



NUTRIBAND Inc.

ABOUT NUTRIBAND

- Nutriband Inc (Nasdaq : NTRB) is a pharmaceutical company with a specific focus on transdermal technologies.
- 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 we believe to be 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 \$200 million.



ABOUT NUTRIBAND

- We have structured our company to not follow the typical Biotech set up.
- 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.



OUR 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



Dr. Jeff Patrick
CSO Nutriband



Gerald Goodman
CFO Nutriband



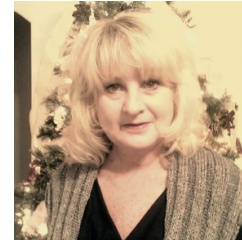
Paddy Ryan
CTO Nutriband



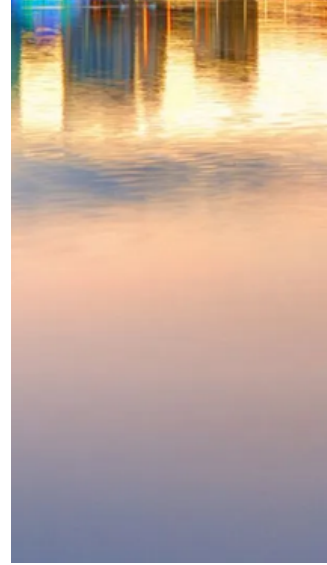
Michael Myer
President Pocono
Pharmaceutical



Tyler Overk
Head of Active Intelligence



Dianna Mather
VP Finance



OUR STRUCTURE

Nutriband



4P Therapeutics

Clinical and Regulatory Subsidiary

- 4P leads the execution of the clinical/regulatory program
- Supports design for manufacturing
- Manages key contract manufacturing relationships during scale-up and commercialization.

Pocono Pharmaceutical

Contract Manufacturing Subsidiary

- Contract manufacturer for wide range of clients from small to multinational

Active Intelligence

Product Subsidiary - Kinesiology Tapes

- Focused on creating sports recovery tape for the consumer market.



AVERSA

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

AVERSA

- Our lead product is the AVERSA™ abuse deterrent fentanyl transdermal system
- AVERSA™ incorporates aversive agents to prevent the Abuse, DiVERsion, MiSuse and Accidental exposure of drugs with abuse potential
- Upon approval of AVERSA™ 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



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



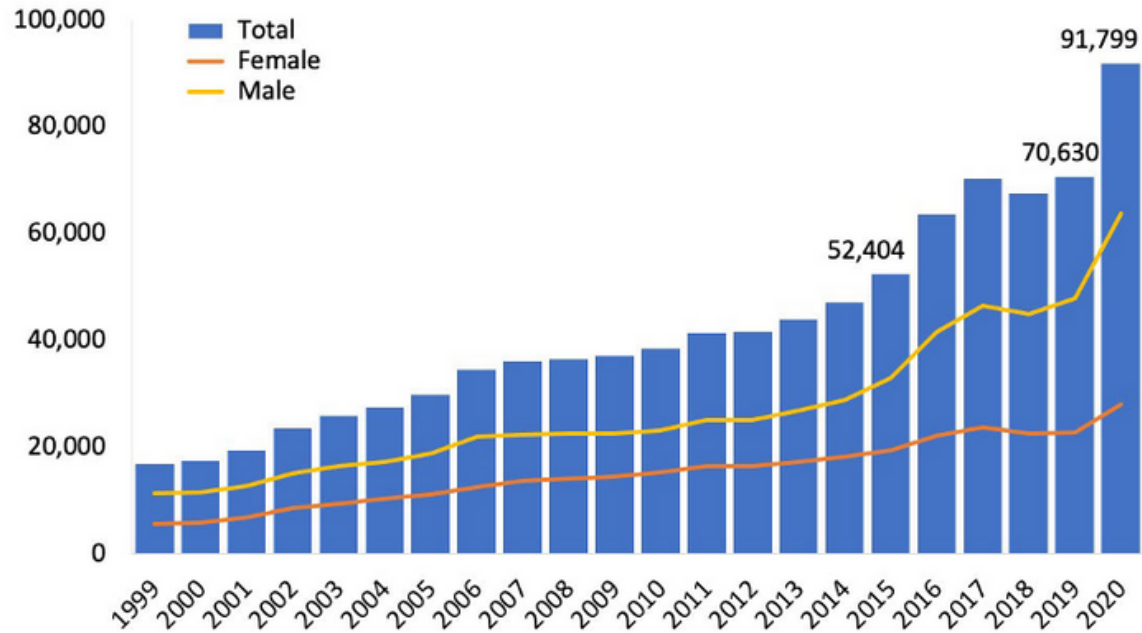
Nov. 17, 2021, 3:03 PM GMT / Updated Nov. 17, 2021, 4:36 PM GMT

