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Zacks Small-Cap Research

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Nutriband Inc. (NTRB-NASDAQ)

NTRB: Expanding Footprint, Boosting Patent Protection & Share Liquidity

NTRB, an emerging a biopharma and medical device company developing a portfolio of transdermal pharmaceutical products, continues to move its product portfolio forward, expand its addressable market and gain traction, as illustrated by recent revenue growth. The company's initial focus is on solutions to help mitigate the abuse of opioids such as fentanyl and other addictive drugs. To expand its geographic footprint, Nutriband recently registered a new location in Ecuador, consistent with the goal to expand into the South American market.

Current Price (9/30/22)	$3.59
Valuation	**$10.00**

OUTLOOK

NTRB's initial development focus is a Fentanyl transdermal patch that leverages its AVERSA™ technology. A recently signed feasibility agreement with Kindeva Drug Delivery (formerly 3M Drug Delivery Systems) is expected to accelerate AVERSA Fentanyl's commercialization. Nutriband recently received a Notice of Allowance from the Canadian Intellectual Property Office for the AVERSA Abuse Deterrent Transdermal Technology Patent. The company already has patent protection in the U.S. and Mexico. Thus, aith this Canadian patent, NTRB's IP is protected across North America. Additionally, other patents have been granted in Europe, Japan, Korea, Russia and Australia. Patent protection in China is pending. Separately, NTRB has initiated the application process to dual list its shares on Upstream and Nasdaq to expand the pool of potential investors in and increase trading liquidity of NTRB shares.

SUMMARY DATA

52-Week High	**$10.57**
52-Week Low	**$2.41**
One-Year Return (%)	**-35**
Beta	**-0.23**
Average Daily Volume (sh)	**56,644**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$28**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of US$)

	Q1 (Apr)	Q2 (Jul)	Q3 (Oct)	Q4 (Jan)	Year (Jan)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 A	0 A	1 A
2022	0 A	0 A	0 A	0 A	1 A
2023	0 A	0 A	1 E	1 E	2 E

EPS or Loss Per Share

	Q1 (Apr)	Q2 (Jul)	Q3 (Oct)	Q4 (Jan)	Year (Jan)
2020	-$0.11 A	-$0.08 A	-$0.14 A	-$0.17 A	-$0.50 A
2021	-$0.08 A	-$0.04 A	-$0.01 A	-$0.35 A	-$0.51 A
2022	-$0.05 A	-$0.08 A	-$0.27 A	-$0.57 A	-$0.94 A
2023	-$0.09 A	-$0.12 A	-$0.08 E	-$0.05 E	-$0.34 E

4QF21 includes 1-time noncash charges of about $2M.
Quarters might not sum due to rounding & share counts

Disclosures on page 13

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KEY POINTS EXPANDING GEOGRAPHIC FOOTPRINT, BOOSTING PATENT PROTECTION

- According to the NIH (National Institutes of Health), the opioid overdose crisis increasingly is becoming a global challenge. Nutriband is working to protect its IP with patent applications and patents granted in multiple geographic markets.

- Nutriband's lead technology is an abuse deterrent fentanyl transdermal system, incorporating its abuse deterrent technology, AVERSA®. AVERSA is a patented technology and NTRB is optimistic about its prospects.

- The company's initial focus is on solutions to help mitigate the abuse of opioids such as fentanyl and other addictive drugs, including buprenorphine and methylphenidate. The need to address the opioid epidemic in the U.S. and globally creates opportunities for solutions such as those that Nutriband is developing.

- To expand its geographic footprint and address the South American market, Nutriband recently registered a new company branch located in Ecuador, South America. The branch is consistent with the company's goal to expand into the South American market. Nutriband intends to expand its product offering to the region through product registration and contract services.

- Nutriband recently received a Notice of Allowance from the Canadian Intellectual Property Office for the AVERSA Abuse Deterrent Transdermal Technology Patent. The company already has patent protection in the U.S. and Mexico. With this Canadian patent, NTRB's IP is protected across North America. Additionally, other patents have been granted in Europe, Japan, Korea, Russia and Australia. Patent protection in China is pending.

- Transdermal drug delivery systems have gained traction in recent years, including the widespread use of nicotine and pain patches, partially due to their convenience and effectiveness. Transdermal drug delivery methods are less intrusive than many other delivery mechanisms and can be absorbed evenly through the skin into the blood system.

- NTRB has initiated the application process to dual list its shares on Upstream and Nasdaq to enable domestic and international investors using digital currency, and other payments, to invest in NTRB shares. This is consistent with the company's goal to increase trading liquidity of NTRB shares.

- Separately, another step that is consistent with the goal to increase NTRB trading liquidity is that following the company's recent authorization to recover 1.2 million shares, the shares were cancelled and NTRB's board approved a subsequent 7:6 forward split of NTRB shares.

