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): March 5, 2021

NeuroBo Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	001-37809	47-2389984
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Berkeley Street, Office 19th Floor
Boston, Massachusetts 02116
(Address of principal executive offices, including Zip Code)

Registrant's Telephone Number, Including Area Code: (857) 702-9600

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 $0.001 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.

Representatives of NeuroBo Pharmaceuticals, Inc. will be presenting the slides attached as Exhibit 99.1 to this report at the H.C. Wainwright Global Life Sciences Conference taking place virtually from March 9-10, 2021.

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

Exhibit Number	Exhibit Description
99.1	Company Presentation, dated March 5, 2021

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 thereunto duly authorized.

NEUROBO PHARMACEUTICALS, INC.

Date: March 5, 2021

By: /s/ Richard Kang
Richard Kang
President and Chief Executive Officer

Exhibit 99.1

NeuroBo PHARMACEUTICALS

Disclaimers

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, potential strategic partnerships or 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 candidates. 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 Annual Report on Form 10-K for the year ending December 31, 2019 and our other filings with the SEC, including our Quarterly Reports on Form 10-Q. 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.

Developing and commercializing multimodal disease-modifying therapies for viral, neuropathic and neurodegenerative diseases

Company Overview and Merger with ANA Therapeutics

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Repurposing ANA001 as a rapid COVID-19 treatment (Priority)

ANA001–COVID-19 Trial

- Compelling in-vitro data showing evidence of efficacy, with 50+ years of safety data
- Shows great broad-spectrum antiviral activity
  - Data suggests effectiveness against other viruses such as influenza
  - Likely effective against novel SARS-CoV-2 variants
- Shows anti-inflammatory properties, without suppressing immune response
- Shows promise as a prophylactic

Pipeline Programs Addressing Large Unmet Needs

Gemcabene: Assessing for acute COVID-19

- 25 Phase 1 and Phase 2 trials completed in Chronic Orphan Dyslipidemia indications

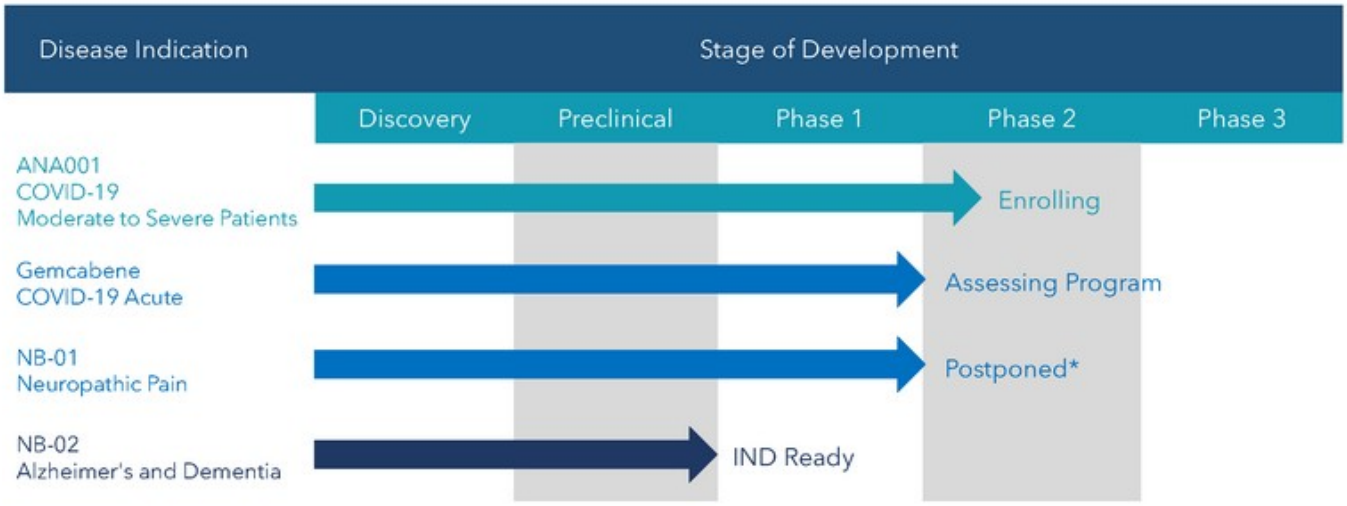
NB-01–Targeting Pain in Orphan Indication