By [Kaitlin Sullivan](#) and [Reynolds Lewis](#)

Drug overdose deaths in the United States surpassed 100,000 in a 12-month period for the first time, the [Centers for Disease Control and Prevention](#) said Wednesday, a troubling milestone amid an already

AVERSA

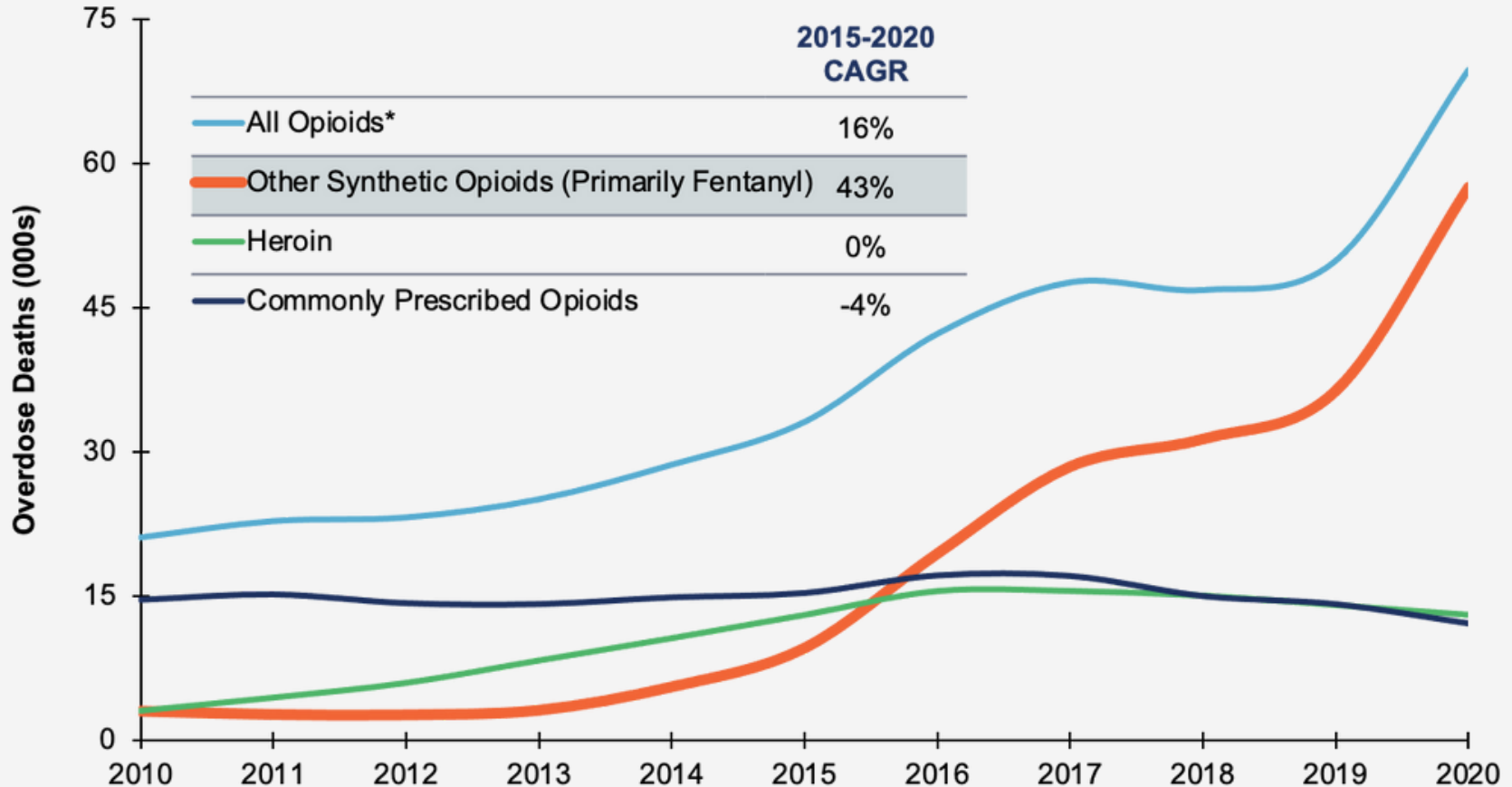
**Figure 1. National Drug-Involved Overdose Deaths*
Number Among All Ages, by Gender, 1999-2020**