AVERSA FENTYNOL MOVES FORWARD TOWARDS APPROVAL, COMMERCIALIZATION

Nutriband (NASDAQ:NTRB), an emerging biopharma and medical device company developing a portfolio of transdermal pharmaceutical products, continues to expand opportunities for its product portfolio. The company's lead technology is an abuse deterrent fentanyl transdermal system, incorporating its abuse deterrent technology, AVERSA®. AVERSA is a patented technology and NTRB is optimistic about its prospects. AVERSA stands for **A**buse, Di**VER**sion, Mi**S**use and **A**ccidental, as the technology incorporates aversive agents designed to deter and minimize the risk of abusing drugs such as fentanyl. The company's goal is to improve the safety profile of drugs such as fentanyl and others so that they can be prescribed and used legitimately as they are intended. The AVERSA technology can be applied broadly to improve the safe delivery of a wide range of drugs and medications; NTRB plans to develop additional transdermal pharmaceutical products, in addition to its initial focus on a safer fentanyl

transdermal patch. As noted, the company's Initial product extension focus is expected to be on developing AVERSA patches to improve the safe delivery of buprenorphine and methylphenidate.

Transdermal drug delivery systems have gained traction in recent years, including the widespread use of nicotine and pain patches, partially due to their convenience and effectiveness. Transdermal drug delivery methods are less intrusive than many other delivery mechanisms and can be absorbed evenly through the skin into the blood system.

The company's initial focus is on solutions to help mitigate the abuse of opioids such as fentanyl and other addictive drugs, including buprenorphine and methylphenidate. The need to address the opioid epidemic in the U.S. and globally creates opportunities for solutions such as those that Nutriband is developing. The CDC is in the process of updating its 2016 guidelines for prescribing opioids for chronic pain and is requesting public feedback on the update process. NTRB has announced its support for the updates.

Lead Technology - AVERSA

AVERSA is NTRB's lead technology. It is an abuse deterrent transdermal system (transdermal means delivered through the skin). Transdermal patches for delivering medications have several advantages, including that drug delivery is non-invasive and absorbed into the blood stream relatively quickly. An estimated 1+ billion transdermal patches are produced annually, according to the NCBI (National Center for Biotechnology Information).

The company is developing AVERSA to provide extended-release dosage transdermal therapy to help manage chronic pain that generally requires 24-7 treatment. Nutriband expects its AVERSA fentanyl patch to mitigate, if not significantly diminish, misuse of the drug via AVERSA's abuse deterrent technology. The AVERSA deterrent technology incorporates aversive agents to deter the abuse of the drugs in the patch in order to make the pain treatment safer. Specifically, the patch is coated with a layer of protective coating that deters people from abusing it orally or otherwise and which management believes improves the safety profile of the therapy. AVERSA does not interact with the actual drug itself and can be applied to just about any drug that is delivered via a transdermal patch, according to management.

AVERSA combines two food grade, highly unpleasant substances as an adherent on the back of the patch: denatonium benzoate and capsasin. Neither is toxic, but both have extremely bitter and hot flavors that act as a deterrent to chewing, ingesting or even smoking the actual drug in the patch. For instance, according to the National Institute of Health (NIH), denatonium benzoate is a bittering agent that is often added to detergents and other household cleaners to deter ingestion by children, although it has a low toxicity. Capsaicin is found in several different types of extremely hot and spicy peppers. Adding these substances to the back of the patch makes it extremely difficult to extract the drug or abuse the drug through oral, buccal, rectal, smoking or dissolving methods to name but a few. Both denatonium and capsasin are safe for human consumption and non-toxic food grade, which is a key part of the company's strategy, however, because of their bitter and extremely hot characteristics, they act as strong deterrents.

Nutriband believes its abuse deterrent technology can reduce the abuse of the fentanyl patch, while concurrently providing chronic pain management. The company believes AVERSA abuse deterrent patch technology can be used for other opioid and pain medication patches, as well. Another future application could include the development of generic transdermal patches for the transdermal delivery of drugs that usually are administered by injection.

NTRB's initial development focus leveraging the AVERSA technology will be with a Fentanyl transdermal patch, as noted, with AVERSA buprenorphine and methylphenidate products expected to follow. Fentanyl is what the National Institute on Drug Abuse describes as "a powerful synthetic opioid that is similar to morphine but is 50 to 100 times more potent." Fentanyl is a prescription medication that is generally prescribed to treat severe pain. In fact, fentanyl transdermal patches have been added to the World

Health Organization's (WHO) list of essential medicines. Fentanyl is often misused and abused. In fact, according to the National Institute on Drug Abuse, synthetic opioids such as fentanyl are "the most common drugs involved in drug overdose deaths in the United States." According to *Science Direct*, "[i]n 2018, 81.7% of fentanyl consumption was concentrated in 10 countries" led by the U.S. In fact, CDC data indicates that domestic deaths from drug overdoses in a 12-month period recently passed 100,000 for the first time ever, with overdose deaths up 29% from 78,056 in the 12-months ended April 2020, to 100,306 in 12-months ended April 2021.

