

# NUTRIBAND

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**NASDAQ: NTRB** 

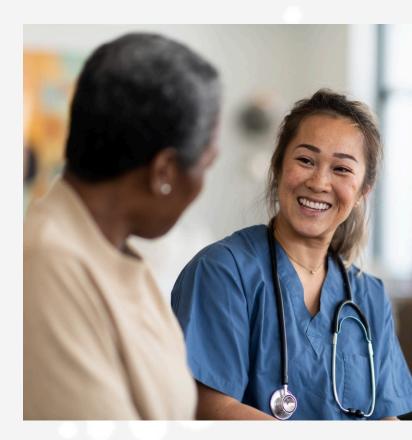
# **ABOUT NUTRIBAND**

- Nutriband Inc (Nasdaq : NTRB) is a pharmaceutical company with a specific focus on transdermal technologie s.
- Our model is to apply Transermal Tech to existing FDA approved drugs with a goal to improve safety, efficacy, patient comfort and more.
- Our first product and lead platform technology is **AVERSA**, and abuse deterrent tech which is applicable to any patch on the market today.
- According to Health Advances' assessment and upon approval by the United States FDA, Aversa Fentanyl is expected to reach peak annual sales of <u>\$200 million</u>.



# **ABOUT NUTRIBAND**

- We have structured our company to <u>not</u> follow the typical Biotech standard when it comes to time and cost.
- At Nutriband, we have 2 revenue generating subsidiaries, 4P Therapeutics and Pocono Pharmaceutical along with Active Intelligence which specializes in sports recovery products
- We are earning revenues to keep our development burn at a minimum
- We own our own manufacturing and clinical development capabilities which drastically reduces our costs for AVERSA and other technologies.



# CORE TEAM



Gareth Sheridan Founder and CEO Nutriband



Serguei Melnik Founder and President Nutriband



Dr. Alan Smith President 4P Therapeutics FDA Expert Committee on Complex Generics



Jeff Patrick PharmD CSO Nutriband



Gerald Goodman CFO Nutriband



Dianna Mather VP Finance



Michael Myer President Pocono Pharmaceutical



Tyler Overk Head of Active Intelligence

# **OUR STRUCTURE**



### **4P Therapeutics**

Clinical and Regulatory Subsidiary

- 4P leads the execution of our clinical/regulatory program
- Supports design for manufacturing
- Oversees AVERSA project development and clinical operations

### **Pocono Pharmaceutical** Contract Manufacturing

### Subsidiary

 Contract manufacturer for wide range of clients from small to multinational Clients include KT Tape and FFL

### **Active Intelligence**

Product Subsidiary - Kinesiology Tapes

 In House Sports and Kinesiology Tape Brand. AI is the basis for many white label orders at Pocono Pharmaceutical

Our Patented Abuse Deterrent Platform Technology

Our lead product is the AVERSA™ fentanyl abuse deterrent transdermal patch

• Our lead product is the AVERSA<sup>™</sup> abuse deterrent fentanyl transdermal system

- AVERSA<sup>™</sup> incorporates aversive agents to prevent the Abuse, DiVERsion, MiSuse and Accidental exposure of drugs with abuse potential
- Upon approval of AVERSA<sup>™</sup> fentanyl, we expect that FDA will consider requiring all fentanyl patches be abuse deterrent as was required for all Oxycontin generics
- Pipeline products include AVERSA™ buprenorphine and AVERSA™ methylphenidate

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# 'A staggering increase': Yearly overdose deaths top 100,000 for first time

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The largest increases were seen in Vermont, West Virginia and Kentucky.



Overdose deaths due to opioids, including fentanyl, accounted for more than 75 percent of the deaths. Chelsea Stahl / NBC News

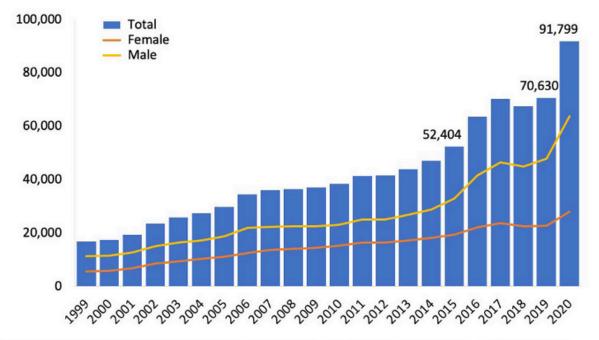
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Nov. 17, 2021, 3:03 PM GMT / Updated Nov. 17, 2021, 4:36 PM GMT By Kaitlin Sullivan and Reynolds Lewis

