



Enalare Therapeutics Inc.

Developing and commercializing novel therapies to address the
national health crisis of Acute Respiratory Depression

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Enalare presents a compelling investment opportunity

Poised to fundamentally change clinical practice in the treatment of acute respiratory depression



Significant medical need

- Convergence of health emergencies with commonality of respiratory depression
- Critical need for a safe, agnostic ventilatory stimulant in multiple treatment settings



Robust proof-of-concept

- Positive safety and efficacy results across four human trials
- Extensive pre-clinical platform, including 12 toxicology studies in multiple animal species



Clear & expedient path to market

- Well defined development program with clear endpoints for reversal of respiratory depression
- Initiating registration trials for lead indication – estimate approval in ~ 2 years



Large market opportunities

- Broad medical and health economic benefits driving \$1.5B+ sales potential*
- Novel mechanism-of-action with patent protection through 2031, additional patents pending



Proven top-tier team

- Demonstrated ability to develop and launch blockbuster products with consistent value creation
- Industry leading scientists and advisors



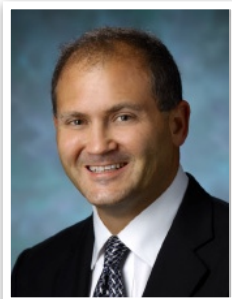
*Enalare internal analysis

Enalare Senior Management & Board of Directors



Herm Cukier
Chief Executive Officer
& Board Member

- CEO and Board Member of BioDelivery Sciences (NASDAQ: BDSI)
- SVP of Allergan - leading several multi-billion dollar divisions
- Chief Marketing Officer and Member Company Management Team - Organon Biosciences
- Executive positions with top tier companies including Bayer, BMS, and Pfizer
- MBA Columbia Business School
- BSE University of Pennsylvania



Dr. Joseph Pergolizzi
Chief R&D Officer
& Board Member

- Internationally recognized thought leader in areas of perioperative and pain medicines, drug development and regulatory affairs
- Highly published in top tier journals
- Frequent scientific advisor for public and private companies
- Serial entrepreneur, started more than 20 companies
- Johns Hopkins School of Medicine
- Georgetown School of Medicine - residency



Daniel Motto
Chief Business Officer

- EVP of Hikma Pharmaceuticals leading US Injectable Division
- SVP Allergan (Actavis) - Head of Business Development, Portfolio & Business Intelligence, Global Generic Medicines
- SVP Teva, Global Business Development
- Executive positions with top tier companies including Johnson & Johnson and Novartis
- MBA Johnson College of Business, Cornell University
- MS Engineering, Cornell

Board of Directors

Gino Santini

Former member of Eli Lilly's executive committee leading Corporate Strategy and Business Development. Prior roles over a career spanning nearly three decades included president of US operations, various leadership positions in international regions and president of the women's health franchise.

- Eli Lilly & Co
- Board Member:
 - Horizon Pharma
 - Amag Pharma
 - Intercept Pharma
 - Collegium Pharma

Bob Yedid

30 yrs of experience as a buy-side analyst, portfolio manager, private equity investor and investment banker. Currently focuses on providing CEOs and CFOs with strategic advice on key investor issues. Former Board member of The Medicines Co. and Vaxart. MBA Stanford School of Business, BA Yale University.

- LifeSci Advisors
- Principal Capital
- Warburg Pincus
- Bear Stearns & Co (now JPM)

Joseph Petko

20 yrs experience in corporate finance and investment analysis. Currently co-Chief Investment Officer for public equity investing, with a focus on small cap growth companies. Prior experience in financial positions in the pharmaceutical industry. MBA Lehigh University, BBA Wharton, University of Pennsylvania.

- Ashford Capital Management
- Merck & Co.



Acute Respiratory Depression – A National Health Emergency

Respiratory Depression

Respiratory Depression is a condition characterized by slow and ineffective breathing resulting in:

- low levels of oxygen (hypoxemia) and/or
- high levels of carbon dioxide (hypercapnia)

If left untreated it can cause life-threatening complications, including death.