The U.S. DEA (U.S. Drug Enforcement Administration) is aggressively attempting to eliminate fentanyl and other abusive drugs. For instance, as part of what the agency calls "The One Pill Can Kill" initiative, with its law enforcement partners, DEA seized more than 10.2 million fentanyl pills and about 980 pounds of fentanyl powder from May 23, 2022, through Sept. 8, 2022. Moreover, the agency noted that fentanyl is sold in a variety of "bright colors, shapes, and sizes," with *rainbow fentanyl* was first reported to the DEA in February 2022. Subsequently, the agency has seized *rainbow fentanyl* in 21 states.

Go-to-market strategy

The company believes its technology is consistent with – and could be additive to – government regulatory actions to address the opioid crisis. NTRB will jointly develop AVERSA™ Fentanyl with Kindeva. Kindeva was recently spun out of 3M in 2020 and has more than 50 years of experience. The jointly developed solution will be based on NTRB's proprietary AVERSA™ abuse deterrent transdermal technology and Kindeva's FDA-approved transdermal fentanyl patch (fentanyl transdermal system). The two have signed a feasibility agreement to work together to bring AVERSA Fentanyl to market. The feasibility agreement is focused on adapting Kindeva's commercial transdermal manufacturing process to incorporate AVERSA technology. Kindeva produces millions of branded and generic transdermal patches that it distributes primarily in the U.S., Europe and Asia.

Expanding Geographic Reach … Expanding IP Protection

Nutriband also recently registered a new company branch located in Ecuador, South America. The branch is consistent with the company's goal to expand into the South American market. The new branch is located in Quito, Ecuador. Nutriband intends to expand its product offering to the region through product registration and contract services.

Nutriband recently received a Notice of Allowance from the Canadian Intellectual Property Office for the AVERSA(TM) Abuse Deterrent Transdermal Technology Patent. The notice regards NTRB's patent application, CA 2937649, entitled "*Abuse and Misuse Deterrent Transdermal Systems*," that protects its AVERSA™ transdermal abuse deterrent technology. The company already has patent protection in the U.S. and Mexico. With this Canadian patent, NTRB's IP is protected across North America. Additionally, other patents have been granted in Europe, Japan, Korea, Russia and Australia, as well as Mexico and the U.S., as noted.

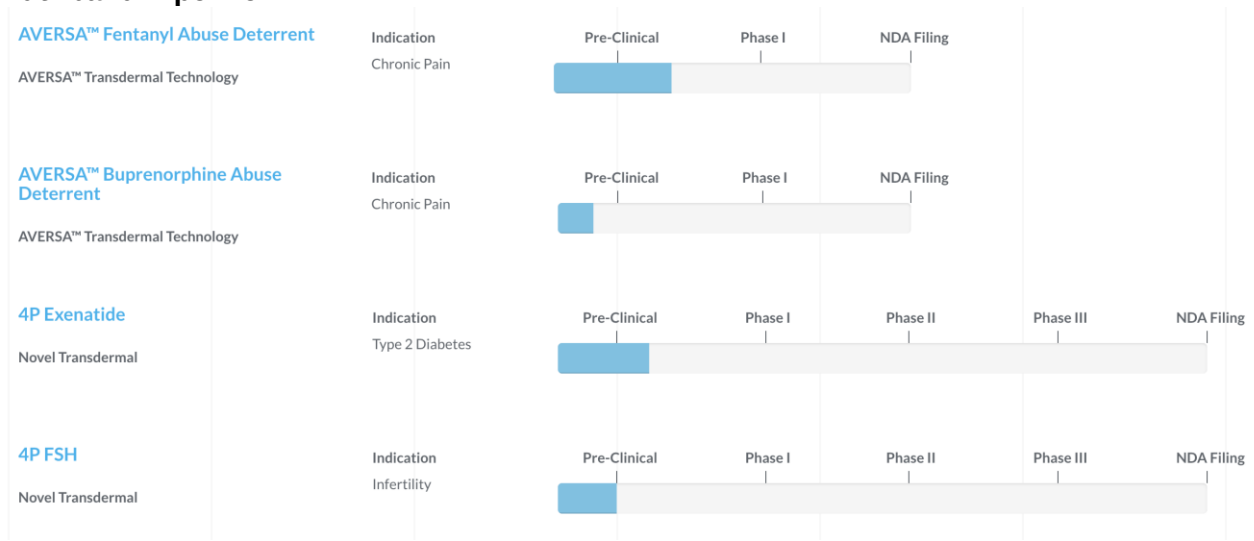
4P Therapeutics has filed an international patent application to protect the AVERSA technology in the U.S. and globally. The company has received patent protection for a range of markets, including from the European Patent Office, and patent offices in Mexico, Korea, Russia, Australia and Japan and from the USPTO protecting its AVERSA™ transdermal abuse deterrent technology in the U.S.[1] The patent protects AVERSA™ Fentanyl, which is based on its proprietary AVERSA™ abuse deterrent transdermal technology. The Korean Intellectual Property Office (KIPO) also has fully issued its patent titled "Abuse and Misuse Deterrent Transdermal System" which is related to the Company's lead technology AVERSA™.

