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 8, 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

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.

Representatives of NeuroBo Pharmaceuticals, Inc. will be presenting the slides attached as Exhibit 99.1 to this report at the H.C. Wainwright BIOCONNECT 2021 Conference, which is scheduled to take place from January 11-14, 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 No.	Description
99.1	Company Presentation, dated January 8, 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 hereunto duly authorized.

NEUROBO PHARMACEUTICALS, INC.

Date: January 8, 2021

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

Exhibit 99.1


NeuroBo
PHARMACEUTICALS
Company Presentation
January 8, 2021
Confidential

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, 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 Annual Report on Form 10-K for the year ending December 31, 2019 and our other filings with the SEC, including our quarterly Q and R 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.

COMPANY OVERVIEW AND MERGER WITH ANA THERAPEUTICS

NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company focused on developing and commercializing multimodal disease-modifying therapies for viral, neuropathic and neurodegenerative diseases.

Repurposing ANA-001 as a rapid COVID-19 treatment (Priority)

ANA-001 – COVID-19 Trial

- Compelling in-vitro data showing efficacy, with 50+ years of safety
- Shows great broad-spectrum antiviral activity
  - Effective against other viruses such as influenza
  - Likely effective against novel COVID-19 variants
- Shows great anti-inflammatory properties, without suppressing immune response
- Shows promise as a prophylactic

Pipeline Programs Addressing Large Unmet Needs

NB-01 – Targeting Pain in Orphan Indication

- Compelling Phase 2 data showing 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; Solid preclinical data

Gemcabene: Originally Targeting Chronic Orphan Dyslipidemia indications:

- Reassessing target for acute COVID-19 indication
- 25 Phase 1 and Phase 2 trials completed

PROVEN LEADERSHIP TEAM

Richard J. Kang, PhD
President & CEO

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

Akash Bakshi, MsC.
Chief Operating Officer

- Founder and CEO of ANA Therapeutics
- Founder and CEO of YourChoice Therapeutics
- Previously Assistant Director of Marketing and Technology Analysis at UC Berkeley.

Nikki Shannon, RegN, BA
VP, Clinical Operations

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

EXPERT SCIENTIFIC ADVISORY BOARDS

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 anaylst

ALZHEIMER'S DISEASE & OTHER DEMENTIAS

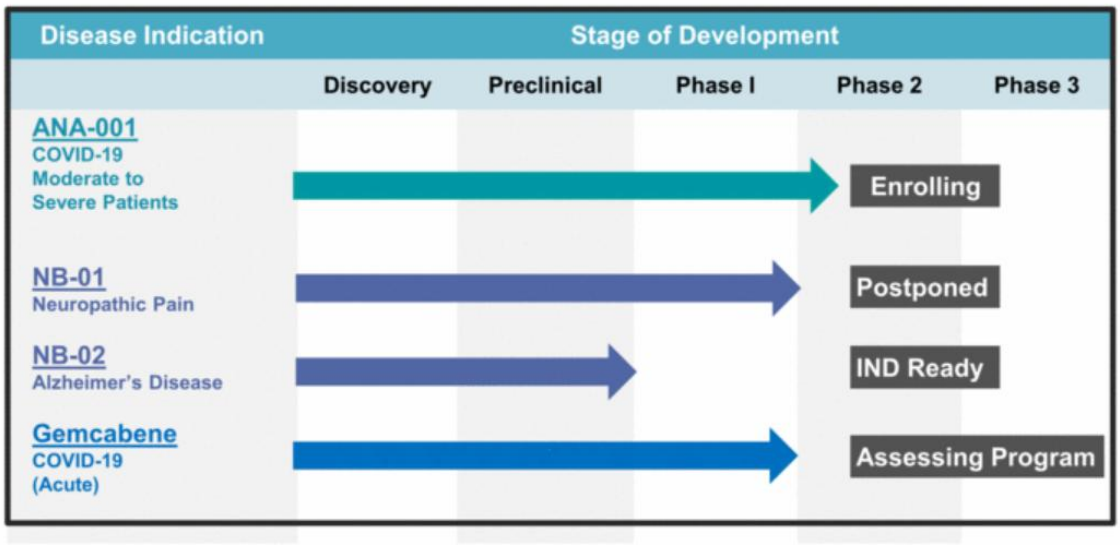
Brian Bacskai, PhD
Expert in Alzheimer's Disease Research

