

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 31, 2020

or

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-55654

**NUTRIBAND INC.**

(Exact name of registrant as specified in its charter)

<b>Nevada</b> (State or other jurisdiction of Incorporation or organization)	<b>81-1118176</b> (I.R.S. Employer Identification No.)
<b>121 South Orange Ave., Suite 1500, Orlando, FL</b> (Address of principal executive offices)	<b>32801</b> (Zip Code)

Registrant's telephone number, including area code: (407) 377-6695

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Exchange Act: Common stock, par value \$0.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Note - Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendments to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: \$97,425,012 as of July 31, 2019.

As of April 10, 2020, the registrant had 5,512,928 shares of common stock outstanding.

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References to “we,” “us,” “our” and words of like import refer to us and our subsidiaries, including 4P Therapeutics LLC following our acquisition of 4P Therapeutics on August 1, 2018, unless the context indicates otherwise. References to 4P Therapeutics refer to the business and operations of 4P Therapeutics prior to our acquisition unless the context indicates otherwise.

The market data and certain other statistical information used throughout this annual report are based on independent industry publications, government publications and other published independent sources. Some data is also based on our good faith estimates. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications.

## FORWARD LOOKING STATEMENTS

This annual report on Form 10-K contain “forward-looking statements,” within the meaning of the Private Securities Litigation Reform Act of 1995, all of which are subject to risks and uncertainties. Forward-looking statements can be identified by the use of words such as “expects,” “plans,” “will,” “forecasts,” “projects,” “intends,” “estimates,” and other words of similar meaning. One can identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address our growth strategy, financial results and product and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ from our forward looking statements. These factors may include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward looking statement can be guaranteed and actual future results may vary materially.

These risks and uncertainties, many of which are beyond our control, include, and are not limited to:

- Our ability to raise the financing which we require for the continuation and development of our business, failing which we may not be able to continue in business;
- The terms of any financing we may be able to obtain;
- The effects of the COVID-19 pandemic, the steps taken to address the pandemic and the market’s reaction to the pandemic on our ability to raise necessary financing or enter into a joint venture agreement;
- Our ability to receive FDA marketing approval for any products we may develop;
- Our ability to get and enforce any United States and foreign patent we may seek;
- Our ability to design and execute clinical trials to the satisfaction of regulatory authorities;
- Our ability to engage, if and when necessary, an independent preclinical or clinical testing organization to design and implement our trials;
- Our ability to launch any products for which we receive FDA marketing approval;
- Our ability to generate sufficient revenue from our contract services to cover our operating expenses;
- The effects of the COVID-19 pandemic on both our contract service customers engaging us to perform services and our ability to perform such services;
- The effect of our financial condition and our scaled-back operations resulting from our financial position on generating contract services;
- If we obtain FDA approval for marketing any products, our ability to establish a distribution network for such products;
- Our ability to establish manufacturing facilities in compliance with FDA good manufacturing practices or to enter into manufacturing agreements for the manufacture of our products in an FDA approved manufacturing facility;
- Our ability to enter into joint venture or other strategic relationship with respect to any of our proposed products and the terms of any sure relationships, particularly in view of our precarious financial position;
- The ability of the other party to any joint venture or strategic relationship to implement successfully any plans for the development, clinical testing, manufacturing and marketing of the products subject to the joint venture or strategic relationship;
- Our ability to evaluate potential acquisitions, and the consequences of our failure to accurately evaluate the acquisitions;
- Our ability to integrate any business we acquire with our business;
- Changes in national, regional and local government regulations, taxation, controls and political and economic developments that the market for our products;