Common Causes:

Medications	Health Conditions
<ul style="list-style-type: none">• Sedative medications• Narcotics for pain• Alcohol• Other substances that depress brain function• Synergistic effect from drug combinations	<ul style="list-style-type: none">• Obesity and aging• Viral or bacteria infections (e.g. COVID)• Neuromuscular diseases• Sleep apnea• Chronic lung diseases



Initial Target Markets

Drug overdose

- Substance abuse epidemic accelerating
- US deaths exceeded 70K, record high expected in 2020
- Polysubstance (multi-drug) abuse a growing issue
- Current treatment option is incomplete – only addresses opioid overdose
- Expedited pathway to market

Post-operative care

- Large and growing at-risk populations
- Unmet medical need – very limited treatment options
- 50mil+ surgeries performed annually
- Compelling health economic benefits by reducing ICU/overall hospital length of stay
- Significant long-term commercial potential – US and Ex-US

Respiratory infections

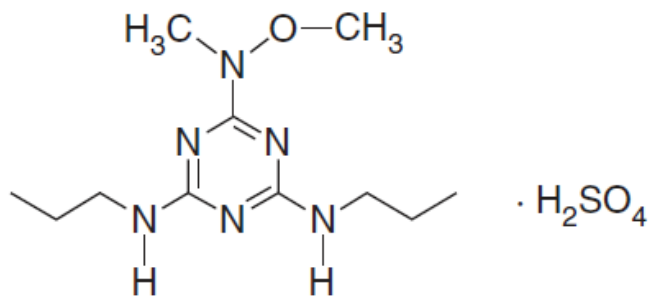
- Acute and chronic respiratory complications associated with infections
- COVID-19 pandemic highlighting risks
- High mortality rate if require ventilator
- Urgent need for new therapies to address on-going incidence and pandemic spikes



ENA-001: A first-in-class New Chemical Entity (NCE)

Agnostic Ventilatory Stimulant

- A new molecule (NCE) with novel Mechanism-of-action (MoA) - Inhibits Big Potassium (BK) ion channels
- It does not interfere with pain suppression or sedation – safely restores respiration without combative withdrawal



ENA-001 hydrogen sulphate salt

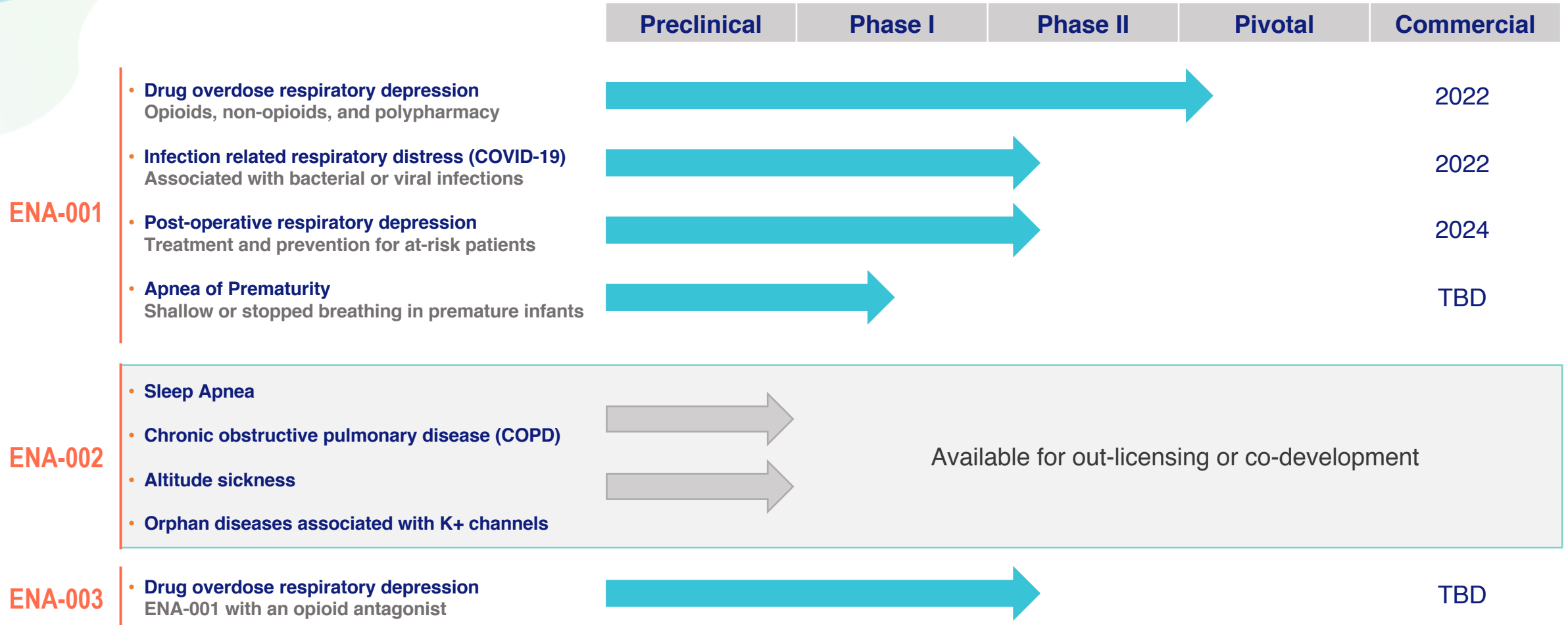
2-N,O-dimethylhydroxylamino-4,6-bispropylamino-s-triazine