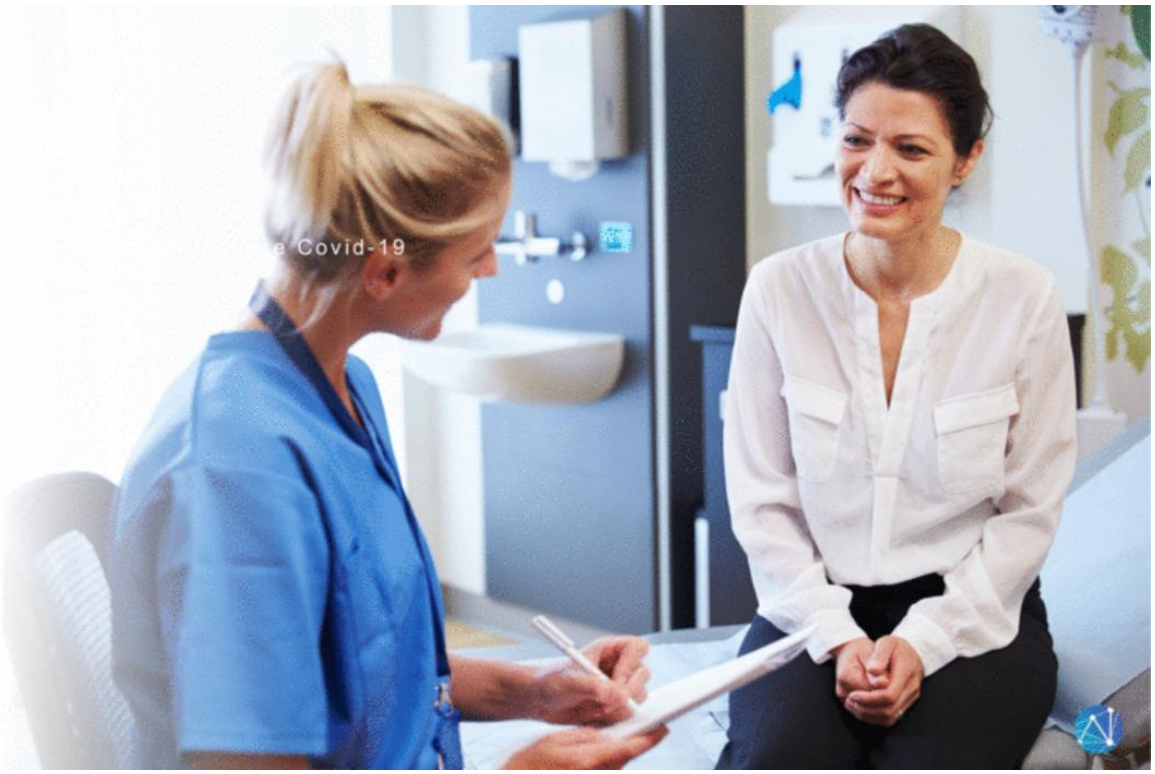
- Professor of Neurology, Harvard Medical School
- Principal Investigator, Neurology, Massachusetts General Hospital