[1] NTRB received Issue Notification from the USPTO for its U.S. patent, *"Abuse and Misuse Deterrent Transdermal System"*

With the Canadian protection, the AVERSA™ intellectual property portfolio now has patents issued in 45 countries. AVERSA™ patent coverage encompasses the U.S., Canada, Europe, Japan, Korea, Mexico, Australia, and Russia, as noted. Patents are pending in China.

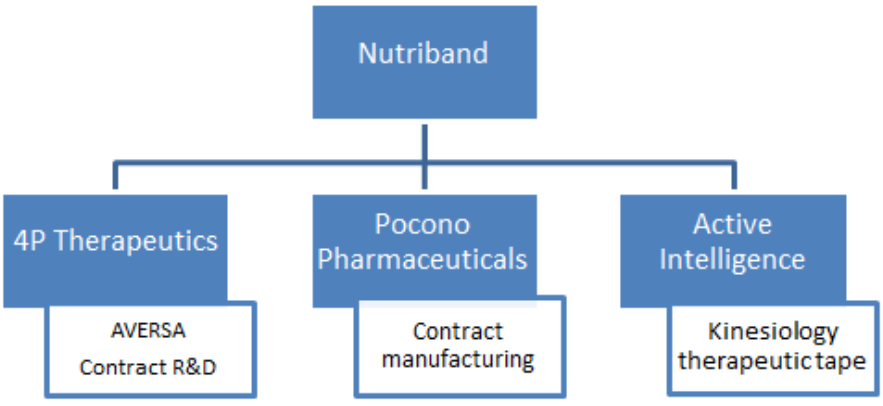
… And Growing The Services & Product Portfolio

Nutriband Pipeline



Source: Company reports

While other companies are also developing other drug deterrent technologies to combat the opioid crisis, NTRB believes that none are utilizing aversive agents on the backing layer of transdermal patches as the AVERSA technology does. With the 4P Therapeutics transaction, Nutriband also acquired a pipeline of other products that leverage the same delivery technology, including exenatide for type 2 diabetes (T2D) and FSH for infertility (see figure below). NTRB is evaluating the development of a transdermal delivery system for these drugs, as well, using its dermal ablation technology intended to create a route of administration for larger molecule drugs such as peptides and proteins. For example, one possible product candidate is the development of a generic scopolamine patch. The company has leveraged M&A to expand its development product portfolio and efforts. Through a series of M&A transactions, the company operates the following units.



Source: Company reports

In 2020, NTRB acquired Pocono Coated Products, which is a transdermal, topical, cosmetic and nutraceutical business. With the addition of Pocono, the company also manufactures transdermal, topical, coated and consumer products on a contract, white-label basis at its North Carolina production

facility. Pocono provided the company its contract manufacturing capabilities and also an existing partnership with Best Choice Inc. Best Choice Inc. provides consulting for and contract manufacturing services to a broad range of customers, primarily in Asia.

In addition, Pocono Pharmaceutical's subsidiary Active Intelligence (AI) produces kinesiology therapeutic tape that is used to support muscles and joints, generally in the sports fields by athletes to minimize pain associated with movement. AI's kinesiology tape has transdermal and topical properties. Active Intelligence has received cGMP certification following a full cGMP audit. The certification will enable the company to expand its contract manufacturing product offerings and thereby expand NTRB's revenue prospects. Last month, NTRB announced today it has booked about $234,000 in contract manufacturing orders through Pocono Pharma.

Separately, AI recently registered as a Class I medical device manufacturer with the U.S. Food and Drug Administration (FDA) to manufacture and distribute its proprietary AI Tape, to compete in the growing kinesiology tape market. The company believes the FDA medical device manufacturing registration represents a milestone that sets the stage for commercial sales of the AI Tape product in the U.S. through proprietary branded sales or via white label agreements.

The company intends to begin offering contract manufacturing services for liquid based topical, transdermal and cosmetic products. NRTB's objective is to continue expanding its contract manufacturing capabilities to boost revenue. Adding liquid based options such as lotions and cosmetics to its contract capabilities is core to this goal. NTRB also recently signed an exclusive contract manufacturing deal with San Diego-based Diomics for its Diocheck™ technology intended to monitor the presence of antibodies to SARS-CoV-2. The Diocheck patch is intended to monitor the time between obtaining a COVID-19 vaccine and developing a protective level of antibodies. The technology could also signal when the antibodies stimulated by a vaccine have declined, signaling that the person needs a booster vaccine.

ADDRESSABLE MARKET

According to the NIH (National Institutes of Health), the opioid overdose crisis increasingly is becoming a global challenge. Nutriband is working to protect its IP with patent applications and patents granted in multiple markets, as well as with the recently announced new branch in South America to conduct operations in that market.