- Compelling Phase 2 data showing evidence of efficacy and safety for neuropathic pain
- Multimodal mechanism of action to treat pain supported by preclinical evidence

NB-02–Targeting Alzheimer's Disease (AD) and other dementias

- IND Ready; compelling preclinical data

Development Pipeline



*Due to constraints on initiating and conducting clinical studies during pandemic

Proven Leadership Team

NeuroBo PHARMACEUTICALS

Richard J. Kang, PhD
President & CEO

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

Akash Bakshi, MsC.
Chief Operating Officer

- Co-Founder and CEO of ANA Therapeutics
- Co-Founder and CEO of YourChoice Therapeutics, a Y Combinator backed startup
- Previously Assistant Director of Marketing and Technology Analysis at UC Berkeley

Nadja Mannowetz, PhD
SVP, Scientific Affairs

- Co-Founder and CSO of ANA Therapeutics
- Co-Founder and CSO of YourChoice Therapeutics, a Y Combinator backed startup
- PhD in Infectious Biology from Eberhard Karls University, Tübingen, Germany

Andrew Bartynski, PhD
SVP, Manufacturing and CMC

- Co-Founder and COO of ANA Therapeutics
- Founding CEO for AesculaTech, a Y Combinator backed startup
- PhD in Chemical Engineering from the University of Southern California

Expert Scientific Advisory Boards

NeuroBo PHARMACEUTICALS

NEUROPATHIC PAIN SCIENTIFIC CHAIR

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

COVID-19

Warner Greene, M.D., Ph.D.
Expert in virology

- Director of the Gladstone Institute
- Professor at UCSF
- Member of the national Academy of Medicine

Gunda Georg, Ph.D.
Expert in medicinal chemistry

- Professor and Head of the Department of Medicinal Chemistry at University of Minnesota
- Member of the national Academy of Medicine

Christopher Davis, Ph.D.
Expert in virology and clinical aspects

- Ex-BARDA
- Managed a NATO drug development program
- 10 years at British Intelligence as principal bioweapons analyst

ALZHEIMER'S DISEASE & OTHER DEMENTIAS

Brian Bacskai, Ph.D.
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

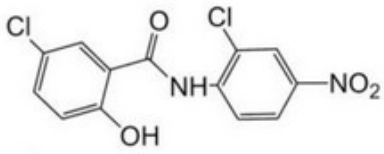
NeuroBo PHARMACEUTICALS

What is Niclosamide?

NeuroBo PHARMACEUTICALS

Background

- On World Health Organization's (WHO) list of essential medicines
- Safely treated millions of patients
- Currently used to treat tapeworm



NICLOSAMIDE

Safety Profile

- Well-established drug: oral administration known to be safe for 50+ years
- Very few, non-severe side effects
- Appealing characteristics for most at risk population: elderly patients, high comorbidity, and children

NeuroBo PHARMACEUTICALS

Acquired proprietary capsule formulation of niclosamide for COVID-19 treatment and prophylaxis

- ANA001 being studied in U.S. Phase 2/3 trial (currently enrolling patients)
- Generic niclosamide used safely for 50+ years globally as a treatment for tapeworm infections
- Niclosamide prevents replication of SARS-CoV-2 at very low concentrations
- Niclosamide also shown to have three distinct mechanisms of action:
  - Potential Antiviral: Lowers SARS-CoV-2 and a broad homology of other virus including Influenza.
  - Anti-Inflammatory: Unique MOA does not suppress immune system while reducing inflammation.
  - Bronchodilation: Useful mechanism for at-risk patients with underlying cardio/pulmonary conditions.

