ltd. and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Gemphire, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the proposed Merger are not satisfied, including the failure to obtain stockholder approval for the proposed Merger in a timely manner or at all; uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Gemphire and NeuroBo to consummate the Merger; risks related to Gemphire's ability to correctly estimate and manage its operating expenses and its expenses associated with the proposed Merger pending closing; risks related to Gemphire's continued listing on the Nasdaq Capital Market until closing of the proposed Merger; risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed Merger; the risk that as a result of adjustments to the exchange ratio, Gemphire stockholders or NeuroBo stockholders could own more or less of the combined company than is currently anticipated; risks related to the market price of Gemphire Common Stock relative to the exchange ratio; the risk that the conditions to payment under the contingent value rights will be not be met and that the contingent value rights may otherwise never deliver any value to Gemphire stockholders; risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger, including with respect to future financial and operating results; the ability of Gemphire or NeuroBo to protect their respective intellectual property rights; competitive responses to the Merger and changes in expected or existing competition; unexpected costs, charges or expenses resulting from the proposed Merger; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed Merger; the success and timing of regulatory submissions and pre-clinical and clinical trials; regulatory requirements or developments; changes to clinical trial designs and regulatory pathways; changes in capital resource requirements; risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Gemphire's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC as well as Gemphire's registration statement on Form S-4, filed with the SEC on September 3, 2019, and the preliminary proxy statement/prospectus/information statement included therein. Gemphire can give no assurance that the conditions to the Merger will be satisfied. Except as required by applicable law, Gemphire undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

### **Important Additional Information Will be Filed with the SEC**

On September 3, 2019, Gemphire filed a registration statement on Form S-4 with the SEC which included a preliminary proxy statement/prospectus/information statement. A definitive proxy statement/prospectus/information statement will be filed with the SEC and mailed to the stockholders of NeuroBo and Gemphire once the registration statement becomes effective. Each party may file other documents with the SEC in connection with the Merger. **INVESTORS AND STOCKHOLDERS OF GEMPHIRE AND NEUROBO ARE URGED TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN, OR WILL CONTAIN, IMPORTANT INFORMATION ABOUT GEMPHIRE, NEUROBO, THE MERGER AND RELATED MATTERS.** Investors and stockholders may obtain free copies of the documents filed with the SEC through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). Investors and stockholders may also obtain free copies of the documents filed by

Gemphire with the SEC by contacting Gemphire by mail at Gemphire Therapeutics Inc., P.O. Box 130235, Ann Arbor, MI 48113, Attention: Corporate Secretary. Investors and stockholders are urged to read the definitive proxy statement/ prospectus/information statement and the other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

**No Offer or Solicitation**

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

**Participants in the Solicitation**

Gemphire and its directors and executive officers and NeuroBo and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Gemphire in connection with the Merger. Information regarding the special interests of these directors and executive officers in the Merger will be included in the proxy statement/prospectus/information statement referred to above. Additional information about Gemphire's directors and executive officers is included in Gemphire's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019. These documents are available free of charge at the SEC website ([www.sec.gov](http://www.sec.gov)) and from the Corporate Secretary of Gemphire at the address above.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">NeuroBo Presentation, dated September 24, 2019.</a>