The company believes AVERSA Fentanyl has the potential to be the world's first fentanyl transdermal system with abuse deterrent properties. Currently the transdermal fentanyl market in the United States is comprised of generic ANDA products that do not have any abuse deterrent properties. The FDA response to the opioid crisis includes a goal to expand access to abuse-deterrent formulations to discourage abuse as outlined in the FDA's Opioid Action Plan.[2] The company recently announced an expanded product development pipeline that includes AVERSA buprenorphine and AVERSA methylphenidate, which management believes each have the potential to be the first abuse deterrent versions of those transdermal drugs. The recent issuance of the US patent will protect the AVERSA technology platform that can be deployed in almost any transdermal product that carries a risk of abuse or misuse.

Based on a third-party evaluation from Health Advances, a healthcare consulting company that NTRB engaged to assess the market opportunity, the company estimates that the AVERSA Fentanyl patch could reach peak annual sales of $80 million to $200 million. Once approved by the United States FDA, Aversa Fentanyl will be priced competitively with generic fentanyl patches. Management estimates it could reach peak **domestic** sales within about five years after its commercial launch.

Moreover, the company believes there could be upside to this forecast, if Aversa Fentanyl drives the entire transdermal fentanyl market towards abuse deterrent patches. NRTB notes that this is similar to what occurred in the extended-release oral opioid market. For instance, in 2010, an abuse-deterrent formulation of OxyContin was introduced that was intended to make OxyContin more difficult to solubilize or crush and thereby deter its abuse through injection and inhalation that "successfully reduced [its] abuse," according to the New England Journal of Medicine. According to the FDA, it is "encouraging the development of prescription opioids with abuse-deterrent formulations (ADFs) to help combat the opioid crisis. The agency recognizes that abuse-deterrent opioids are not abuse- or addiction-proof but are a step toward products that may help reduce abuse." In addition, NRTB believes that developing the product for strategic **international** markets that are protected by its global abuse deterrent patent portfolio represents further upside.

Moreover, in addition to the opportunities regarding Fentanyl, NTRB recently announced an expanded product development pipeline for AVERSA™ technology, which can be applied to any transdermal patch that has a risk of abuse, misuse or accidental exposure. It is based on incorporating aversive agents into the patch that do not contact the drug matrix and are not delivered to the skin.

Expanding product development pipeline: AVERSA Methylphenidate & AVERSA Buprenorphine

Based on a preliminary market assessment, Nutriband has identified other valuable markets for transdermal products with a risk of abuse, misuse, diversion or accidental exposure that could benefit from its AVERSA technology. Currently marketed transdermal products that have labeled warnings for the risk of abuse include buprenorphine and methylphenidate and both products have reports of abuse or misuse. These two products, AVERSA buprenorphine and AVERSA methylphenidate, will be added to the product development pipeline with AVERSA Fentanyl. AVERSA buprenorphine has the potential to be an abuse deterrent version of transdermal buprenorphine, a partial opioid agonist, marketed as Butrans® or its generics, which is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. AVERSA methylphenidate has the potential to be an abuse deterrent version of transdermal methylphenidate, a central nervous system (CNS) stimulant, marketed as Daytrana®, indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The company believes that the opportunity to protect against intentional or accidental abuse of opioid and other drugs is substantial. The misuse of and addiction to opioids has led to a rise in overdoses and related deaths. In the late 1990s, healthcare professionals began prescribing opioid drugs at increasing rates under the mistaken belief that patients would not become addicted. In turn, this led to rising abuse of these prescription medications. Consequent opioid overdose rates began to increase.

According to the NIH (National Institute of Health), in 2019, nearly 50,000 people in the U.S. died from opioid-involved overdoses. This data is in-line with National Institute on Drug Abuse data that indicates that roughly 2.3 million people in the U.S. were addicted to prescription opioids or illicit opiates such as heroin in 2017 and about 47,000 died of an overdose, including prescription opioids, heroin, and illicitly manufactured fentanyl. In that same year, an estimated 1.7 million people suffered from substance use disorders related to prescription opioid pain relievers in the U.S.

Fentanyl is a leading factor in overdoses. The National Institute on Drug Abuse notes that 59.8% of opioid-related deaths involved fentanyl in 2017, up from 14.3% in 2010. Fentanyl can be administered as an injection, through a patch or sometimes orally.

In 2018, the healthcare sector introduced HEAL (Helping to End Addiction Long-term), an initiative to mitigate the opioid crisis. The FDA has issued draft guidance outlining ways for drug developers to consider measuring and demonstrating the effectiveness and benefits of new or existing medication-assisted treatments (MAT) for patients battling opioid addiction. The data suggests that the chances a person will develop an opioid use disorder depend on factors such as the length of time the person is prescribed opioids to treat acute pain. According to CDC data:

- About 21%-29% of patients prescribed opioids for chronic pain misuse these drugs
- About 8%-12% of people using an opioid for chronic pain develop an opioid use disorder
- An estimated 4%-6% of patients who misuse prescription opioids transition to heroin
- About 80% of people who use heroin initially misused prescription opioids

In addition to deliberate abuse of fentanyl and other drugs, there is a high risk of accidental harmful and potentially lethal ingestion. For instance, FDA instructions on improving the safety of fentanyl include a webpage titled, *'Accidental Exposures to Fentanyl Patches Continue to be Deadly to Children,'* citing unintended exposure to medication as a leading cause of poisoning in children.