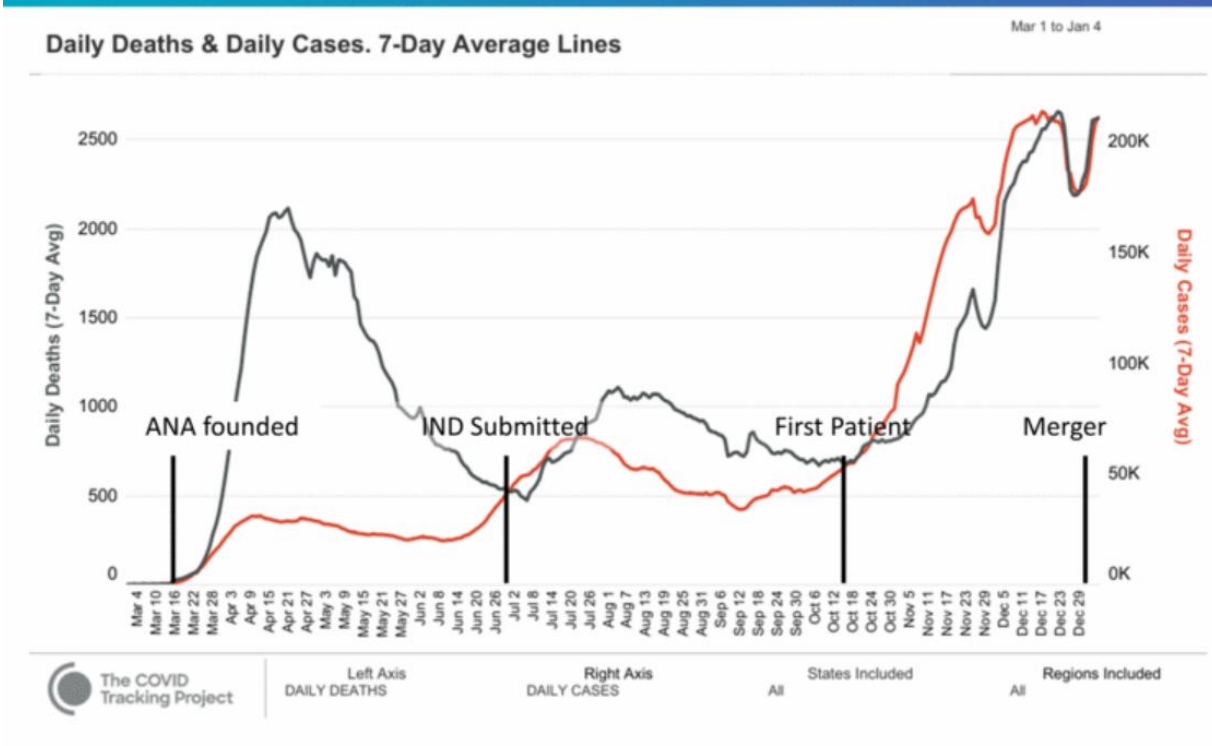
Pierre N. Tariot, M.D.
Award-Winning Leader in Dementia

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

NEUROBO DEVELOPMENT PIPELINE



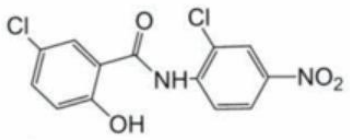

e Covid-19


Daily Deaths & Daily Cases. 7-Day Average Lines
Mar 1 to Jan 4
Daily Deaths (7-Day Avg)
Daily Cases (7-Day Avg)
2500
2000
1500
1000
500
0
200K
150K
100K
50K
0K
ANA founded
IND Submitted
First Patient
Merger
Mar 4
Mar 10
Mar 16
Mar 22
Mar 28
Apr 3
Apr 9
Apr 15
Apr 21
Apr 27
May 3
May 9
May 15
May 21
May 27
Jun 2
Jun 8
Jun 14
Jun 20
Jun 26
Jul 2
Jul 8
Jul 14
Jul 20
Jul 26
Aug 1
Aug 7
Aug 13
Aug 19
Aug 25
Aug 31
Sep 6
Sep 12
Sep 18
Sep 24
Sep 30
Oct 6
Oct 12
Oct 18
Oct 24
Oct 30
Nov 5
Nov 11
Nov 17
Nov 23
Nov 29
Dec 5
Dec 11
Dec 17
Dec 23
Dec 29
The COVID Tracking Project
Left Axis
DAILY DEATHS
Right Axis
DAILY CASES
States Included
All
Regions Included
All

What is Niclosamide?