Drug overdose deaths in the United States surpassed 100,000 in a 12month period for the first time, the Centers for Disease Control and



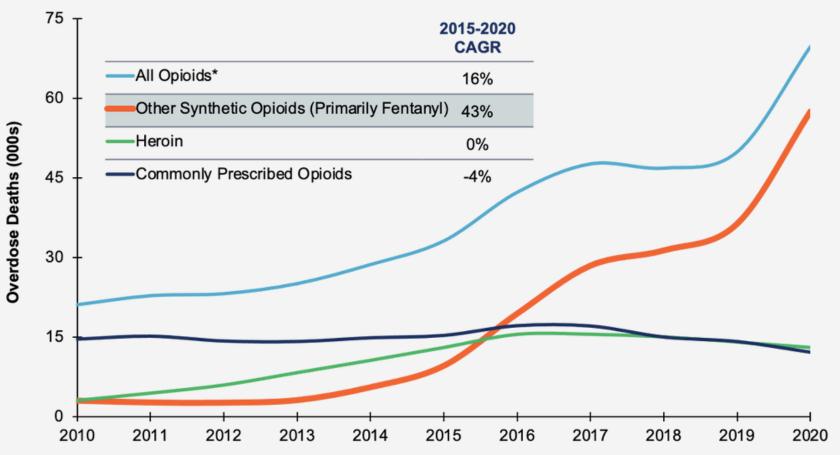
### Figure 1. National Drug-Involved Overdose Deaths\* Number Among All Ages, by Gender, 1999-2020



\*Includes deaths with underlying causes of unintentional drug poisoning (X40–X44), suicide drug poisoning (X60–X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y10–Y14), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2020 on CDC WONDER Online Database, released 12/2021.



### **US Opioid Overdose Deaths**



Opioid categories are not mutually exclusive due to the overlap in opioids that may have contributed to a single overdose case.
Source: Health Advances interviews and analysis, NIH NIDA, CDC WONDER.

# **AVERSA FENTANYL**

### Fentanyl Patch Can Be Deadly to Children

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#### Español

Young children have died or become seriously ill from accidental exposure to a skin patch containing fentanyl, a powerful pain reliever. As a result of this, the Food and Drug Administration (FDA) is issuing a Drug Safety Communication to warn patients, cation and health care professionals about the dangers of accidental exposure to and improper storage and disposal of the fentanyl patch.

"These types of events are tragic; you never want this to happen. We are looking for ways that we can help prevent this from happening in the future," says Douglas Throckmorton, M.D., deputy director of FDA's Center for Drug Evaluation and Research. "This reinforces the need to talk to patients and their families to make sure that these patches are stored, used and disposed of carefully."

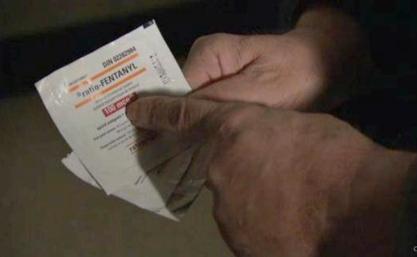


Young children and pets can easily remove discarded medicines from household trash. FDA and other federal agencies recommend following instructions on medication labels and talking to health care professionals about safe storage and disposal of medicines. To learn more, watch the "Lock It Up: Medicine Safety in Your Home" video.

- AVERSA<sup>™</sup> Technology significantly reduces the likelihood of accidental exposure to fentanyl for children and pets.
- 32 cases of accidental fentanyl exposure have occurred resulting in 12 deaths and dozens of hospitalizations, mostly involving young children.