Broad Coverage Across Viral Homology is Important

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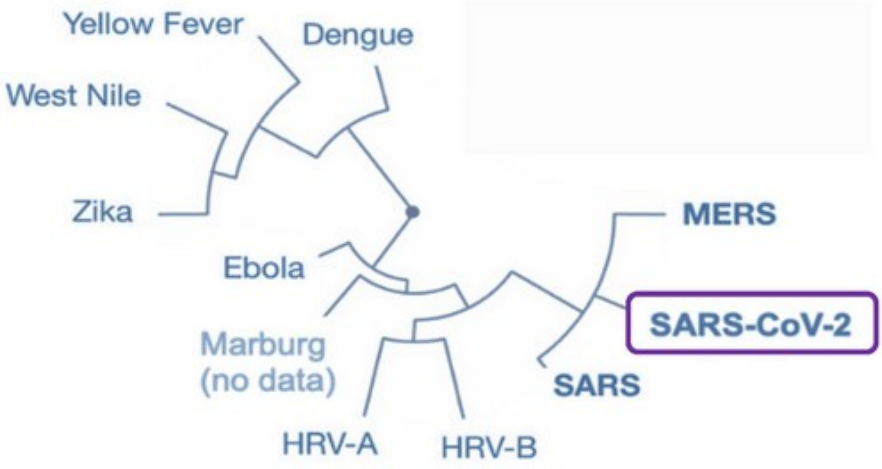
Mutations / Another Corona Virus / Influenza

Niclosamide is effective against diverse virus families *in vitro*.



Source: https://pubs.acs.org/doi/10.1021/acsinfecdis.0c00052

Evidence: *In-Vitro* Efficacy Related to COVID-19

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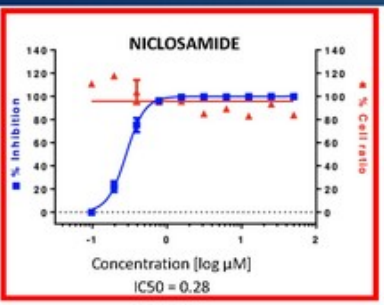
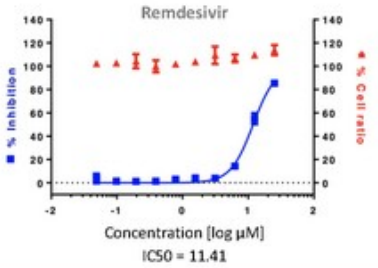
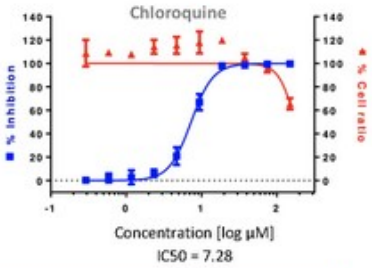
Inhibition of SARS-CoV-2 replication

(Jeon *et al.*, 2020, *Antimicrob. Agents Chemother.* doi:10.1128/AAC.00819-20)

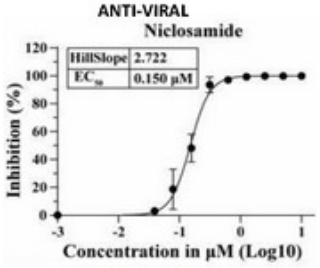






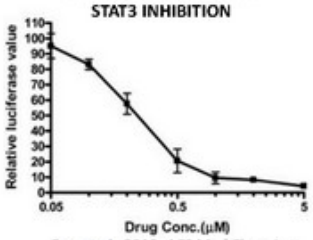
Studies highlighting properties of niclosamide as COVID-19 treatment

ANTI-VIRAL



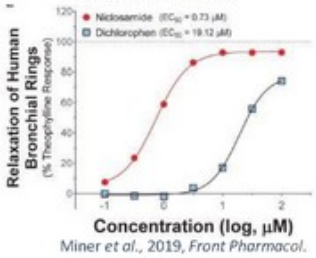
Shi *et al.*, 2020, unpublished

ANTI-INFLAMMATORY: STAT3 INHIBITION



Ren *et al.*, 2010, *ACS Med Chem Lett.* doi:10.1021/ml100146z

BRONCHODILATION



Miner *et al.*, 2019, *Front Pharmacol.* doi:10.3389/fphar.2019.00051

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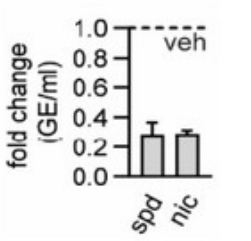
Pre-treating cells with niclosamide reduces viral replication by ~70%