- Our ability to develop and market products with the most current technology;
- Our ability to obtain and maintain any permits or licenses necessary for our business;
- Our ability to identify, hire and retain qualified executive, administrative, regulatory, research and development, and other personnel;
- Our ability to negotiate licenses on favorable terms with companies that have experience in marketing products such as ours;
- The costs associated with defending and resolving potential legal claims, even if such claims are without merit;
- The effects of the SEC settlement;
- The effects of competition on our and our licensee's ability to price, market and sell our product;
- Our ability to achieve favorable pricing for our products with third party reimbursement parties with respect to our products;
- Our ability to accurately estimate anticipated expenses, capital requirements and needs for additional financing;
- Our ability to accurately estimate the timing, cost or other aspects of the commercialization of our product candidates;
- Any failure of any international distributor to comply with applicable laws, including the failure of our South Korean distributor to obtain regulatory approval to market our consumer products in South Korea;
- The failure or inability of any international distributor to develop an effective marketing program or to sell our products in any meaningful quantity in their territory;
- The effects of the COVID-19 pandemic on both the market for our over-the-counter products in any country where we have a distributor and the regulatory process for approval of the marketing of our products in such country;
- Actions by third parties to either sell or purchase our common stock in quantities that would have a significant effect on our stock price;
- Risks generally associated with pre-revenue development stage companies in the pharmaceutical industry;
- Current and future economic and political conditions, including the effects of the COVID-19 pandemic;
- The impact of changes in accounting rules on our financial statements;
- Other assumptions described in this annual report; and
- Other matters that are not within our control.

Information regarding market and industry statistics contained in this annual report is included based on information available to us that we believe is accurate. It is generally based on industry and other publications that are not produced for purposes of securities offerings or economic analysis. We have not reviewed or included data from all sources. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. We do not assume any obligation to update any forward-looking statement.

The forward-looking statements in this annual report speak only as of the date of this annual report and you should not to place undue reliance on any forward-looking statements. Forward-looking statements are subject to certain events, risks, and uncertainties that may be outside of our control. When considering forward-looking statements, you should carefully review the risks, uncertainties and other cautionary statements in this annual report as they identify certain important factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. These factors include, among others, the risks described in this annual report, including those described under "Item 1. Business," "Item 1A. Risk Factors" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as in other reports and documents we file with the SEC. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements.

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## PART I

### ITEM 1. BUSINESS

#### Our Business

Our primary business is the development of a portfolio of transdermal pharmaceutical products. Our lead product is our abuse deterrent fentanyl transdermal system which we are developing to provide clinicians and patients with an extended-release transdermal fentanyl product for use in managing chronic pain requiring around the clock opioid therapy combined with properties designed to help combat the opioid crisis by deterring the abuse and misuse of fentanyl patches. We believe that our abuse deterrent technology can be broadly applied to various transdermal products and our strategy is to follow the development of our abuse deterrent fentanyl transdermal system with the development of additional transdermal prescription products for pharmaceuticals that have risks or a history of abuse. In addition, we are developing a portfolio of transdermal pharmaceutical products to deliver commercially available drugs or biologics that are typically delivered by injection but with the potential to improve compliance and therapeutic outcomes.

Because of our financial position, we have put our development efforts with respect to these products on hold, and our only business is the performance of contract services for a small number of customers. Because of both our financial position and the effects of the COVID-19 pandemic, our contract service business has also been scaled back. The description of our business in this annual report is based on our ability to raise significant financing or enter into a joint venture agreement with a third party that has the financial ability to fund the joint venture's operations. We cannot assure you that we will be able to obtain necessary financing or enter into a joint venture agreement on reasonable, if any, terms. If we are not able to continue obtain financing or enter into a joint venture agreement, we may not be able to continue in business.

Through July 31, 2018, we had not generated any revenue from our business, which was the development and marketing of a range of transdermal consumer patches. Consumer products are products that can be sold over-the-counter and do not require a prescription. Most of our consumer products are considered drugs in the United States and cannot be marketed in the United States without approval from the FDA. We have not taken any steps to seek to obtain FDA approval for any of our consumer products, and we have no plans to do so in the near term. As a result, we are not selling our consumer transdermal patch products in the

United States. Any revenue we generate from our consumer products will be from the sale of products to distributors for distribution outside of the United States.

We acquired 4P Therapeutics on August 1, 2018 for \$2,250,000 consisting of 62,500 shares of common stock, valued at \$1,850,000, cash of \$400,000, and a 6% royalty on any revenues we generate or derive from the abuse deterrent intellectual property developed by 4P Therapeutics payable to Steve Damon, who has been one of our directors since April 2018 and who was the sole equity owner of 4P Therapeutics. As a result of the acquisition, the focus of our business has changed from the development and marketing of consumer transdermal products to the development of 4P Therapeutics' portfolio of pharmaceutical transdermal system, with the lead product being the abuse deterrent fentanyl transdermal system.

