



FOR IMMEDIATE RELEASE

FIRST SHIPMENT OF RiVive™ BRINGS LIFE-SAVING OVER-THE-COUNTER NALOXONE NASAL SPRAY ONE STEP CLOSER TO THOSE WHO NEED IT MOST

- RiVive™ is now available – *Remedy Alliance* has begun distributing RiVive to community harm reduction groups working to save lives that would otherwise be lost to opioid overdose
- Nonprofit *Harm Reduction Therapeutics* will begin fulfilling orders for RiVive more broadly in early 2024, making it available across the US for free of charge or at a low breakeven cost
- *Harm Reduction Therapeutics* is seeking additional funding partners who can save lives by helping to increase the manufacturing of RiVive, further lower its price, and/or increase the amount of RiVive that HRT can make available free of charge through *Remedy Alliance*

PITTSBURGH, PA, DECEMBER 18, 2023 — *Harm Reduction Therapeutics (HRT), Inc.*, a 501(c)(3) nonprofit pharmaceutical company, has shipped its first order of over-the-counter (OTC) RiVive™ (naloxone HCl nasal spray 3 mg) for the emergency treatment of opioid overdose. This delivery to *Remedy Alliance/For the People* marks a crucial step in *HRT's* singular mission of preventing opioid overdose deaths by making free-of-charge or low-cost over-the-counter naloxone available to everyone in the United States, primarily through community harm reduction organizations and governments.

“With the manufacturing of FDA-approved OTC RiVive well underway, we now need additional funding partners so that naloxone can be made as widely available as possible to help stem the tide of fentanyl and other opioid overdose deaths across the U.S.,” said Michael Hufford, PhD, co-founder and chief executive officer of *Harm Reduction Therapeutics, Inc.* “Charitable funding will allow us to further reduce the selling price of RiVive or make more doses available to local community organizations free of charge.”

Earlier this year [when FDA approved RiVive](#), it was announced that *HRT* is [donating 200,000 doses](#) (10% of projected initial annual product production) to *Remedy Alliance* which will supply RiVive to those who need it most, including people who use drugs, through community harm reduction organizations. *Remedy Alliance* has also made an additional purchase of about 28,000 twin packs of RiVive.

“Harm reduction programs were the original innovators of community-based naloxone distribution almost 30 years ago,” said Eliza Wheeler, co-founder and director of *Remedy Alliance/For the People*. “*HRT's* product donation is a game changer: We will be able to provide an affordable OTC naloxone nasal spray in addition to generic injectable naloxone to the programs we work with, over 80% of which are inadequately funded or do not receive enough affordable naloxone from other sources.”

With additional funding partners, nonprofit *HRT* may be able to make more product donations or decrease the product selling price for harm reduction organizations, public charities, and other local community groups. *HRT's* nonprofit business model means:

- No company, entity or individual will profit from sales of RiVive, including its unpaid volunteer Board of Directors and minimal staff who receive no additional compensation as sales are made.
- The product, which can save lives, will be available at cost or less, with its initial selling price set at \$36 per twin pack. This price covers the hard costs (ingredients, nasal spray devices, vials) and production, packaging, testing, and transportation costs, which comprise 92% of RiVive’s overall cost, plus *HRT’s* virtual organization’s minimal costs to coordinate manufacturing and distribution, meet ongoing regulatory obligations, and run the nonprofit (8%).
- Charitable funding partners are required to sustain operations, including manufacturing, and can help to reduce the selling price and/or increase the number of doses made available for free of charge.

“It is both encouraging and frustrating to see the ONDCP¹, mayors² and commissioners³ across the US continuously issue warnings and advisories urging all Americans to carry naloxone”, said Hufford.

"Although these efforts raise awareness for naloxone accessibility, we continue to seek funding partners to increase resources and provide low-cost or naloxone free of charge to communities affected by the opioid crisis. By funding organizations like *HRT* or *Remedy Alliance*, you can help to prevent further deaths from opioid overdoses.”

RiVive uses an easy-to-use standard unit dose system that can be used in an emergency situation to reverse the life-threatening effects of known or suspected opioid overdose. Each RiVive nasal spray device contains one dose of naloxone. If the person does not respond after 2-3 minutes, additional doses of RiVive may be given until the person wakes up. RiVive will be exclusively available in twin packs containing two single-dose devices, initially to community organizations and governments.

RiVive is currently being produced under a commercial supply agreement with *Catalent*, a leading global contract development and manufacturing organization, at their facility in Morrisville, North Carolina.

To broaden the distribution of RiVive, *HRT* is actively seeking additional funding partners who will play a pivotal role in helping *HRT* to provide more low-cost or naloxone free of charge across the U.S.

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About Harm Reduction Therapeutics, Inc.

Harm Reduction Therapeutics (HRT), Inc. is a 501(c)(3) nonprofit pharmaceutical company whose single mission is to prevent opioid overdose deaths by making free of charge or low-cost over-the-counter naloxone available to everyone. It is the first nonprofit company to achieve FDA approval of a naloxone nasal spray. Founded in 2017 in response to the severe price and access limits to existing naloxone products, HRT brings together experts in drug development, harm reduction, substance dependence,

¹ [Letter-to-Schools.pdf \(whitehouse.gov\)](#)

² [Mayor Adams Concludes Two-Day Summit on Fentanyl Crisis in America | City of New York \(nyc.gov\)](#)

³ [Opioid overdose crisis sweeps Cook County, prompting urgent action: 'the time to act is now' \(FOX 32 Chicago\)](#)

public health policy, and over-the-counter switches of prescription pharmaceuticals. For more information, please visit www.harmreductiontherapeutics.org or call 1-888-412-7454.

About RiVive™

RiVive™ (naloxone HCl nasal spray 3 mg) is a novel over-the-counter intranasal formulation of naloxone (3.0 mg) delivered as an atomized spray (0.1 ml) that can save lives. It uses an easy-to-use standard unit dose system for single administration for the emergency treatment of opioid overdose without a prescription. RiVive produces a 3-fold higher systemic exposure with comparable early absorption to the reference naloxone product (0.4 mg delivered via intramuscular injection). Human factors validation work demonstrated that laypeople were able to administer RiVive in a simulated emergency overdose situation. **Warning: when using this product, some people may experience symptoms when they wake up such as shaking, sweating, nausea, or feeling angry.** For more information on Drug Facts call toll free (888) 412.7454 or go to: RiVive.com

About Naloxone

Naloxone is a safe and effective FDA approved opioid antagonist that has been used for decades to safely and effectively reverse opioid overdoses.⁴ To learn more, visit: Naloxone - Harm Reduction Therapeutics.

Note to Editors: The approved and official product name is RiVive™ and it should always be so capitalized and trademarked. High quality images of RiVive™ logos, product packaging, and an instructional video can be found [here](#).

⁴ For example: Avetian, et al. (2018) DOI : 10.1080/03007995.2017.1334637 ; Bennett, et al. (2018) DOI : 10.1080/02791072.2018.1430409; Campbell (2020). ISBN: 978-0262043663; <https://remedyallianceftp.org/pages/history>.