### **AVERSA** Buccal / Chewing Accidental Swallowing Misuse Routes of Abuse Extraction Extraction & Smoking & Snorting **Extraction & Oral/Buccal**

- AVERSA<sup>™</sup> Fentanyl's goal is to provide a significantly less easily abused patch for the treatment of chronic pain
- 70+% of Fentanyl Patch Abusers Choose Oral Routes of Abuse
- Taste aversion addresses primary routes of abuse



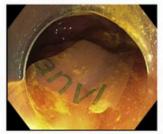
#### IMAGE OF THE MONTH

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#### Colonoscopy Enables the Diagnosis of Opiate Abuse

Andrew P. Copland," Jonathan P. Gaspar,<sup>1</sup> and Andrew Y. Wang\*

"Division of Gastroenterology and Hepatology, University of Virginia, Charlottesville, Virginia; <sup>4</sup>Gastroenterology Associates of Fairfax, Virginia



A 64-year-old man with a history of chronic opioid dependence was referred for endoscopic mucosal resection of a large flat cecal polyp. During colonoscopy the occum was reached, and on clearing the occum of residual effluent in preparation for endoscopic mucosal resection, a carefully cut square of plastic material was found with the letters "and" visible on the surface (Figure A). This appeared to be a portion of a transdermal fentanyl patch that was cut and ingested for absorption of any residual opiate.

Fentanyl sis a potent, rapid-acting oplate, and abuse of fentanyl patches is well known. It is notable that 28% to 84% of the initial drug may be present even in a used fentanyl patch.<sup>1</sup> Ingestion, transbuccal absorption, and rectal insertion are all known methods for fentanyl misuse, and the gastrointestinal mucosa has been shown to have a more than 30-foid increase in fentanyl

absorption.<sup>12</sup> Overdose through fentanyl patch ingestion can be challenging to diagnose and manage, particularly because the patch is unlikely to be seen on abdominal radiographs, opiate release is ongoing, and removal is not always possible. A case series using poison control data identified 76 fentanyl whole-patch ingestions in which 64% of patients presented with coma and 18% of patients required intubation.<sup>2</sup> Seventy-eight percent of these fentanyl ingestions were intentional.<sup>2</sup> We suspect ubata there is a sophisticated subset of fentanyl patch misusers who attempt to control the opiate dose by cutting the patches into smaller pieces.

This case shows that colonoscopy can be diagnostic for opiate abuse in the case of ferntanyl patch ingestion. When the patient was asked if he purposely had ingested a cut fentanyl patch, he stated, "I might have eaten the patch in my sleep," Later, when confronted by his pain management specialist, he admitted to purposely ingesting used fentanyl patches to augment his narcotic dosing.

#### References

 Nelson L, Schwaner R. Transdemoi lentaryl: pharmacology and toxicology. J Med Toxicol 2009;5:230–241.
Mrvos R, Feuchter AC, Katz KD, et al. Whole fentaryl patch

ingestion: a multi-center case series. J Emerg Med 2012; 42:549-552.

#### Conflicts of interest

This author discloses the following: Andrew Wang has received research support from Cook Medical instal bilary starts were provided free of charge to our with think and to patients as part of a prospective multicenter study for which Dr Wang was the site principal investigatory. The remaining authors declose no conflicts.

#### ( Most current article

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1542-3065/\$36.00 http://dx.doi.org/10.1016/j.cgh.2016.05.014

#### **SPECIAL REPORT: Fentanyl Abuse**



SPECIAL REPORT: Fentanyl abuse

By Jason Dennis | July 19, 2016 at 11:07 PM EDT - Updated July 9 at 6:16 PM

COLUMBUS, GA (WTVM) - It's 40 times more powerful than heroin and 80 times stronger than morphine. Fentanyl is claiming thousands of lives.

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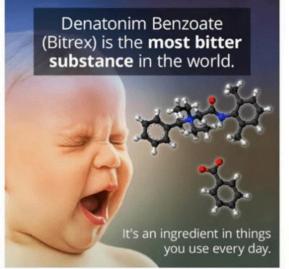
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The prescription version of the opioid is highly regulated, but what's on the street is an illegal chemistry creation also known as Apache, China Girl, TNT, Dance Fever, China White, and Murder 8.

It's a wakeup call in our area and nationwide, because fentanyl is so strong that when dealers secretly lace it into heroin, customers experience a new, extreme high, one that can kill them. A drug that

### **AVERSA - ABUSE DETERRENT TECHNOLOGY**

### A SOLUTION - Make it EXTREMELY unpleasant when misused



Nutriband's ADF Patches incorporate Denatonium Benzoate AND Capsaicin in each backing layer.