Advanced Development Status

- Ready to initiate registration studies in Q2 2021
- Existing human proof-of-concept studies
- Safe and well tolerated
- Strong IP including issued composition-of-matter patents extending through Dec. 2031
- Existing clinically effective formulation with next generation re-formulation underway
- Clear and rapid path to market for lead indication (drug overdose) with potential for accelerated FDA review
- Significant potential for near-term value inflection

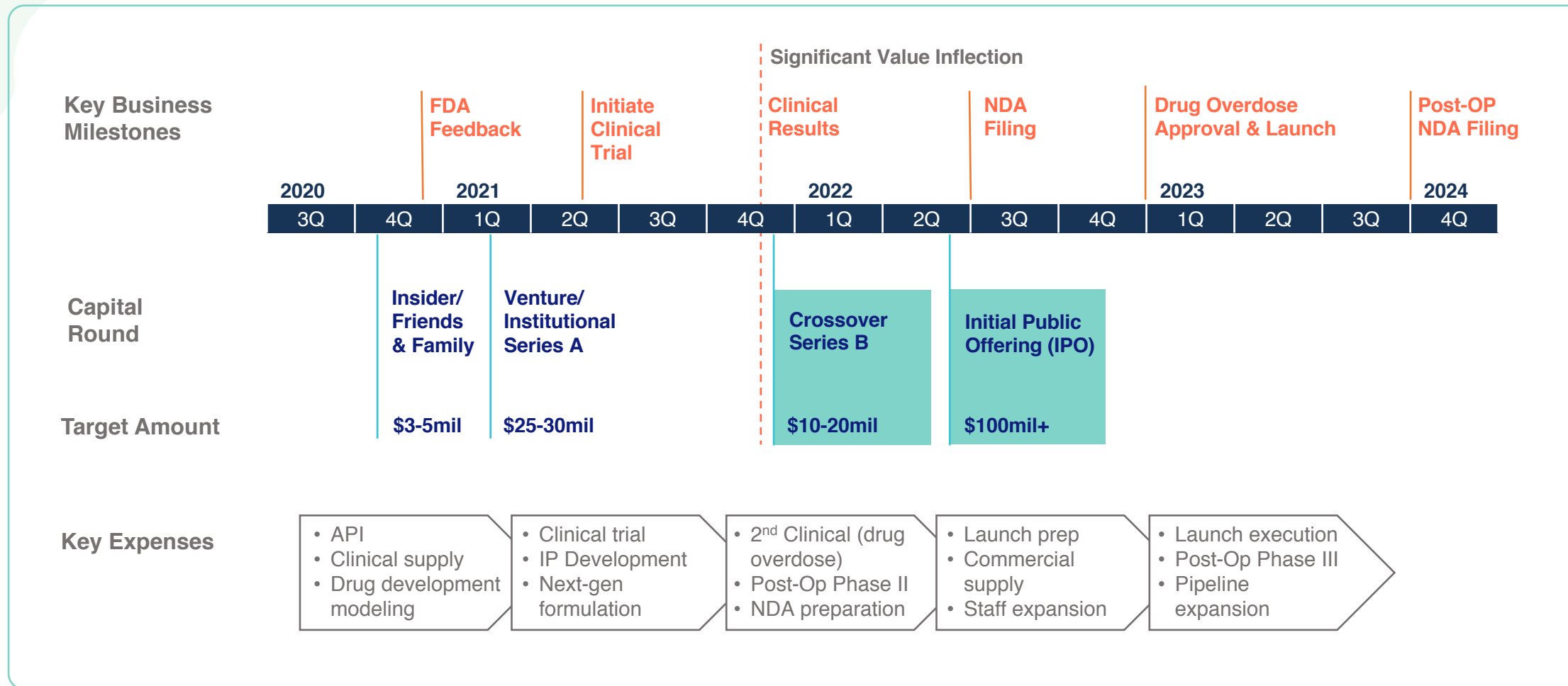


Enalare's pipeline has the potential to dramatically improve medical practice and patient outcomes in multiple settings



ENA-001/ENA-003: Ex-US geographies available for out-licensing

Enalare proposed capital plan with key milestones

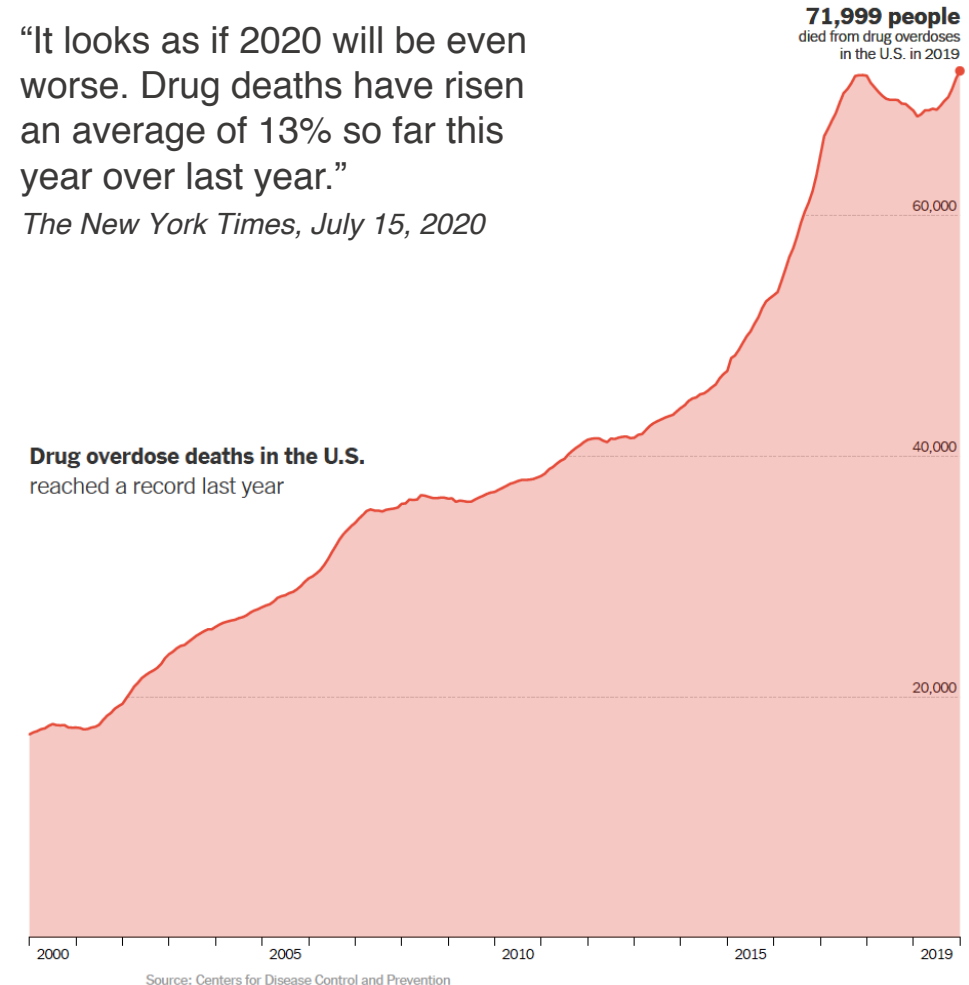


The drug overdose epidemic is escalating and evolving - dire need for an agnostic breathing stimulant