**NeuroBo**  
PHARMACEUTICALS

**Novel Treatments for  
Neurodegenerative Conditions**

*Multi-modal, disease-modifying therapies*

# DISCLAIMER

**Forward-Looking Statements**—All statements in this presentation other than statements of historical facts, including statements regarding the proposed transaction with Gemphire Therapeutics, Inc. ("Gemphire") and other contemplated transactions, expected future results of operations and financial position of NeuroBo, its business or strategy, the clinical development of its product candidates and its objectives for future operations, are forward-looking statements. The words "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions are intended to identify these forward-looking statements. Such forward-looking statements are based on expectations and involve risks, uncertainties and assumptions, including, without limitation: the risk that conditions to closing the proposed transaction are not satisfied, risks related to Gemphire's ability to correctly estimate and manage its expenses, the risk that as a result of adjustments to the exchange ratio, Gemphire stockholders or NeuroBo stockholders could own more or less of the combined company than anticipated, the risk that the conditions to payment under the CVRs will not be met and that the CVRs may otherwise never deliver any value to Gemphire stockholders, risks related to the timing of completion of and availability of data from NeuroBo's planned clinical trials, the clinical utility, potential benefits and market acceptance of NeuroBo's product candidates, developments relating to NeuroBo's competitors and its industry, the impact of government laws and regulations, NeuroBo's ability to protect its intellectual property position, the strength of NeuroBo's intellectual property portfolio, the strength of NeuroBo's financial position, and changes in NeuroBo's capital resource requirements. Consequently, actual results may differ materially from those expressed or implied in the statements. New risks emerge from time to time and it is not possible to predict all such factors. Forward-looking statements included in this presentation are based on information available to Gemphire and NeuroBo as of the date of this presentation. Neither Gemphire nor NeuroBo undertakes any obligation to update such forward-looking statements to reflect events or circumstances after the date of this presentation.

**Market and Statistical Data**—This presentation contains estimates and other statistical data made by independent parties and by NeuroBo relating to market size and growth and other data about NeuroBo's industry. This data involves assumptions and limitations, and you are cautioned not to give undue weight to such estimates and statistical data. Neither NeuroBo nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation.



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## ADDITIONAL INFORMATION & WHERE YOU CAN FIND IT

Important Additional Information Will be Filed with the SEC. In connection with the proposed transaction, Gemphire intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement/prospectus/information statement. GEMPHIRE URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT GEMPHIRE, NEUROBO, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and stockholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Gemphire with the SEC (when they become available) through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). In addition, investors and shareholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Gemphire with the SEC by written request to Gemphire Therapeutics Inc., 17199 N. Laurel Park Drive, Suite 401, Livonia, MI 48152, Attention: Corporate Secretary. Investors and stockholders are urged to read the proxy statement/prospectus/information statement and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation—Gemphire and NeuroBo, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Gemphire's directors and executive officers is included in Gemphire's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement relating to the transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

No Offer or Solicitation—This presentation shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No public offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.



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# COMPANY SUMMARY

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

## Drug Programs

- **NB-01:** Phase 3-ready; targeting neuropathic pain (NP)
- **NB-02:** IND-ready; targeting Alzheimer's and tauopathies
- Multi-modal with potential to be disease-modifying

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## Therapeutic Focus

- Diabetic Neuropathic Pain (DNP), also known as **Painful diabetic neuropathy (PDN)** affects **8.4M** people globally; current drugs have insufficient efficacy and are poorly tolerated
- **Chemotherapy-induced peripheral neuropathy** in cancer patients undergoing chemotherapy
- **Alzheimer's disease** affects **10.6M** people globally
- **Tauopathies:** rare diseases with no approved therapies

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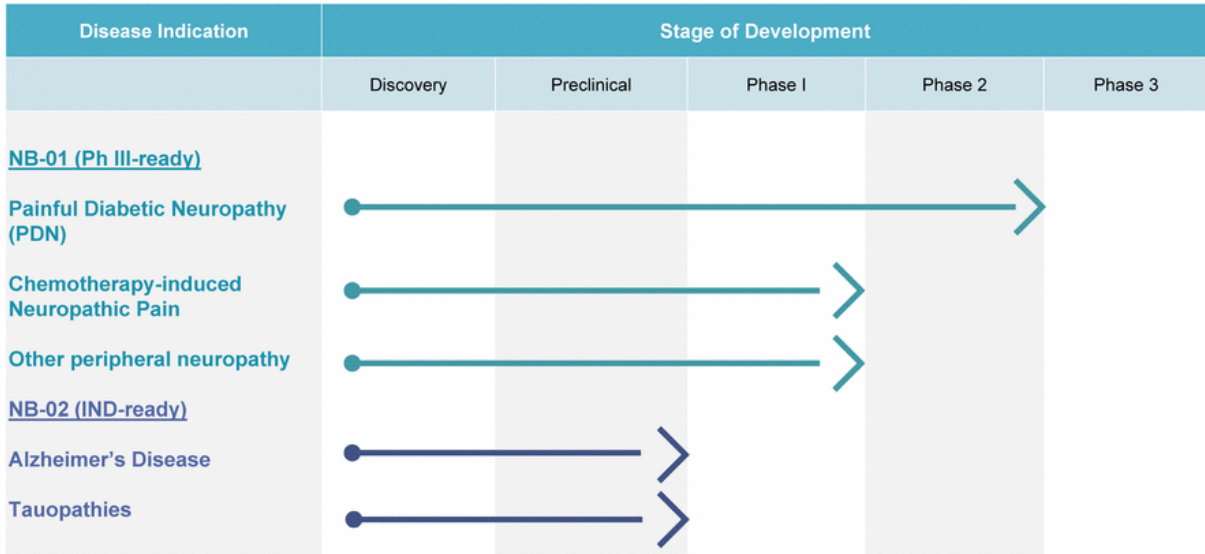
## Financing & Executive Leadership