*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.

AVERSA

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

Subscribe to Email Updates

f Share

🐦 Tweet

in LinkedIn

✉ Email

🖨 Print

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, car[No Title] and health care professionals about the dangers of accidental exposure to and improper storage and disposal of the fentanyl patch.

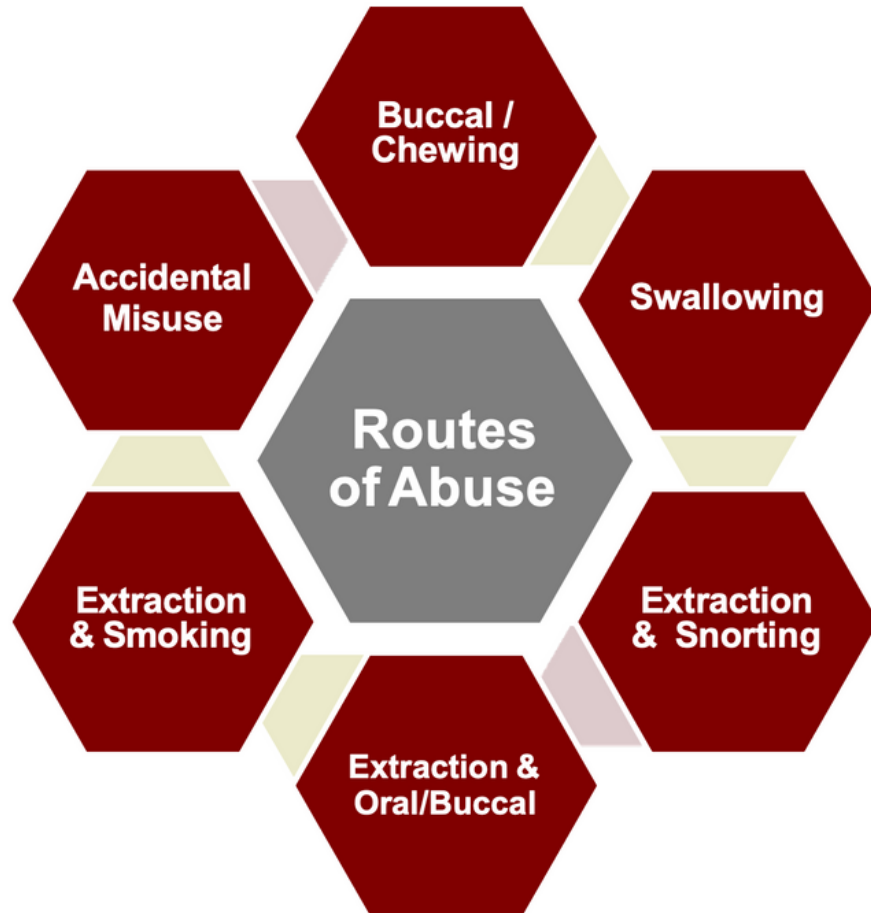
“These types of events are tragic; you never want this to happen. We are looking for ways that we can help prevent this from happening in the future,” says Douglas Throckmorton, M.D., deputy director of FDA’s Center for Drug Evaluation and Research. “This reinforces the need to talk to patients and their 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™ Technology significantly reduces the likelihood of accidental exposure to fentanyl for children and pets.
- 32 cases of accidental fentanyl exposure have occurred since 1997, resulting in 12 deaths and 12 hospitalizations, mostly involving young children.