- Drug deaths in the US rose to record levels in 2019
- Early signs indicate that COVID-19 has only further accelerated this substance abuse trend
- Poly-pharmacy (multiple drug) abuse is estimated at greater than 40% and rising¹
- For every drug overdose that results in death, there are many more non-fatal overdoses
 - Approximately 20mil users misuse opioids and other depressant drugs annually²
 - Significant burden on healthcare systems, hospital resources and payors³
- Naloxone (approved in 1971) is the only marketed reversal agent – problematic and incomplete:
 - Efficacy limited to opioid overdose
 - Agitated patients consume significant ER resources

“It looks as if 2020 will be even worse. Drug deaths have risen an average of 13% so far this year over last year.”

The New York Times, July 15, 2020



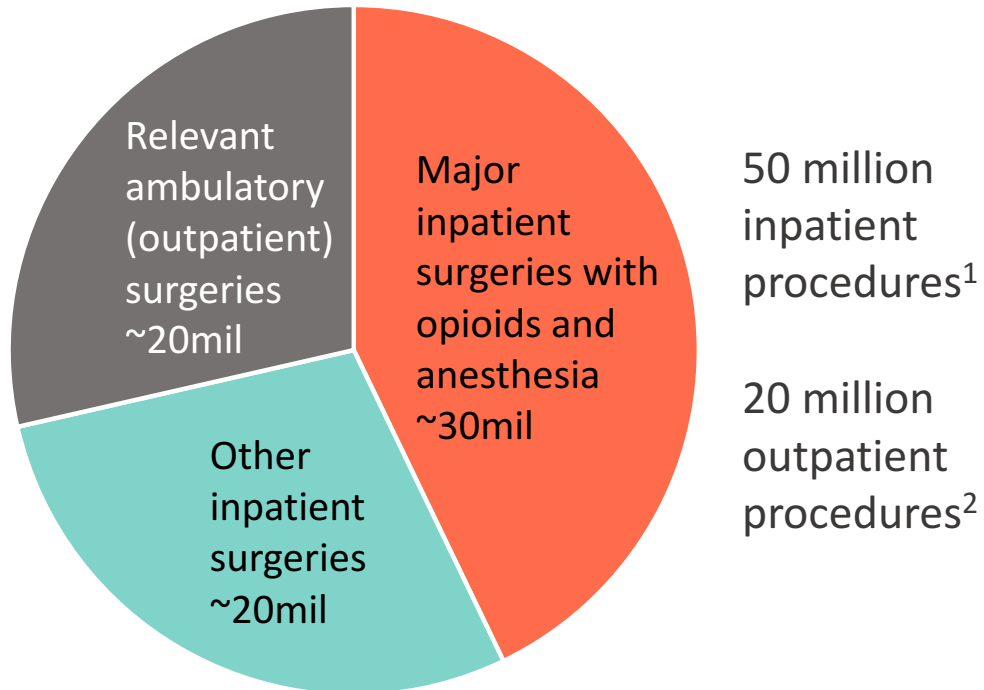
¹ NIH National Institute on Drug Abuse

² Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health, SAMHSA, U.S. Department of Health and Human Services

³ Opioid Overdoses Costing U.S. Hospitals an Estimated \$11 Billion Annually, Premier Inc, January 2019

Large post-operative market opportunity with compelling health economics around treatment of respiratory depression

70+ million procedures performed annually in the US



Respiratory Distress presents a major cost burden on hospitals^{3,4,5,6}

Incremental hospital stay with a respiratory event	<ul style="list-style-type: none">• 5-9 days• 2-3X multiple
Incremental costs with a respiratory event	<ul style="list-style-type: none">• Avg. \$50-60K/hospitalization• 4X+ multiple
ICU Admissions (unplanned)	<ul style="list-style-type: none">• 17-47% have a respiratory indication
Mechanical ventilation costs	<ul style="list-style-type: none">• \$27 billion annually (1/3 of ICU costs)

¹ Chronic Opioid Use After Surgery: Implications for Perioperative Management in the Face of the Opioid Epidemic, *Anesth Analg*. 2017 November ; 125(5): 1733-174