- VeroFM cells were pre-treated with spermidine (spd, 100 µM), niclosamide (nic, 5 µM) or control (veh) 24 h prior to infection with SARS-CoV-2
- Spermidine is a natural enhancer of autophagy to protect the body
- 24 h after infection, viral replication was assessed (normalized to control)



GE: SARS-COV-2 GENOME EQUIVALENTS (DETERMINED BY REAL-TIME RT-PCR)

Gassen *et al.*, 2020, Preprint from *bioRxiv*, doi: 10.1101/2020.04.15.997254

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ANA001 and COVID-19

Clinical Program

Update on ANA001-002 (Phase 1 study)

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SAD n=30 (8 subjects on ANA001, 2 on placebo / per cohort)	Date	Outcomes
Cohort 1: 1,000 mg	Nov 17, 2020	no AEs
Cohort 2: 2,000 mg	Nov 20, 2020	no AEs
Cohort 3: 3,000 mg	Nov 24, 2020	no AEs

COMPLETED

Clinical Trial Design: Phase 2/3

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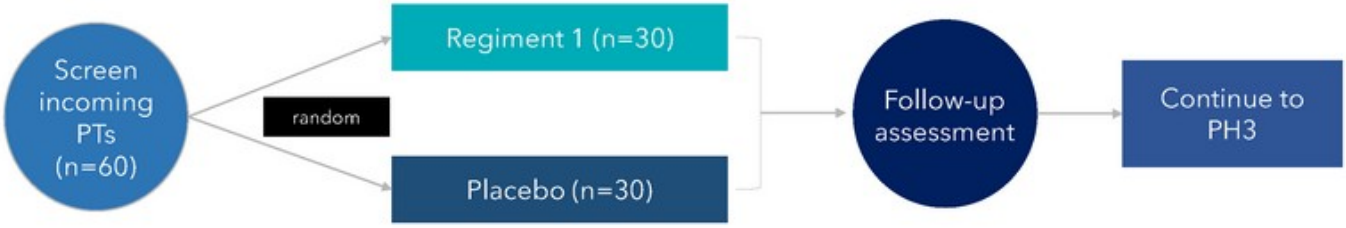

4 days → 7 days → 60 days

Criteria:

✓ Age >18

✓ Moderate/Severe COVID-19

✓ Confirmed by RT-PCR

✓ Not on a ventilator

Primary Objective:

Evaluate effect of dosing regimen on clinical outcomes after niclosamide therapy with 60 patients

Primary Endpoint:

Safety and adverse events

Outcomes:

Continue to Phase 3 to test efficacy

Competitive Activity in Clinical Development for Niclosamide

NeuroBo PHARMACEUTICALS

We believe NRBO is the lead program to NDA for niclosamide capsule formulation in the U.S.

Company Name	NCT	Phase	Start	End	Formulation	Sites	N
ANA Therapeutics	**NCT04603924**	**2 & 3**	**Oct-20**	**Nov-22**	**O**	**20 sites**	**436**
Imuneks Farma ilac San. Tic A. S.	NCT04558021	3	Oct-20	Feb-21	O/Suspension	8 in Turkey	200
First Wave Bio	NCT04542434	2	Nov-20	May-21	O	N/A	148
First Wave Bio	NCT04436458	2	Dec-20	Apr-21	O	not listed	100
Bayer through Charite Research Organization GmbH	2020-002233-15	2	Jun-20	Feb/Mar 2021	O	Germany	72
Tufts	NCT04399356	2	Oct-20	Feb-21	O	not listed	100
Daewoong Pharmaceutical	NCT04592835	1	Oct-20	Dec-20	IM	Australia	24
Daewoong Pharmaceutical	NCT04541485	1	Oct-20	Jan-21	IM	Phillippines	40
Daewoong Pharmaceutical	NCT04524052	1	N/A	Dec-20	IM	India	32
Union Therapeutics	EU	1	Aug-20	N/A	Inhaled	N/A	N/A