AVERSA



- AVERSA™ Fentanyl's goal is to provide a much 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

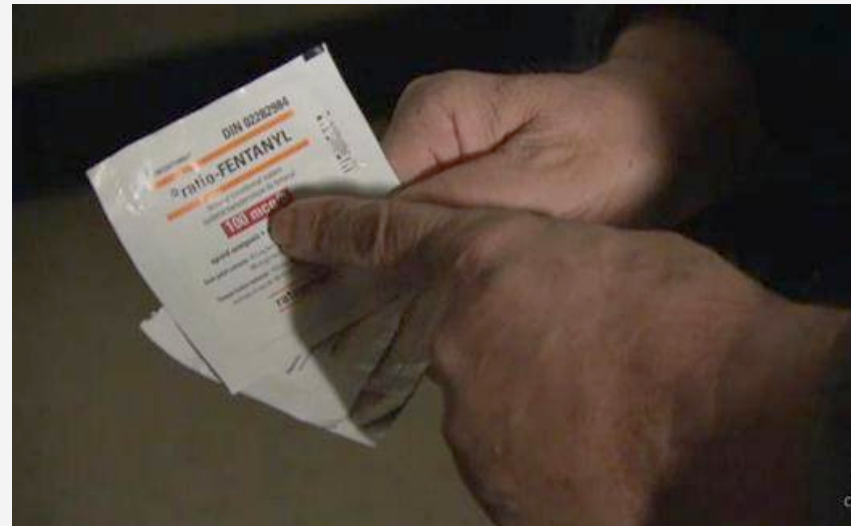


IMAGE OF THE MONTH

Colonoscopy Enables the Diagnosis of Opiate Abuse

Andrew P. Copland,¹ Jonathan P. Gaspar,² and Andrew Y. Wang¹

¹Division of Gastroenterology and Hepatology, University of Virginia, Charlottesville, Virginia; ²Gastroenterology Associates of Fairfax, Virginia



absorption.^{1,2} 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 46% of patients presented with coma and 18% of patients required intubation.³ Seventy-eight percent of these fentanyl ingestions were intentional.³ We suspect that 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 fentanyl 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

1. Nelson L, Schwamer R. Transdermal fentanyl: pharmacology and toxicology. *J Med Toxicol* 2009;5:230-241.
2. Myrse R, Faucher AC, Katz KD, et al. Whole fentanyl 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 (metal biliary stents were provided free of charge to our institution and to patients as part of a prospective multicenter study for which Dr Wang was the site principal investigator). The remaining authors disclose no conflicts.

Most current article

© 2016 by the AGA Institute
1542-3565/336.00
<http://dx.doi.org/10.1016/j.cgh.2016.05.014>

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 cecum was reached, and on clearing the cecum of residual effluent in preparation for endoscopic mucosal resection, a carefully cut square of plastic material was found with the letters "avni" 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 is a potent, rapid-acting opiate, 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.³ 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-fold increase in fentanyl

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

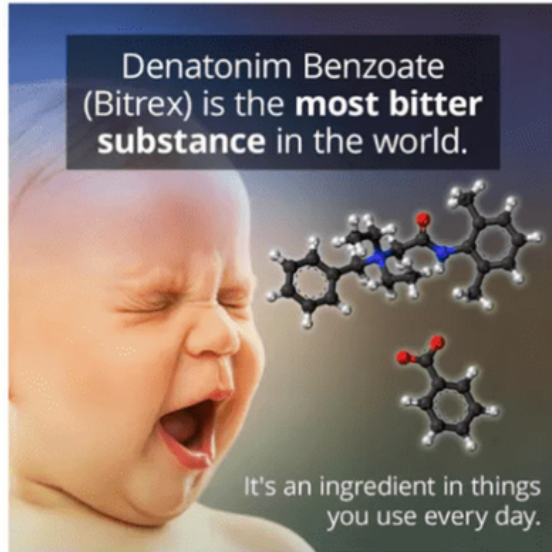
COLUMBUS, GA (WTVM) – It's 40 times more powerful than heroin and 80 times stronger than morphine. Fentanyl is claiming thousands of lives.