In addition to the needless deaths, there is a significant economic cost associated with the abuse of opioids. The CDC (Centers for Disease Control and Prevention) estimates the domestic cost of prescription opioid misuse at about $78.5 billion per annum, when factoring in the cost of healthcare, lost productivity, addiction treatment and the involvement of the criminal justice system.

Separately, NTRB believes that the healthcare sector's focus on COVID-19 over the past nearly two years could mask an increase in occurrences of opioid abuse and / or rising overdose rates. In fact, recent data analyzed in *Science Direct* and noted earlier supports this view. In turn, this could imply increased focus on the ongoing opioid epidemic going forward, management believes. By improving the safety profile via the use of AVERSA, the company expects that legitimate use of fentanyl and other pain killers might grow. Moreover, the increase in injection drug use has also contributed to the spread of infectious diseases including HIV, which could further support the use of transdermal delivery therapy as a viable alternative delivery system.

CLINICAL STUDIES

AVERSA is advancing through clinical studies. AVERSA produced positive results in pre-clinical studies. Now, Nutriband intends to conduct studies testing the human abuse liability (HAL) and abuse deterrent formulation (ADF) of AVERSA in order to evaluate its safety and deterrent capability.

The recent USPTO patent and partnership with Kindeva are expected to accelerate commercializing AVERSA in the U.S., which management believes could entail a commercial opportunity equal to that of the rest of the world combined. Development of Aversa Fentanyl will follow a regulatory path towards a 505(b)(2) NDA, with a clinical program to establish abuse deterrent claims. Although the clinical timeline could be impacted by several factors, including the ongoing pandemic and the receipt of regulatory approvals and the outcomes and data from clinical trials, the company expects that it could have AVERSA ready for FDA submission by the end of 2024.

RECENT RESULTS

In 2Q23 (quarter ended July), NTRB generated record quarterly revenue of $0.5 million, more than double (up 113% year-over-year) compared to 2Q22. Revenue growth was driven primarily by the company's Pocono Pharmaceuticals operating segment.

The company registered a gross margin of 33% compared to a negative gross margin in the prior year 2Q. As NTRB continues to advance the development of Aversa™, R&D expenses increased to $0.3 million and S,G&A to $0.9 million, compared to $0.5 million. The company reported a loss per share of ($0.12) compared to a loss per share of ($0.08) in 2Q FY2022.

Balance Sheet

Nutriband had cash and cash equivalents were $3.3 million at the end of the quarter and working capital of $3.3 million. These metrics compare to $4.9 million and $4.7 million, respectively, at the end of the January 31, 2022 quarter.

Separately, the company recently received authorization to recover 1.2 million shares (adjusted for a 2018 reverse share split, or 4.8 million pre-2018 reverse split), which equates to about 15% of total shares outstanding. NTRB issued the shares in 2017 following a negative court ruling which has recently been overturned and is a binding judgement that cannot be appealed, according to NTRB. Following the cancellation, NTRB's board approved a 7:6 forward split of NTRB shares effective as of August 15, 2022. Every six NTRB shares were converted into seven shares. The company's goal was to increase the liquidity of the shares. Existing shareholders received one additional share for each six shares held. Following the split, there were about 7.8 million NTRB shares outstanding. The company also recently initiated the application process to dual list its shares on Upstream to increase trading liquidity.

VALUATION

Given NTRB's steps to expand its operating footprint and protect its IP, we are optimistic about AVERSA's commercial prospects, as the potential range of applicable uses for the AVERSA technology, the rising incidences of overdose deaths and high related healthcare costs could translate, we believe, into high demand for AVERSA following clinical studies.

We are encouraged by the estimates from Health Advances. We believe *in success* NTRB could attain annual revenue in the $10 million to $15 million range by 2025-26 on its way to achieving scale and peak sales, depending on the commercialization timeline. We believe these forecasts are supported by the growing size of the target markets and AVERSA's expected ability to improve the safety profile of fentanyl and other prescription medications. Moreover, we also believe that competitive pressure could lead to adoption of the AVERSA technology by several large pharma companies in a short period, if the technology proves as efficient as NTRB believes it will. In fact, fentanyl transdermal patches have become such an important pain therapy that they have been added to the WHO list of essential medicines, as noted, which we believe supports the positive outlook for AVERSA if clinical test results support its efficacy and safety. If the company can maintain its expected timeline and commercialize AVERSA by late 2024, our forecast could prove conservative, depending on several factors.