² Ambulatory Surgery Data From Hospitals and Ambulatory Surgery Centers: United States, National Health Statistics Reports, Number 102, February 28, 2017

³ Characterisation and monitoring of postoperative respiratory depression: current approaches and future considerations, S. Ayad, *et al*. *British Journal of Anaesthesia*, 123 (3): 378e391, 2019

⁴ Association of Opioids and Sedatives with Increased Risk of In-Hospital Cardiopulmonary Arrest from an Administrative Database, February 25, 2016

⁵ Premier Market Research Hospital Database Study, Galleon Pharmaceuticals, 2012

⁶ Rao, et al. "Postoperative Respiratory Impairment Is a Real Risk for Our Patients: The Intensivist's Perspective," *Anesthesiology Research and Practice*, vol. 2018



COVID-19 and other viral and bacterial infections leading to lung complications and acute respiratory distress

COVID-19

- The COVID-19 pandemic and others like it will be a concern for the global population in the years ahead
- Over 9 million US infections, deaths now exceed 200,000¹
- Virus expect to persist even with vaccines and improved treatment
- US Federal programs for accelerated pathways to market for new therapeutics:
 - Emergency Use Authorization (EUA)
 - Coronavirus Treatment Acceleration Program (CTAP)
 - Expanded access, Op. Warp Speed



Lung Damage & Respiratory Distress

- COVID-19 can cause lung complications such as pneumonia and, in the most severe cases, Acute Respiratory Distress Syndrome (ARDS)
- Sepsis, and other possible complications of COVID-19, can also cause lasting harm to the lungs
- ~5% of symptomatic COVID-19 patients require admittance to ICU
- Respiratory distress may require CPAP and/or mechanical ventilation for serious cases
- Currently 30-50% mortality rate for patients put on ventilators



Role of ENA-001

- ENA-001 has been called a “pharmacologic ventilator”² and it may have role as an add-on therapy for certain cases
 - Delay or prevent mechanical ventilation
 - Enhance CPAP
 - Aid in weaning off ventilator
- A recent study in COVID patients with a similar compound, almitrine, showed potential beneficial effects
- ENA-001 may improve patient outcomes by a reduction in the risk for oxygen deprivation
- Potential management option for acute and chronic symptoms



¹ Johns Hopkins University, as of Sept 28, 2020

² Joseph F. Cotten, MD, PhD, Editorial, *Anesthesiology*

ENA-001's strong intellectual property includes issued composition-of-matter patents

Issued Patents

- **US 9,351,972**
Compounds as Respiratory Stimulants for Treatment of Breathing Control Disorders or Diseases
Includes NCE and Pharmaceutical Composition claims
Expires 11/29/2031 (+ PTE opportunity)
- **US 9,162,992**
Compounds and Compositions for Treatment of Breathing Control Disorders or Diseases
Includes NCE, Pharmaceutical Composition and Method of Treatment claims
Expires 11/29/2031

Patent and Trademark Applications

- Pending International PCT Application directed to combination therapy for the treatment of opioid overdose, stimulant overdose and polypharmacy overdose. Anticipated expiration of 2040
- Pending U.S. Provisional Application directed to composition and methods for the treatment of respiratory depression in infected patients (including Covid-19). Anticipated expiration of 2041
- 'Enalare' and 'Enalare Therapeutics' trademark applications pending and website domains secured (www.enalare.com)

Patent term extension (PTE) opportunity of up to 5 years on issued patent
Filing strategy in place for future patent opportunities including pharmaceutical formulations, pharmacokinetic/pharmacodynamic profiles, new indications and dosing regimens



ENA-001 shown to be safe and efficacious across four clinical trials totaling ~100 subjects