Background

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



Niclosamide

- **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**

ANA-001

ANA Therapeutics has developed a proprietary capsule formulation of niclosamide for COVID-19 treatment and prophylaxis

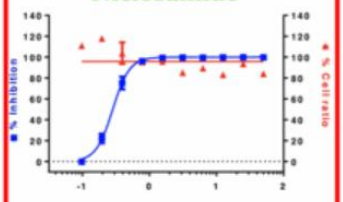
- ANA-001 is being studied in a Phase 2/3 trial in the US that is currently enrolling patients
- Generic niclosamide has been used safely for 50 years globally as a treatment for tapeworm infections
- Niclosamide prevents replication of SARS-CoV-2 at very low concentrations
- Niclosamide has also been shown to have three distinct mechanisms of action:
  - Potent Anti-Viral at lowering SARS-CoV-2 and a broad homology of other virus including **Influenza**.
  - Anti-Inflammatory – Unique MOA that does not suppress immune system while reducing inflammation.
  - Bronchodilation – Useful pulmonary mechanism for at-risk patients with underlying cardio/pulmonary conditions.

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

Inhibition of SARS-CoV-2 replication

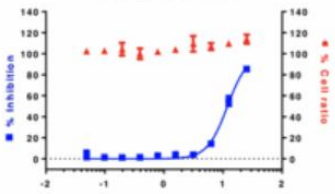
(Jeon *et al.*, 2020, *Antimicrob. Agents Chemother.* doi:10.1128/AAC.00819-20)

Niclosamide



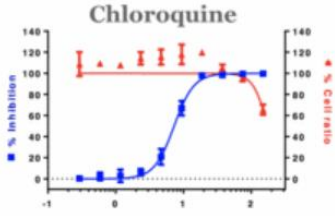
Concentration [log µM]
IC50 = 0.28

Remdesivir



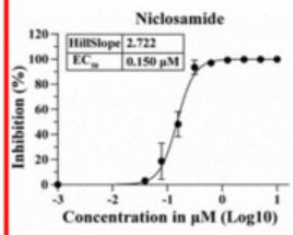
Concentration [log µM]
IC50 = 11.41

Chloroquine



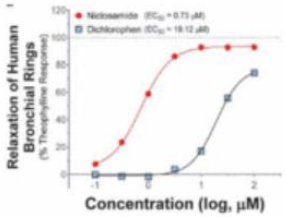
Concentration [log µM]
IC50 = 7.28

Anti-Viral



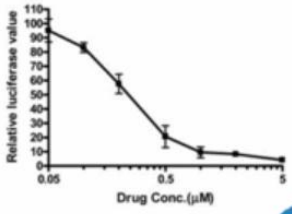
Shi et al., 2020, unpublished

Bronchodilation



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

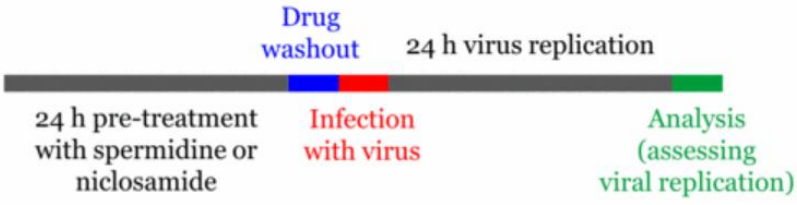
Anti-Inflammatory: STAT3 inhibition

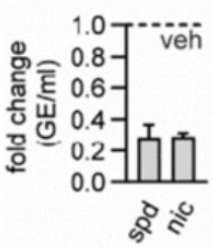


Ren *et al.*, 2010, *ACS Med Chem Lett.* doi: 10.1021/ml100146z

Niclosamide as COVID-19 Prophylaxis

- 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)
- **Main result: Pre-treating cells with niclosamide reduces viral replication by ~70%**