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



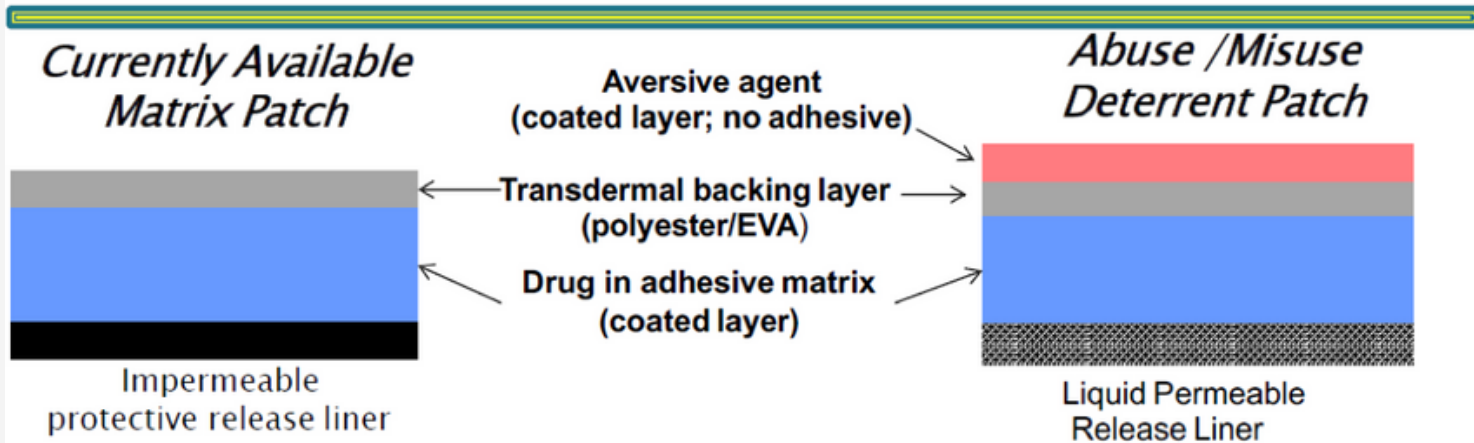
Nutriband's ADF Patches incorporate Denatonium Benzoate AND Capsaicin in each backing layer.



AVERSA

How does the AVERSA technology work?