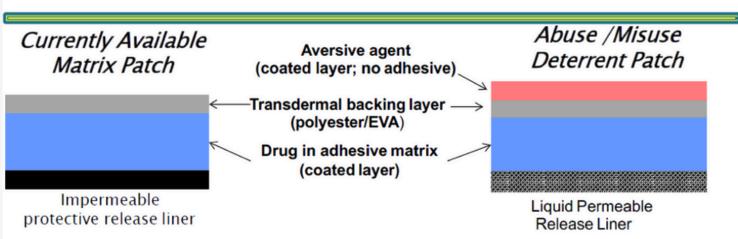






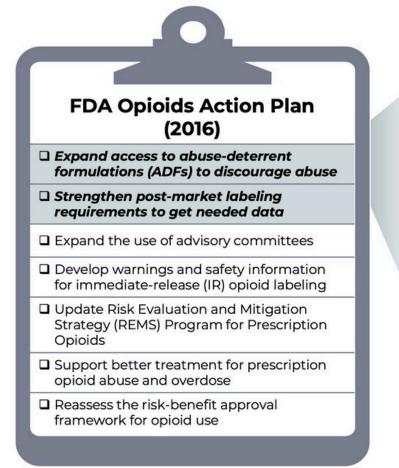
How does the AVERSA technology work?

### Solution Is to Deter Abuse and Misuse



- Aversive agent coated on top of transdermal backing
  - Aversive agent formulation achieves a biphasic release profile (immediate and sustained release) to ensure effectiveness
- Swap Out Impermeable Release Liner for a Permeable Release Liner
  - Liner becomes permeable in liquid, making it more difficult for abuser to separate drug from aversive agent by solvent extraction

Regulation on Opioids: Aversa Fentanyl is well aligned with the mission of the Opioids Action Plan.



Note: PMR = Post-Marketing Requirements, RWD = Real World Data. Source: Health Advances interviews and analysis, FDA.

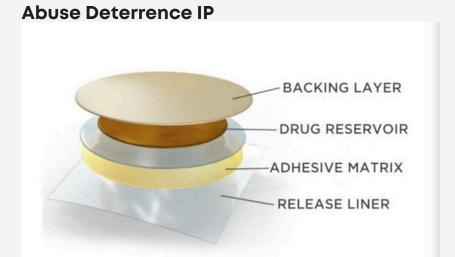
- AVERSA Fentanyl is aligned with the Plan's mission to expand access to ADFs and to consider the risks of misuse not just by the patient, but also "by other persons who obtain [opioids]"
- <u>Conservative pricing will be a key</u> <u>component of capturing</u> and maintaining market share, in addition to real world data and marketing. According to the Health advances report on AVERSA Fentanyl, Nutriband can expect to comfortably charge a 20% premium versus generics while maintaining insurance coverage and support, ideally capturing the market as the safest fentanyl patch in its class.

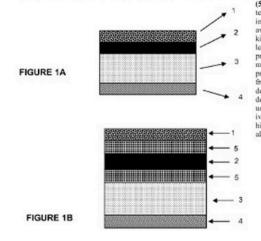
### Regulatory

- AVERSA Fentanyl is a 505(b)(2) registration pathway
- AVERSA Fentanyl will be eligible for a 6month expedited review based on precedent.
- Patented in 44 Countries, China expected to increase to 45



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)





(57) Abstract: An abuse deterrent and misuse deterrent transdermal patch comprising aversive agents incorporated in the backing layer of the patch. The aversive agents can exhibit biphasic or sustained kinetics of release with an immediate portion released rapidly and an extended portion released in a prolonged manner when exposed to a dissolution medium. The prolonged aversive agent release provides deterrence against extraction of drug from fresh and used patches and serves to prevent accidental misuse of used patches by children. The abuse deterrent and misuse deterrent patch systems can be used for transdermal delivery of therapeutically active agents and particularly those drugs that are highly prone to abuse such as opiate and opioid analgesics and stimulants.



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### **KINDEVA PARTNERSHIP**

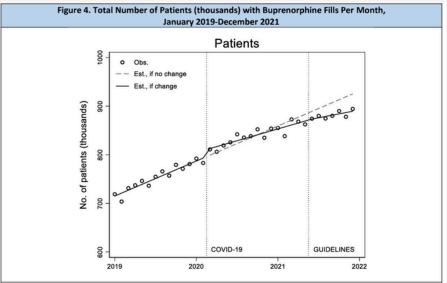
Nutriband and Kindeva have built a strong partnership for AVERSA Fentanyl's commercial development, leading to significant progress in the abuse-deterrent patch's development and manufacturing.