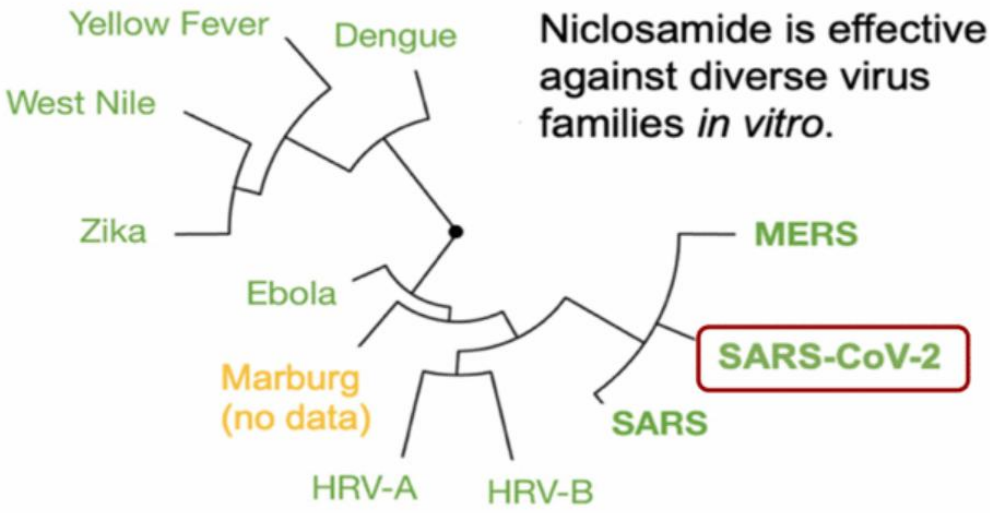




Gassen *et al.*, 2020, Preprint from *bioRxiv*, doi: 10.1101/2020.04.15.997254

GE: SARS-CoV-2 genome equivalents (determined by real-time RT-PCR)

Broad Coverage Across Viral Homology is Important Mutations/Another Corona Virus / Influenza



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

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

Potential Markets

COVID-19 Hospitalized Patients (1M in US) [1]

COVID-19 Infected Individuals (20M in US) [2]

Prophylaxis Over 65 (55M in US) [3] Front Line Healthcare (16M in US) [4]

National Stockpile (25% of US population)

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

Competitive Activity in Clinical Development
for niclosamide

- 10 total studies listed in ClinicalTrial.gov for niclosamide

Currently Active Programs

Competing Niclosamide trials on US and EU trial databases Company Clinical Trials.Gov	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

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

Landscape of Vaccines and Therapeutics

Prevention (Vaccines)	Therapeutics (Treatment)
Pfizer – RNA / 2 shots	Hydroxychloroquine
AstraZeneca – Viral Vector / 2 shots	Convalescent Plasma
Moderna – RNA / 2 shots	Antibody- Regeneron / Lilly
Novavax – Protein Subunit / 2 shots	Remdesivir – Gilead **$875M in Q3/2020**
Sanofi – Protein Subunit / 2 shots	Olumiant - Lilly
Merck – Viral Vector / 1 shot	Dexamethasone
J&J – Viral Vector / 1 or 2 shots	+ Hundreds other drugs in small trials

- Vaccines have a challenge with public trust
- Cost of manufacturing is high especially for 2 shot
- Protective immunity 4-6 months = 4 shots yr.
- Cost of cold chain distribution is expensive
- Still need a therapeutic for those who get sick

- Effectiveness has been underwhelming
- Most lack mortality benefit
- Several temporally lower body's Immune System
- Some have safety concerns
- IV and injectable formulations not ideal

Vaccines are an Important Tool in Battling COVID-19 However There are Challenges to Overcome

- RNA Vaccine - Ultra Cold storage (-100° F) and "cold chain" distribution scale-up
- Manufacturing: scale-up capacity
- Essential supply of vials, syringes, etc.
- 2 administrations necessary 28 days apart
- 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
- Long term impacts of covid infections in vaccinated individuals
- Can vaccinated individuals still spread COVID?