- Series B financing of \$24M in July 2019; **\$42M** raised since inception
- Experienced executive team in drug development, innovation, and corporate strategy
- Reverse merger announced with Gemphire Therapeutics (Nasdaq: GEMP) in July 2019





# NEUROBO DEVELOPMENT PIPELINE



# NB-01

Targeting neuropathic pain

First indication: PDN



# PAINFUL DIABETIC NEUROPATHY OVERVIEW

- PDN affects **8.4M** people worldwide representing global drug sales of **\$3.05B** (2018, GlobalData)
- **Diabetes** and **cancer** are amongst the leading causes of neuropathic pain
- Symptoms range from dull and tingling to **debilitating pain**; limiting mobility, negatively impacting sleep, and hindering **glycemic control** (Ormseth et al. 2011)
- Current treatments show **30% reduction of pain in 40% of patients**
  - Only three approved therapies for PDN with high rates of adverse events
  - When these fail, even in combination, physicians often turn to off-label use of opioids



The most unmet need is the reversal, or treating the **physiopathology**...  
This is a chronic, incapacitating disease...

- US Key Opinion Leader

**Significant market need:**

**Safe, efficacious drugs with potential to modify underlying disease**



# PAINFUL DIABETIC NEUROPATHY (PDN) 2018 MARKET OVERVIEW FIRST INDICATION OF NB-01

	Prevalence	Drug Sales
<b>Global</b>	8.4M	\$3.1B
<b>U.S.</b>	2.4M	\$2.2B

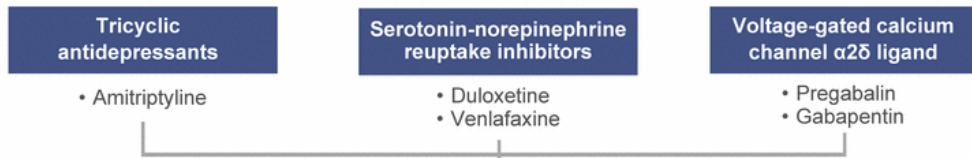
- Prevalence of diabetes continues to increase globally
- Majority of patients are 55-70 years of age; PDN affects men and women equally
- 1/3 of PDN patients are refractory to current treatments

# PDN PATIENT JOURNEY



## Confirmed painful diabetic neuropathy

### First Line



### Second Line



### Third Line



# NB-01 TREATMENT PARADIGM



Confirmed painful diabetic neuropathy



**NB-01**

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**NB-01 has the potential to improve  
first-line therapy safety and effectiveness**





## OUR DISTINCT, MULTI-TARGET APPROACH

- Neuropathic pain is a multi-target disease with a complex pathophysiology
- NB-01 has disease-modifying potential with effects on multiple pathways

### Anti-inflammatory

Reduction of TNF- $\alpha$  and IL-6

### Nerve growth and repair

Elevation of Nerve Growth Factor (NGF)