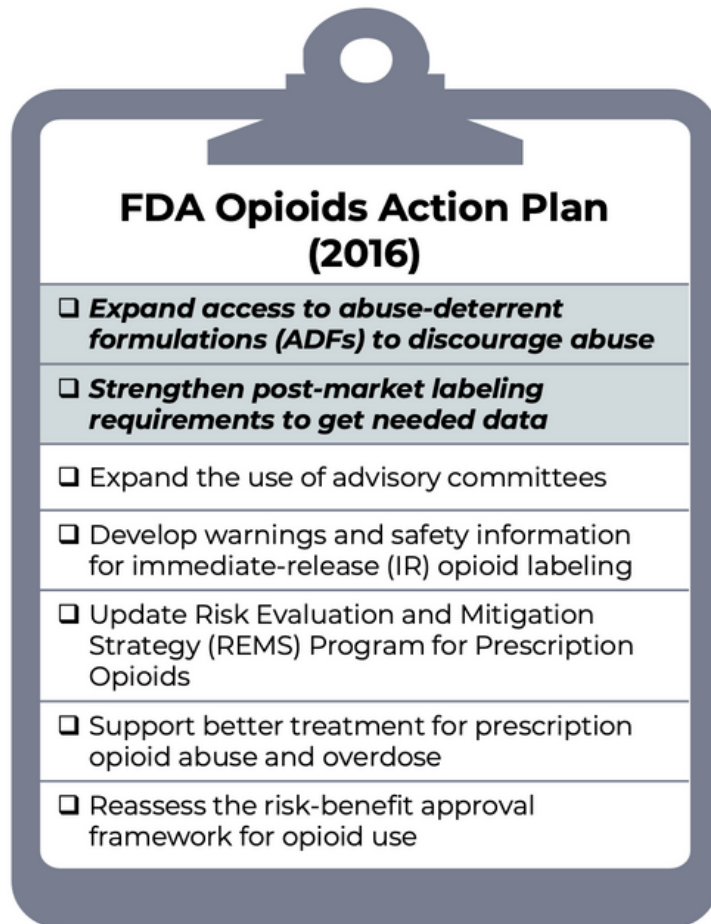
Solution Is to Deter Abuse and Misuse



- ▶ 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

AVERSA

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



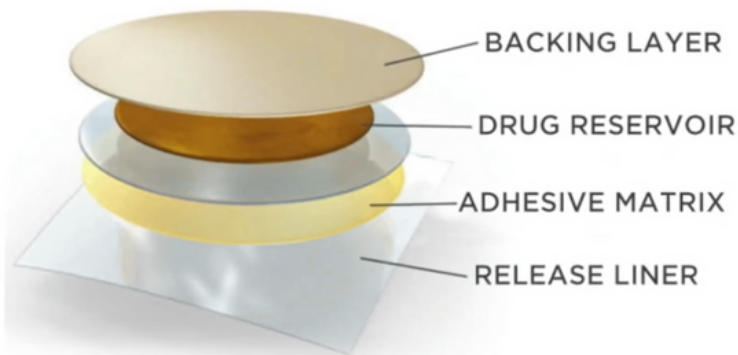
- AVERSA Fentanyl is aligned with the Plan’s mission to expand access to ADFs and to consider the risks of misuse not just by the patient, but also “by other persons who obtain [opioids]”
- Conservative pricing will be a key component of capturing and maintaining market share, in addition to real world data and marketing

AVERSA

Regulatory

- We have received positive Pre-IND feedback from the FDA for AVERSA Fentanyl
- AVERSA Fentanyl is a 505(b)(2) registration pathway
- AVERSA Fentanyl will be eligible for a 6-month expedited review based on precedent.

Abuse Deterrence IP



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)
(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 July 2015 (30.07.2015)

(10) International Publication Number
WO 2015/112563 A2

WIPO | PCT

(51) International Patent Classification:
A61K 9/70 (2006.01)

(21) International Application Number:
PCT/US2015/012196

(22) International Filing Date:
21 January 2015 (21.01.2015)

(25) Filing Language:
English

(26) Publication Language:
English

(30) Priority Data:
61/930,090 22 January 2014 (22.01.2014) US
61/930,104 22 January 2014 (22.01.2014) US
62/014,723 20 June 2014 (20.06.2014) US
62/014,721 20 June 2014 (20.06.2014) US
62/083,620 24 November 2014 (24.11.2014) US

(71) Applicant: 4P THERAPEUTICS [US/US]; 680 Engineering Dr., Suite 150, Norcross, GA 30092 (US).

(72) Inventors: ENSCORE, David, James; 1028 Wetherby Way, Johns Creek, GA 30022 (US). TAGLIAFERRI, Frank; 128 Winmons Drive, Decatur, GA 30030 (US). DAMON, Steven, Paul; 3920 Merrivewether Woods, Johns Creek, GA 30022 (US). SMITH, Alan; 736 Greenview Avenue, Ne, Atlanta, GA 30305 (US). GAULDING, Jeffrey, C.; 5258 Fox Hill Court, Peachtree Corners, GA 30092 (US).

(74) Agents: FOX, Jennifer, L. et al.; Brinks Gilson & Liono, P.O. Box 110285, Research Triangle Park, NC 27709 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,

[Continued on next page]

(54) Title: ABUSE AND MISUSE DETERRENT TRANSDERMAL SYSTEMS

FIGURE 1A

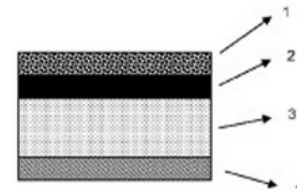
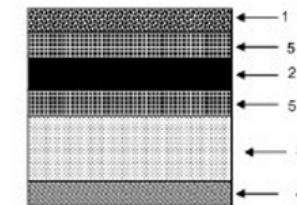


FIGURE 1B



(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.