- Signed feasibility agreement for AVERSA Fentanyl, combining Nutriband's proprietary technology and Kindeva's FDAapproved patch.
- Demonstrated enhanced abuse deterrence, proving Nutriband's aversive coating can be manufactured using standard transdermal processes.
- Progressed to technology transfer from Kindeva's R&D facility to their Northridge, California manufacturing site.
- Selected target AVERSA formulation for commercial scale manufacturing development.

- AVERSA Fentanyl estimated to reach peak annual US sales of \$80M – \$200M.
- Nutriband's AVERSA technology covered by a broad IP portfolio with patents granted globally.
- Kindeva, a leading global CDMO, has a rich history in pharmaceutical innovation and manufactures millions of transdermal patches distributed worldwide.
- Both companies committed to improving safety profiles of transdermal drugs while ensuring accessibility to patients in need.

- Independent analysis conducted by an industry leader for go to market strategy
  AVERSA Fen tanyl estimated to reach \$80-
- 200MM peak annual sales on approval
- AVERSA Fentanyl, with initial study support, could gain wide market access at 20% premium over generics
- AVERSA Fentanyl market potential \$800MM if generics adopt ADT, with current volumes and pricing flexibility.
- AVERSA Buprenorphine is another market we are focused on to follow fentanyl
- Buprenorphine is prescribed for chronic pain management and also to treat substance abuse

Buprenorphine continues to grow as treatment for OUD (Opioid Use Disorder)



NOTES: Data source is IQVIA TPT. "Obs." is a plot of observed data points; "Est. if no change" is a plot of ITS analysis linear

# **AVERSA Platform**

Large, Global Addressable Markets for AVERSA <sup>TM</sup> Platform Technology



### **AVERSA Methylphenidate**

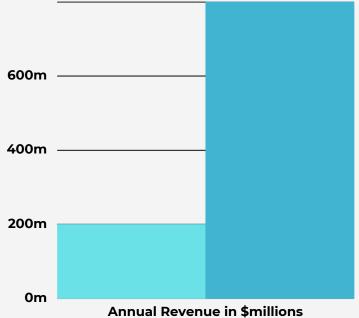


According to Health Advances' assessment and upon approval by the United States FDA, Aversa Fentanyl will be priced competitively with generic fentanyl patches and is expected to reach peak annual sales of \$200 million.

If non-ADF transdermal fentanyl products lose marketing approval, Aversa would have greater pricing flexibility and could generate >\$800MM in revenue.

Possible Market with mandated abuse

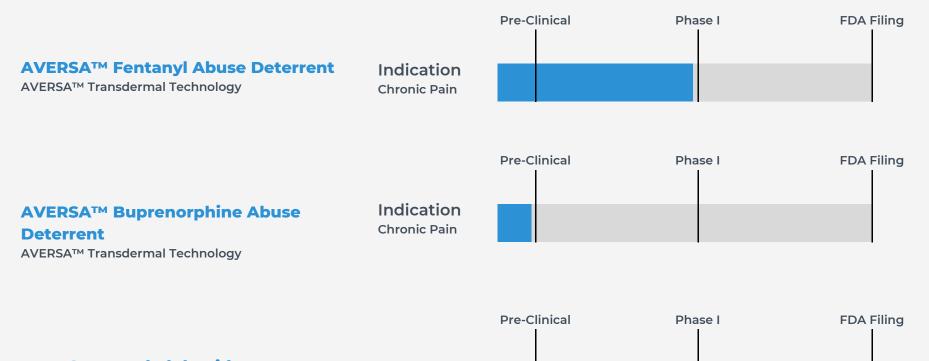
deterrence stance from FDA 800m



NOTE: Values based on current market conditions and do not factor market increasing back towards 2016 levels which are reported close to \$4BN



### **AVERSA PIPELILNE**



### **AVERSA™** Methylphenidate

AVERSA™ Transdermal Technology

Indication

+0.

# Nutriband

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# WANT TO KNOW MORE?

To find out more, or to enquire about our partnership options, please contact our team who can help find the right solution for your business.

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### **NASDAQ: NTRB**