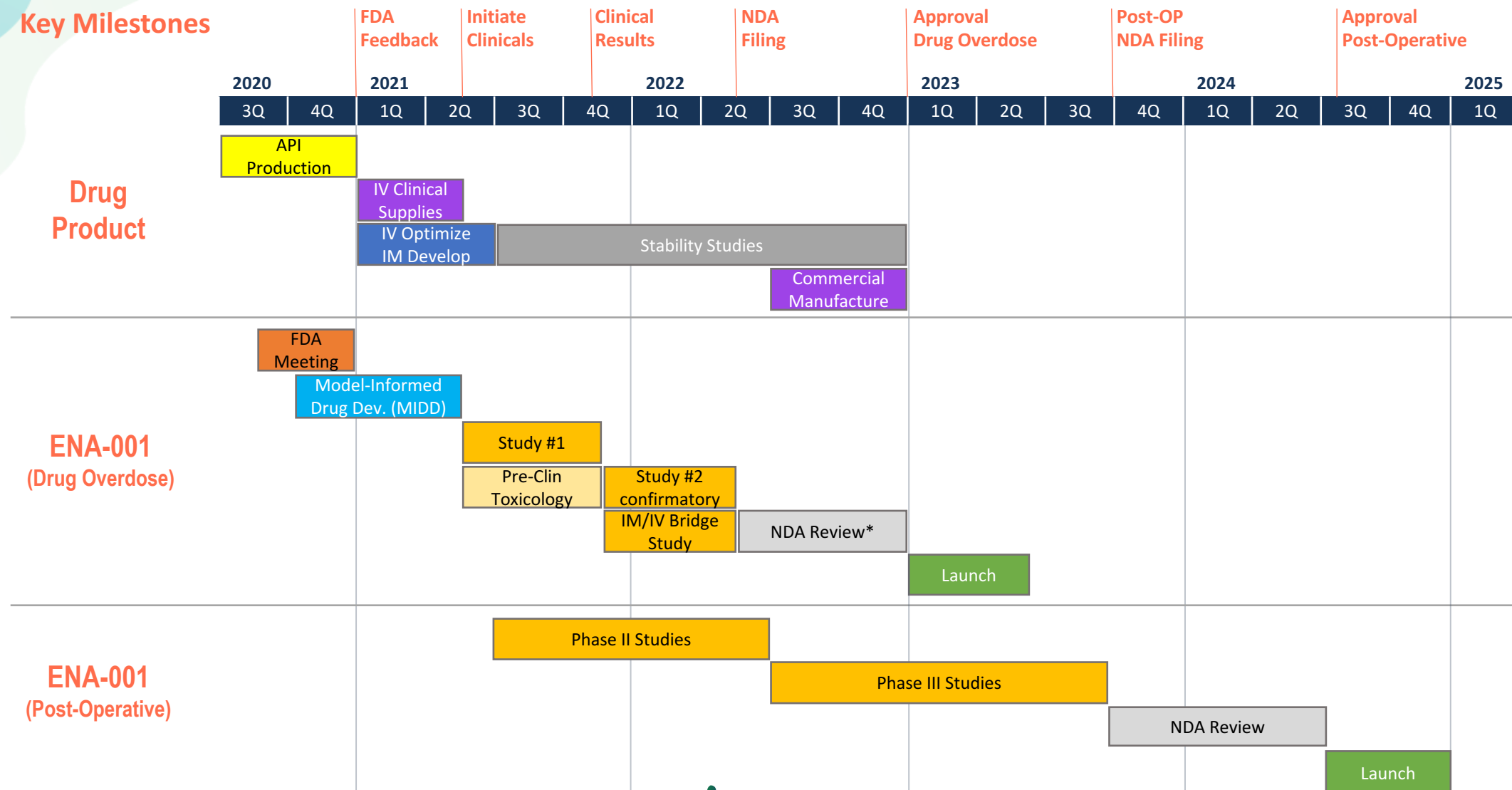
Study	Description	# of Subjects
GAL-021-101	Single, ascending dose study in healthy subjects.	30
GAL-021-102	Extended the dose range explored during the initial study by a factor of 2 and established the maximum respiratory stimulatory dose in the healthy subjects without concomitant use of opioids or anesthetic agents.	18
GAL-021-104	Assessed the potential therapeutic utility under conditions that simulate the post-operative state. Alfentanil was used to suppress ventilation.	23
GAL-021-106	Designed to evaluate the safety and tolerability in healthy subjects during 5 days of 12-hour continuous infusion of 0.125, 0.25, and 0.5 mg/kg.	28

- ✓ Dosing
- ✓ Proof-of-Concept Efficacy
- ✓ Safety & Tolerability



ENA-001 clear and rapid path to market

Key Milestones



*Opportunity to accelerate review via Breakthrough Therapy and/or Fast Track designation