PEPSICO PEP Nasdaq 100 ▲ 0.54% +0.28 \$51.78	PEPSICO PEP Nasdaq 100 ▲ 0.31% +0.49 \$161.11	APPLE AAPL Nasdaq 100 ▲ 0.20% +0.32 \$184.08	STARBUCKS SBUX Nasdaq 100 ▲ 0.42% +0.47 \$111.89	AMAZON AMZN Nasdaq 100 ▲ 0.48% +16.48 \$3,453.84	PAYPAL PYPL Nasdaq 100 ▲ 0.56% +1.05 \$189.20	S&P 500 INDEX SP500 ▲ 1.42% +64.06 4,577.10
NTRB Nasdaq Listed	UNCH 0.00 \$6.23	DJI +617.75 34,639.79	▲ 1.80%			

Nutriband

AVERSA

AVERSA Fentanyl Market Opportunity



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.

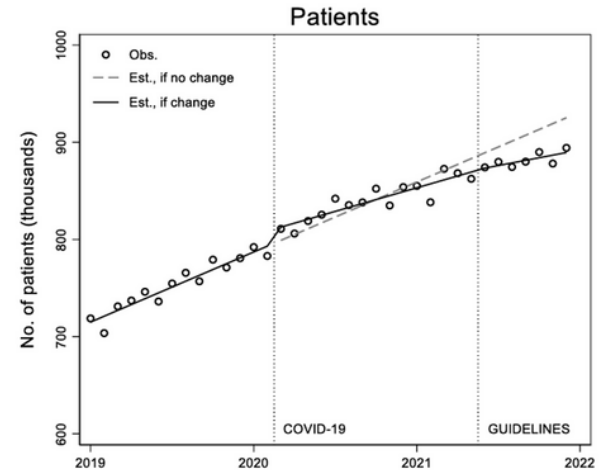
- Signed feasibility agreement for AVERSA Fentanyl, combining Nutriband's proprietary technology and Kindeva's FDA-approved patch.
- Demonstrated enhanced abuse deterrence, proving Nutriband's aversive coating can be manufactured using standard transdermal processes.
- Progressed to technology transfer 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.

AVERSA

- Independent analysis conducted by an industry leader for go to market strategy
- AVERSA Fentanyl 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 will be focusing on
- Buprenorphine is used for pain management and also to treat substance abuse

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

Figure 4. Total Number of Patients (thousands) with Buprenorphine Fills Per Month, January 2019-December 2021



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

Large, Global Addressable Markets for AVERSA™ Platform Technology

AVERSA Fentanyl



12, 25, 37, 50,
75, 100mcg/hr

AVERSA Buprenorphine



5,7.5, 10,
15 and 20
mcg/hr

AVERSA Methamphetamine/Dextroamphetamine



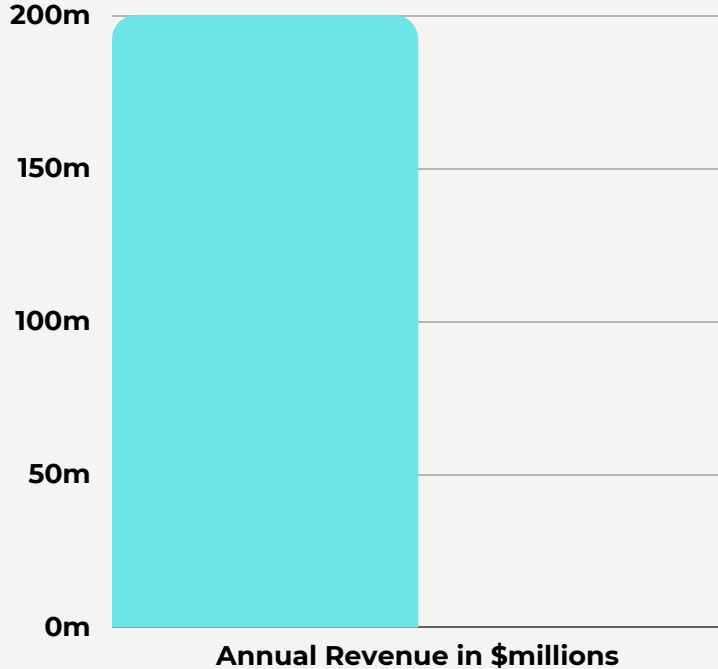
10, 15, 20 &
30mg/9hr

AVERSA

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 >\$500MM in revenue.