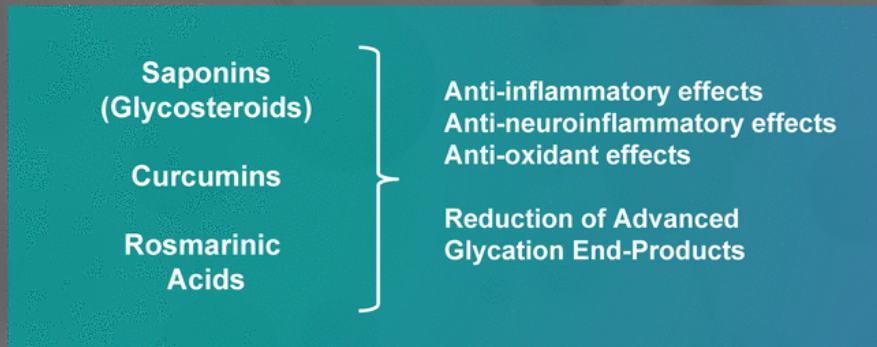
### Reducing cell damage

Reduction of Advanced Glycation End-Products

- Demonstrated effects on both pain alleviation and underlying pathways with extensive studies in rodent models
- Preclinical rodent models have also shown:
  - Improved nerve conduction velocity (NCV)
  - Neurite outgrowth
  - Reduction of thermal and mechanical hyperalgesia



# NB-01 ACHIEVES MULTI-TARGET EFFECTS FROM COMBINED ACTION OF MULTIPLE COMPOUNDS IN ORAL FORMULATION



- 60 compounds isolated and characterized in drug product
- Three structural classes as above correlated with pharmacological activities related to PDN
- Dioscin (glycoesteroid) and allantoin used as marker compounds
- Additional markers being developed for PK assays





# NB-01 ADHERES TO REQUIRED FDA DRUG GUIDELINES FOR NATURAL PRODUCT-BASED DRUG MIXTURES

“ Clinical trials of **botanical drugs** are **no more difficult** than **non-botanical drugs** ”

Sau (Larry) Lee, FDA, 2015

## Raw Material

- Good Agricultural and Collection Practices (GACP) in place
- Two external audits completed on CMC and Quality with no issues

## Drug Substance (API) & Drug Product

- GMP-compliant manufacturing in two facilities in Korea
- Drug substance manufactured as paste
- Drug product manufactured as oral tablets
- QA/QC demonstrated with five batches; two external audits completed no issues
- NB-01 clinical-quality drug ready for human studies

<http://pqri.org/wp-content/uploads/2015/10/01-PQRI-Lee-Botanicals-20151.pdf>  
Lee et al., Science 2015 Jan 16;347(6219 Suppl.):S32-4