10 Active COVID Programs for Niclosamide Trials on U.S. and EU databases–ClinicalTrials.gov

COVID-19: Timeline Slide for ANA001 Commercial Development

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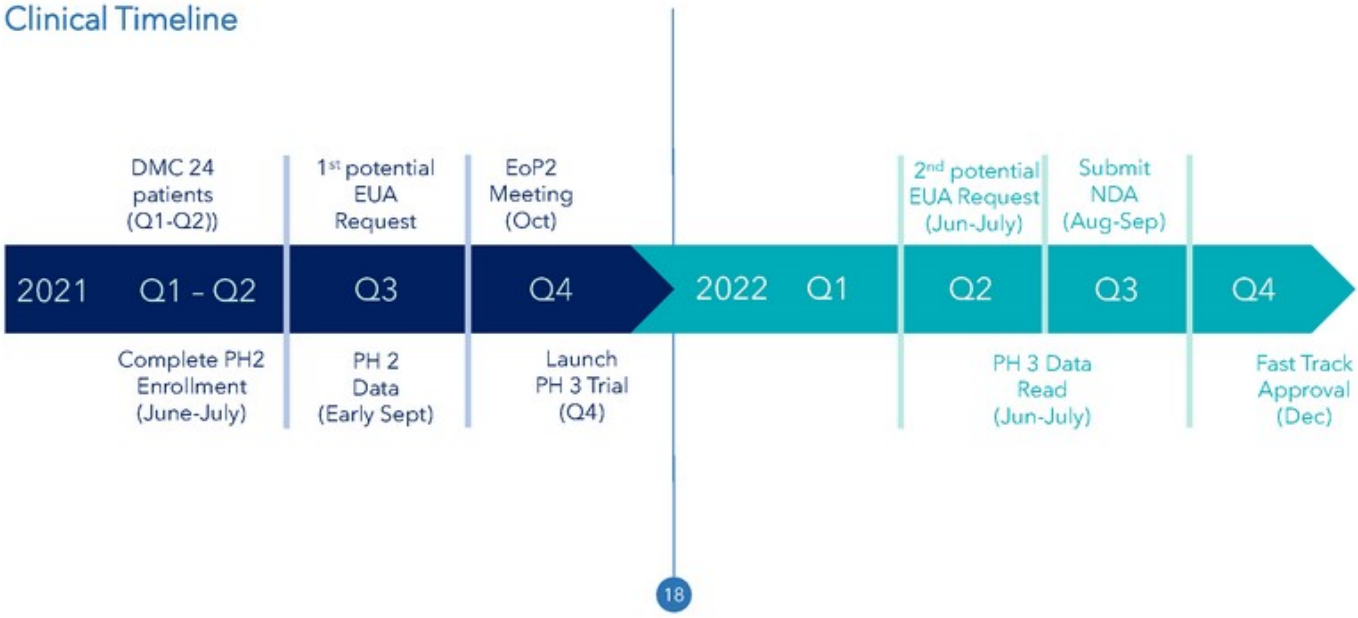
Clinical Timeline



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ANA001 and COVID-19

The Changing Landscape

Potential Markets

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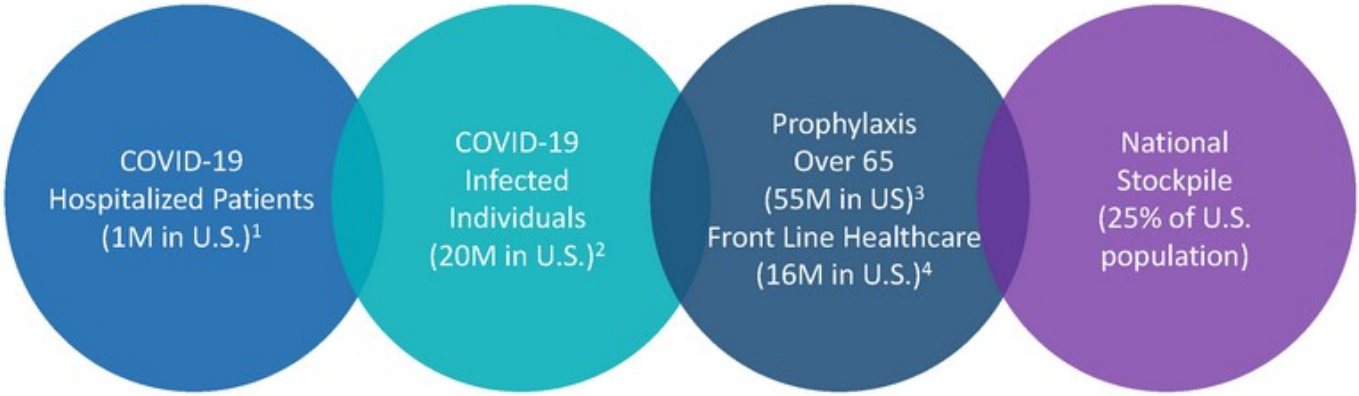