Forecasted peak annual sales if generics remain available



NOTE: Values are with current market conditions and do not factor market increasing back towards 2016 levels

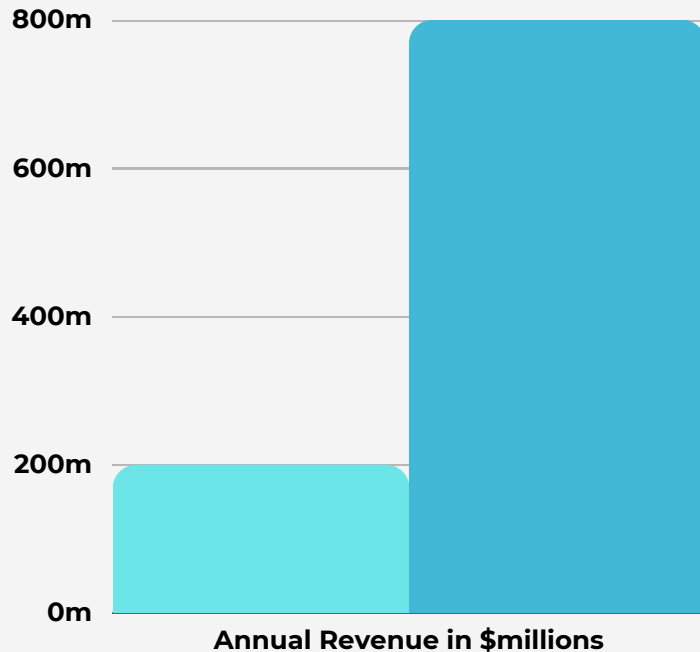


AVERSA

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 >\$500MM in revenue.

Possible Market with mandated abuse deterrence stance from FDA



NOTE: Values are with current market conditions and do not factor market increasing back towards 2016 levels

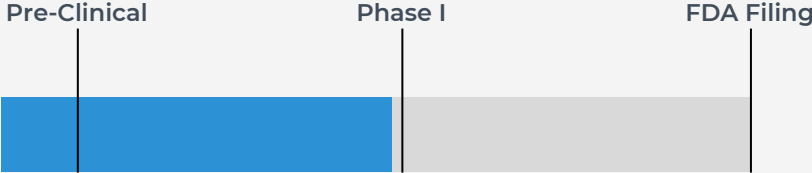


AVERSA PIPELINE

AVERSA™ Fentanyl Abuse Deterrent

AVERSA™ Transdermal Technology

Indication
Chronic Pain



AVERSA™ Buprenorphine Abuse Deterrent

AVERSA™ Transdermal Technology

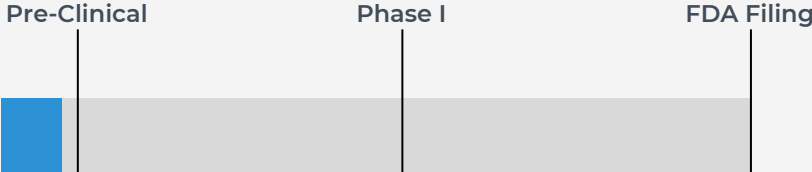
Indication
Chronic Pain



AVERSA™ Methylphenidate

AVERSA™ Transdermal Technology

Indication
ADHD





Our 2022 results and milestones have shown that we remain laser focused on hitting the targets we set ourselves as a company each year. We have made significant progress with AVERSA and our goal to improve the safety profile of easily abused transdermal drugs. Our record financial results and multiple major achievements in fiscal 2022 were a direct result of the hard work and exceptional execution of our dedicated team.

We look forward to continuing to positively update our shareholders as we have laid out major milestone targets for 2023 which we intend to achieve as in previous years.

Gareth Sheridan, CEO of Nutriband

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.

info@nutriband.com

<https://nutriband.com/>

121 S. Orange Ave., Suite 1500, Orlando, FL 32801

NUTRIBAND
Inc 

NASDAQ: NTRB