It is difficult to compare NTRB to other more mature companies, in our view, given the early stage of development of AVERSA and the product portfolio. We would also expect NTRB to have a higher growth rate in the early years. Various other companies that are engaged in introducing new therapies and solutions and are at a similar stage of development have a wide range of price-to revenue multiples on forward estimates. Nevertheless, we believe the average price-to-sales multiple of companies in this comparison of about 14x provides a valuation benchmark for NTRB. Therefore, applying a 14x multiple to our above-noted forecast revenue range and discounting back to the present at 10%/year results in a present value of about $10 to $15 per share on a fully diluted basis, if the company initiates a successful launch of AVERSA. We expect the shares to begin to reflect the low end of this range as it hits certain milestones and incorporate the mid- to high-end as AVERSA development proceeds. Our forecast could change if and when the company expands the number of products leveraging the AVERSA technology.

While there are several risks to the timeline and commercial launch, we think the current share price does not reflect the fundamental value of the company's pipeline and prospects and would anticipate multiple expansion as the company continues to advance AVERSA. Any delay or failure in clinical development or regulatory approval could cause the share price to decline and represent a potential risk to our valuation but we believe the risk / reward ratio could be attractive for investors who have a higher than average risk tolerance and longer time horizon.

RISKS

Risks to NTRB achieving its objectives, and to our valuation, include the following.

- Regulatory approval might take longer than expected or might not come at all.
- NTRB might need to raise additional capital earlier than expected.
- COVID-19 cases could increase, which might, in turn, delay the company's clinical and commercialization timelines.
- The company might not find strategic partners and / or a Big Pharma manufacturer to help advance AVERSA.
- Clinical trials might not produce the results that management anticipates.
- Despite receiving the notice from the USPTO, the full patent approval might take longer than expected.
- Companies exploring other solutions might advance at a faster pace and impact the need for the AVERSA technology.

RECENT NEWS

- On October 3, 2022, Nutriband announced that it had initiated the application process to dual list its shares on NASDAQ and Upstream.
- On September 8, 2022, the company announced 2Q FY2023 results.
- Nutriband provided details on the 7:6 stock split on August 16, 2022.
- On August 1, 2022, the company received Notice of Allowance from the Canadian Intellectual Property Office for the AVERSA technology patent.
- The company registered a new branch in Ecuador on July 22, 2022, to expand operations into the South American market.
- On July 26, 2022, Nutriband announced that 1.2 million shares would be cancelled following a final court judgment in its favor.
- NTRB announced its support of CDC updated guidelines regarding opioids on June 3, 2022.
- Nutriband received May 2022 orders for $230k in contract manufacturing through May 17, 2022.
- Nutriband's AI registered with the FDA as a medical device manufacturer for its AI kinesiology tape on May 11, 2022.
- Nutriband was issued full U.S. patent for AVERSA™ on January 28, 2022.
- Nutriband and Kindeva Drug Delivery signed a feasibility agreement to develop AVERSA™ Fentanyl on January 10, 2022.