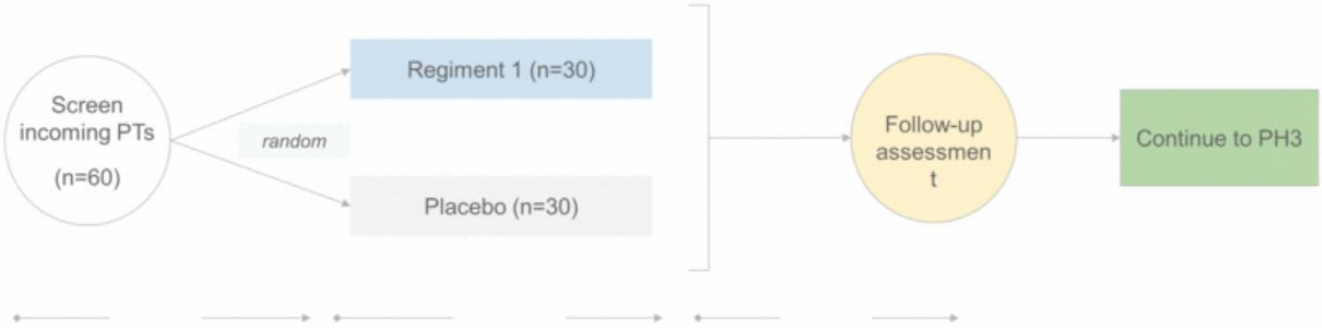
Pharma is still hungry for Antivirals

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.

Clinical Trial Design: Phase 2



Criteria:

- ✓
- ✓
- ✓
- ✓

Primary objective:

Primary Endpoint:

Outcomes:

Update on ANA001-002 (Phase 1 study)

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

Emergency Use Authorization

- The primary mechanism of FDA approval of therapeutics during the COVID-19 pandemic has been **Emergency Use Authorization (EUA)**
- EUA requires a lower level of evidence than the "effectiveness" standard that FDA uses for standard product approvals.
- None of the existing therapeutics approved under EUA have demonstrated any mortality benefit
- Key examples include:
  - Remdesivir (Gilead)
  - Convalescent plasma
  - Hydroxychloroquine
  - Remdesivir + Baricitinib (Eli Lilly)
  - Casirivimab and Imdevimab (Regeneron)
  - Bamlanivimab (Eli Lilly)

EUA Definition & Criteria

What is EUA?

During a public health emergency, the FDA may authorize the introduction of a drug into interstate commerce, including one which is not yet (or currently) approved under 505 of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Per Section 564 of the FD&C Act, EUA is appropriate in consideration of the following conditions

(1) serious of life-threatening disease or condition,

(2) evidence of effectiveness,

(3) risk-benefit analysis, and

(4) no alternatives.

Each of these conditions is met in relation to the potential for ANA001 to treat COVID-19.

Hatch-Waxman Exclusivity and Intellectual Property

- **NRBO is pursuing an abbreviated regulatory 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 is not currently approved in the US, so there is unlikely to be competition**
  - **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**
- **NRBO will continue to supplement the provisional filing, which will include clinical data from COVID positive patients.**
  - **This is a unique opportunity in biotech/pharma and expected to be particularly valuable in priority jurisdictions.**

COVID-19: Timeline Slide for ANA-001 Commercial Development

Clinical Timeline