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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 biowarfare analyst

ALZHEIMER’S DISEASE
& OTHER DEMENTIAS
Brian Bacsai, 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
<table>
<thead>
<tr>
<th>Disease Indication</th>
<th>Stage of Development</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANA-001</strong> COVID-19</td>
<td>Enrolling</td>
</tr>
<tr>
<td>Moderate to Severe Patients</td>
<td></td>
</tr>
<tr>
<td><strong>NB-01</strong> Neuropathic Pain</td>
<td>Postponed</td>
</tr>
<tr>
<td><strong>NB-02</strong> Alzheimer’s Disease</td>
<td>IND Ready</td>
</tr>
<tr>
<td><strong>Gemcabene</strong> COVID-19 (Acute)</td>
<td>Assessing Program</td>
</tr>
</tbody>
</table>
Targeting Covid-

First indication: Moderate/Severe Covid-19
What is Niclosamide?

Background

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

• 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

### Anti-Viral

**Niclosamide**

- **HillSlope**: 2.722
- **EC50**: 0.150 μM

Shi et al., 2020, unpublished

### Anti-Inflammatory: STAT3 inhibition

**Remdesivir**

- **IC50**: 11.41

Miner et al., 2019, *Front Pharmacol.*

doi:10.3389/fphar.2019.00051

**Chloroquine**

- **IC50**: 7.28

Ren et al., 2010, *ACS Med Chem Lett.*

doi: 10.1021/ml100146z

### Bronchodilation

- Niclosamide (IC50 = 0.71 μM)
- Dichlorophen (IC50 = 16.1 μM)

**Concentration [log µM]**

**Inhibition of SARS-CoV-2 replication**

doi:10.1128/AAC.00819-20

**Evidence:**

**Concentration [log µM]**

**IC50 = 0.28**

**Concentration [log µM]**

**IC50 = 11.41**

**Concentration [log µM]**

**IC50 = 7.28**
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%

**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)

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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
Competitive Activity in Clinical Development for niclosamide

- 10 total studies listed in ClinicalTrial.gov for niclosamide

**Currently Active Programs**

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

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

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

- 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

Screen incoming PTs (n=60)

- Random

   Regiment 1 (n=30)

   Placebo (n=30)

Follow-up assessment

Continue to PH3

Criteria:
- ✓
- ✓
- ✓
- ✓

Primary objective:

Primary Endpoint:

Outcomes:
## Update on ANA001-002 (Phase 1 study)

<table>
<thead>
<tr>
<th>SAD n=30 (8 subjects on ANA001, 2 on placebo / per cohort)</th>
<th>Date</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cohort 1: 1,000 mg</strong></td>
<td>Nov 17, 2020</td>
<td>no AEs</td>
</tr>
<tr>
<td><strong>Cohort 2: 2,000 mg</strong></td>
<td>Nov 20, 2020</td>
<td>no AEs</td>
</tr>
<tr>
<td><strong>Cohort 3: 3,000 mg</strong></td>
<td>Nov 24, 2020</td>
<td>no AEs</td>
</tr>
</tbody>
</table>

**COMPLETED**

- **Cohort 2: 2,000 mg**
- **Cohort 3: 3,000 mg**
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.
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

- **Q1 2021**: Start Work Gemcabene (Mar-Apr)
- **Q2 2021**: PH 2 Data (Early Sept), EoP2 Meeting (Sept-Oct)
- **Q3 2021**: 1st EUA Request (Sept), Launch PH 3 Trial (Sept-Oct)
- **Q4 2021**: 2nd EUA Request (Jun-July), 2nd EUA Request (Jun-July), Submit NDA (July-Aug)
- **Q1 2022**: PH 3 Data Read (Jun-July), Fast Track Approval (Dec)

- **DMC 24 patients (Mar-Apr)**
- **Q2 2021**: Launch PH 3 Trial (Sept-Oct)
- **Q3 2021**: 2nd EUA Request (Jun-July)
- **Q4 2022**: Submit NDA (July-Aug)