PROJECTED FINANCIALS

Nutriband, Inc. *($ Fiscal year [FY] ends January 31)*

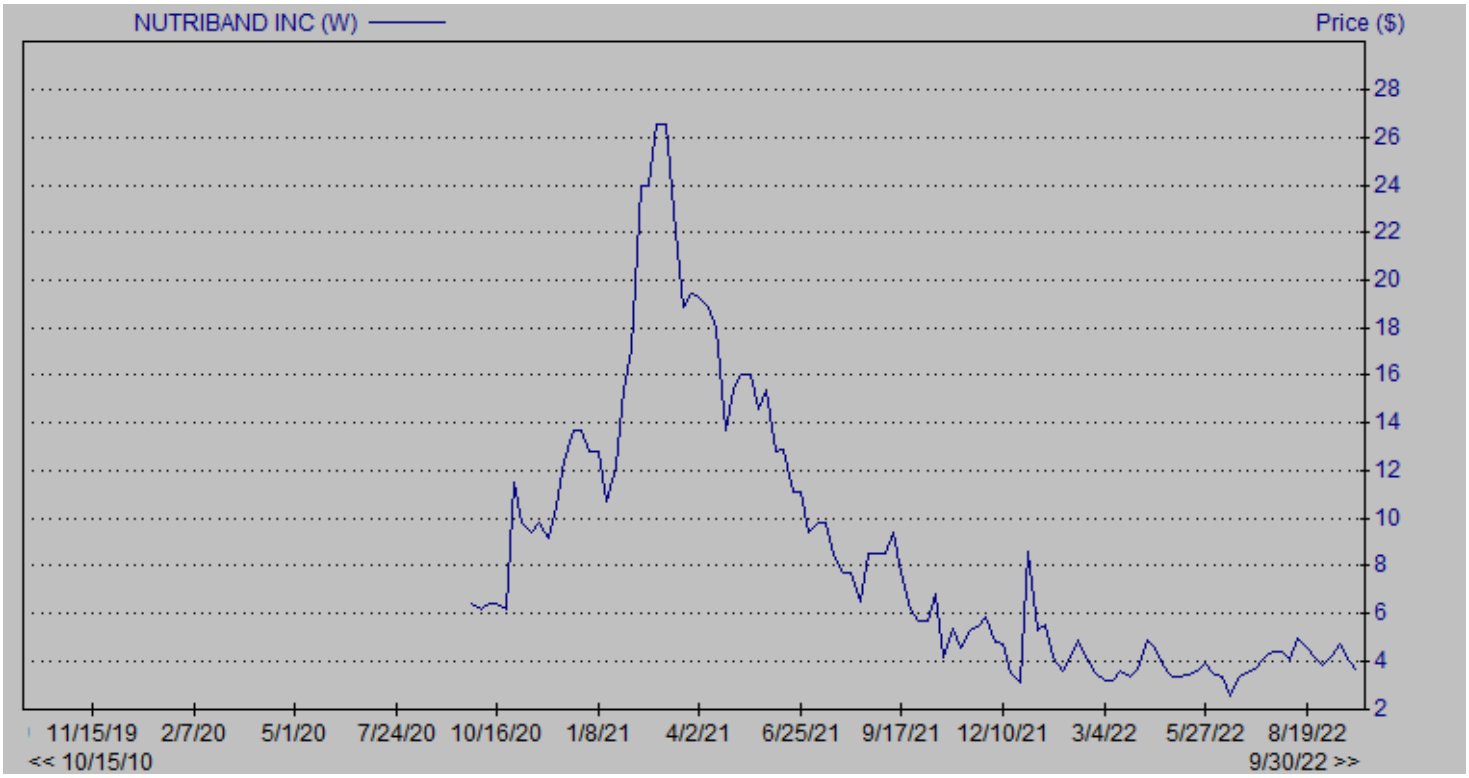
				Apr-21	*Jul-21*	*Oct-21*	*Jan-22*		*Apr-22*	*Jul-22*	*Oct-22*	*Jan-23*	
	FY 2019	**FY 2020**	**FY 2021**	**1Q22**	**2Q22A**	**3Q22A**	**4Q22A**	**FY 2022A**	**1Q23A**	**2Q23A**	**3Q23E**	**4Q23E**	**FY 2023E**
Revenue	$245,285	$370,647	$943,702	$433,488	$213,739	$283,037	$491,890	$1,422,154	$477,922	$456,149	$551,331	$753,934	$2,239,336
Cost of revenues	288,301	549,107	582,378	168,844	186,762	173,694	388,544	917,844	277,436	304,353	285,822	210,666	1,078,276
R&D			* 2,957,269			161,000	250,383	411,383	117,814	277,869	121,375	122,589	639,647
Goodwill impairment							2,180,836	2,180,836	-	-	-	-	-
S,G&A	3,288,224	1,790,980	3,539,647	579,608	509,219	1,486,784	1,447,213	4,022,824	768,551	908,173	791,780	799,698	3,268,203
Total Expenses	3,576,525	2,340,087		748,452	695,981	1,821,478	4,266,976	7,532,887	1,163,801	1,490,395	1,198,977	1,132,952	4,986,125
			(2,595,945)										
Loss from operations	(3,331,240)	(1,969,440)		(314,964)	(482,242)	(1,538,441)	(3,775,086)	(6,110,733)	(685,879)	(1,034,246)	(647,646)	(379,019)	(2,746,790)
			(12,500)										
Debt extinguishment	-		(69,131)	39,876	3,338		(43,214)						
Early debt prepayment fee	-		3,338	-	-		53,028	53,028					
Gain debt forgiveness	-		-	-	-		-						
Derivative expense	-	(767,650)	22,096		-		-						
Chg derivative fair value	-	88,876	(280,686)				-						
Interest expense	-	(73,413)	(336,883)	(40,869)	(41,019)	(33,380)	(3,153)	(118,421)	(4,110)	(4,429)	(4,193)	(4,235)	(16,966)
Total other inc / (exp)	-	(752,187)	(2,932,828)	(993)	(37,681)	(33,380)	6,661	(65,393)	(4,110)	(4,429)	(4,193)	(4,235)	(16,966)
Operating income / (loss)	(3,331,240)	(2,721,627)	(2,932,828)	(315,957)	(519,923)	(1,571,821)	(3,768,425)	(6,176,126)	(689,989)	(1,038,675)	(651,839)	(383,253)	(2,763,756)
			-										
Taxes	-	-		-	-		-	-	-	-	-	-	-
Other						(196,589)	-	(196,589)	-				
Net loss	(3,331,240)	(2,721,627)	(2,932,828)	(315,957)	(519,923)	(1,768,410)	(3,768,425)	(6,372,715)	(689,989)	(1,038,675)	(651,839)	(383,253)	(2,763,756)
Loss per share / EPS	($0.62)	($0.50)	($0.51)	($0.05)	($0.08)	($0.27)	($0.57)	($0.94)	($0.09)	($0.12)	($0.08)	($0.05)	($0.34)
Weighted avg shares out	5,352,321	5,423,956	5,770,944	6,329,438	6,356,269	6,505,249	6,652,437	6,799,624	7,871,356	8,409,141	7,881,356	7,886,356	8,012,052

Source: Company reports, Zacks estimates

*Includes about $2.0m 1-time non-cash acquisition-related charges

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