CONFIDENTIAL INFORMATION

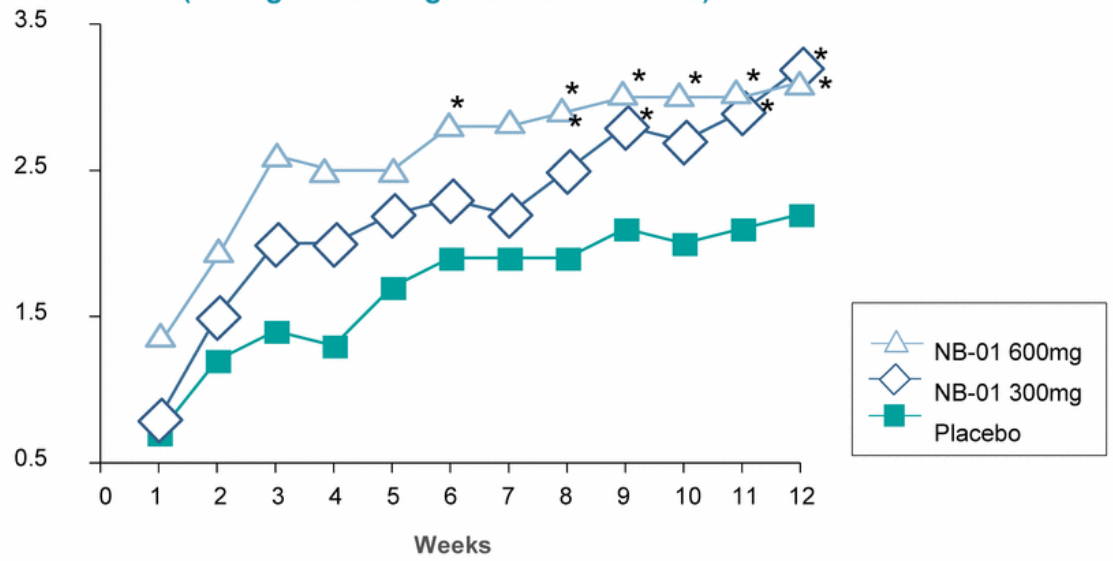


# NB-01 DEMONSTRATED PAIN REDUCTION IN US PHASE 2 STUDY

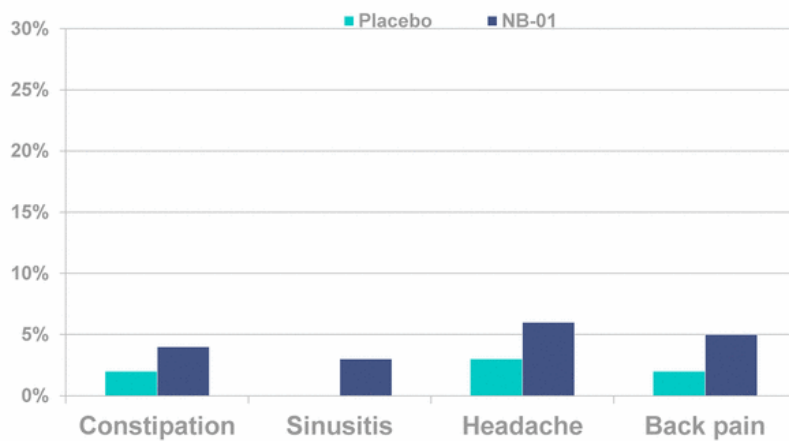
16 US sites, 128 subjects, 3 doses vs. placebo  
(600mg and 300mg doses shown here)

Reduction from Baseline in NRS Score

NRS: 11-point numeric rating scale\* <0.05, \*\* <0.01  
P values are baseline



## NB-01 SHOWN TO BE WELL-TOLERATED IN TWO PHASE 2 STUDIES: SAFETY & TOLERABILITY IS A SIGNIFICANT DIFFERENTIATOR



Adverse events included = 2-3% difference in combined studies from placebo

Safety data compiled from two Phase 2 studies (US and Korea)

Average incidence of adverse events ranges **15-30%** over placebo of approved treatments for PDN