1. COVID-19 Associated Hospitalization Surveillance Network (COVID-NET) Mar-Dec 2020
2. Johns Hopkins Coronavirus Resource Center Mar-Dec 2020
3. Statista: 16.5% of 331M
4. Center for Economic and Policy Research (CEPR) April 2020

Vaccines are Just One Tool for COVID-19

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Challenges:

- RNA Vaccine–Ultra Cold storage
- Manufacturing: scale-up capacity
- Most vaccines are 2 doses
- Willingness of population to get vaccinated
- Mutation of viral sequence may require new vaccines

Unknowns:

- Long-term efficacy
- Efficacy in diverse populations
- Safety – Side effects
- Vaccinated individuals still spread COVID
- Efficacy on new mutations

TFF Pharma and UNION Therapeutics Ink Deal to Develop Niclosamide for COVID-19

Published: Aug 14, 2020 | By Mark Terry

Under the terms of the deal, UNION is paying TFF Pharmaceuticals potential development, regulatory and sales milestones up to $210 million, as well as tiered single-digit royalties on product sales. UNION gains an option to a worldwide exclusive license to TFF technology for niclosamide, including oral and inhaled versions of the drug, potentially for COVID-19, but also for other niclosamide-based therapies. The two companies will also collaborate on securing government contracts and grants to fund the development of the therapies for COVID-19.

Roche Secures Covid-19 Treatment In $350 Million Deal With Boston-Based Atea

Robert Hart Forbes Staff
Business
I cover breaking news.

TOPLINE Swiss pharma giant Roche has signed a $350 million deal with Boston-based Atea Pharmaceuticals for the exclusive right to research, develop and distribute a potential Covid-19 treatment outside the U.S., Atea said Thursday — the oral antiviral is currently in phase 2 clinical trials and there are plans to study it as a way of preventing Covid-19 infection.

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Hatch-Waxman Exclusivity and Intellectual Property

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- NRBO is pursuing an abbreviated regulatory pathway using A 505(b)(2) New Drug Application (NDA).
  - This allows for referencing all the safety data from niclosamide's original approval.
- A 505(b)(2) New Drug Application (NDA) provides 3 years of market exclusivity.
  - Niclosamide NDA was withdrawn in 1996 due to low incidence of tapeworm in the U.S.
  - Three-year exclusivity period would block the approval of any generic drugs.
- The three-year exclusivity period may be extended by 6 months with pediatric exclusivity.
- Continue to supplement the provisional filings, which include clinical data from COVID patients.
  - Potential to strengthen IP in priority regions globally.

Financials & Cap Structure

NeuroBo PHARMACEUTICALS

- Shares outstanding : 22.2 M
- Cash position: $12.4M as of 9/30/20
- $10M Raise in January 2021
- Debt position: No debt

Upcoming Targeted Milestones

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- PK Data (SAD and MAD) (2Q 21)
- Complete Phase 2 enrollment of ANA001 in moderate to severe COVID-19 patients (Jun/Jul 21)
- Topline data from Phase 2 ANA001 in moderate to severe COVID-19 patients (Sep 21)
- Potential consideration for EUA based on Phase 2 topline data (3Q 21)
- Initiate the Phase 3 portion of the ANA001 clinical trials (4Q 21)

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