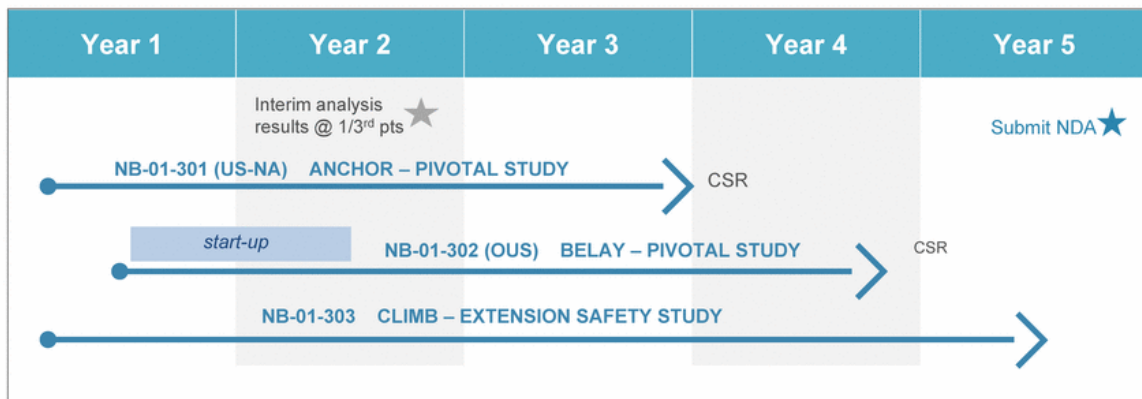
# PLANNED PHASE 2 STUDY: DEMONSTRATION OF EFFICACY & DISEASE MODIFICATION

## NB-01-203 (US)

- Designed to demonstrate pain alleviation, effects on pathway biomarkers, and potential disease modification
- 200 patient study with PDN
- Single high dose of 600mg daily compared with placebo
- Measurement of NRS pain scores in 12-week study
- Measurement of biomarkers – cytokine panel, NGF, AGEs
- Withdrawal of drug after 12 weeks to follow sustained effect of drug on pain alleviation



# PHASE 3-READY STUDIES IN PDN PLANNED: POWERED FOR EFFICACY AND SAFETY



- Two End of Phase 2 (EOP2) meetings completed with FDA
- Endpoint: Change from baseline in weekly mean of daily pain scores





# NB-02

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Targeting Alzheimer's disease  
& Tauopathies



# ALZHEIMER'S & TAU-RELATED DISEASES (TAUOPATHIES)

- Alzheimer's disease affects **10.6M people** globally (2016, Global Data)
- Approved treatments focus on symptomatic management and largely on acetyl cholinesterase (AChE) inhibition
- 650+ drug trials underway targeting Tau inhibition, amyloid plaque inhibition, and combinations with AChE inhibition
- >20 diseases that result from tau protein aggregation in the brain; progressive supranuclear palsy (PSP) is a key focus
- **No current approved therapies** for patients with tauopathies

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



## EXTENSIVE PRECLINICAL STUDIES: IND-READY



**NB-02 is a multi-component drug compound mixture designed to impact multiple pathways involved in neurodegenerative disease**



**Extensive cognitive and behavioral pre-clinical 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





# INTELLECTUAL PROPERTY PORTFOLIO

## NB-01

Drug Mixture  
Composition

Peripheral  
Neuropathy

- Granted patents in US, EU, and Asia on combination of plant species for drug composition – Expires 2027
- Granted patents in EU, Asia, and allowance in US for composition and use in peripheral neuropathy – Expires 2031
- Patents being prosecuted on other peripheral neuropathy indications and quality assays to extend patent life

## NB-02

Drug Mixture  
Composition

Neuro-degenerative  
disease

- Patents in prosecution for US, EU, and Asia on composition for treating degenerative neurological disease including Alzheimer's – Expires 2035
- Patents in prosecution in US, EU, and Asia on method for treating neurological disease including Alzheimer's – Expires 2035



# PROVEN LEADERSHIP TEAM

**John L. Brooks III, BBA, MSBA**  
President & CEO

- Experienced biotech, device, and healthcare executive
- Former President & CEO of Joslin Diabetes Center

**Nandan Padukone, PhD, MBA**  
SVP, Business Development

- Experienced executive in innovation and venture development
- Former President & CEO of Nuvera Biosciences at MD Anderson Cancer Center

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

- Senior medical and clinical drug development experience
- Former Vice President of CNS, Clinical Development, and Medical Affairs at Sunovion

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

- Experienced senior executive in clinical operations
- Former Vice President of Clinical Operations at Kaleido Biosciences

# SCIENTIFIC ADVISORY BOARD

**Roy Freeman, MD**

Founder & Chairman of the SAB  
Expert in Autonomic & Peripheral Nerve Disorders

- Professor of Neurology, Harvard Medical School
- Staff Neurologist and Director of the Center for Autonomic and Peripheral Nerve Disorders at Beth Israel Deaconess Medical Center, Boston

**Robert H. Dworkin, PhD.**

Leader in Neuropathy

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

**Bob Rappaport, MD**

Regulatory Expert

- Former Division Director of Anesthesia, Analgesia and Addiction Products at the FDA
- President and owner of Analgesic Concepts LLC