We have received patent protection from the European Patent Office, the patent offices for Japan, Australia and Russia and the patent office of Mexico has granted a notice of allowance for abuse deterrent transdermal technology patent used in our lead product, an abuse deterrent fentanyl transdermal system. The patent is being prosecuted in the United States and in other countries. The patent applications were filed by 4P Therapeutics prior to our acquisition of 4P Therapeutics and any patents issued in respect of these applications will be in the name of 4P Therapeutics. In addition to applying the technology to developing an abuse deterrent fentanyl transdermal system, we believe that the abuse deterrent patch technology can be applied to other opioids and pain medication patches where there is a risk of abuse and overdose, as well as other transdermal pharmaceuticals where we believe our technology can help prevent abuse or accidental misuse.

Our lead product under development is our abuse deterrent fentanyl transdermal system which we plan to develop to deter the abuse and accidental misuse of fentanyl transdermal patches. Fentanyl is a potent synthetic opioid that is marketed as a transdermal patch for chronic pain management. There are currently a number of generic fentanyl patches on the market but we believe that none of them are abuse deterrent. We believe that our abuse deterrent technology containing aversive agents will significantly deter the abuse and accidental misuse of fentanyl from transdermal patches. In 2017, according to a report from the National Institute on Drug Abuse, of the more than 72,000 drug overdose deaths in the United States, nearly 30,000 occurred due to overdoses of fentanyl and fentanyl analogues.

The development of our abuse deterrent fentanyl transdermal system requires preclinical and clinical trials to be conducted for the purposes of obtaining FDA approval. We require funds for these trials.

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With the acquisition of 4P Therapeutics, we acquired a pipeline of other transdermal products, including peptides and proteins such as exenatide for type 2 diabetes and FSH for infertility, which we anticipate will be the next products for development. These drugs are off-patent but are currently only available as injections, and we are evaluating the possibility of developing a transdermal delivery system for these drugs as an alternative to injection but with improved compliance and safety. In addition we may develop certain generic transdermal products where we think we can make an improvement to existing patches and where we believe we can take significant market share with good profit margins. One example of such a product candidate is the development of a generic scopolamine patch. The prioritization of our portfolio product candidates will be reviewed on an ongoing basis and will take into account technical progress, market potential and commercial interest. We cannot assure you that we will be able to develop and obtain FDA approval for any of these potential products or that we can be successful in marketing any such products. The FDA approval process can take many years to complete successfully and we will require substantial funding for each product that goes through the process. We cannot assure you that we will obtain FDA marketing approval for any of our products.

Since 4P Therapeutics did not have any products that it can market, its sole source of revenue to date was derived from the performance of contract research and development and other services for a small number of clients in the life sciences field on an as-needed basis to support its ongoing operations. The work varied in nature and includes early stage drug and device preclinical studies, commercial biologic manufacturing support, clinical-regulatory consulting, drug or device clinical studies and formulation/analytical services relating to the chemistry, manufacturing and controls function of drug manufacturing. The current continuing arrangements are varied, from purchase order supported per animal study fees, to hourly rate research and development services, to flat rate contract research and development projects. Neither we nor current clients have any long-term commitments, and either party can terminate at any time. We intend to devote our efforts toward the development and testing of our lead product and other product candidates in our pipeline. However, for the near term, we are looking to perform research and development services for third parties although we do not expect to generate significant revenues from these services.

Our marketing effort with respect to our consumer transdermal products is presently limited to our distribution agreement dated April 13, 2018 with EMI-Korea (Best Choice), Inc., whom we refer to as Best Choice, for marketing in certain regions in Asia. Pursuant to an exclusive distribution agreement, we granted Best Choice exclusive distribution rights for all of our transdermal consumer products in South Korea, Taiwan (the Republic of China), the People's Republic of China and South Asia. Best Choice is presently planning to market three of our consumer products only in South Korea, and is responsible for complying with all applicable regulations. The ability of Best Choice to market products at the volume we anticipated when we signed the contract with Best Choice was affected by a number of factors, including its inability to obtain necessary regulatory approval, which, as of the date of this annual report, has not been obtained. Best Choice has advised us that it is working with the South Korean Ministry of Food and Drug Safety ("MFDS") to determine a classification for our products, which is necessary before Best Choice can obtain approval from the MFDS to market our products to consumers. Our supplier had manufacturing problems in the United States because it ran into supply problems for certain foil components used in the transdermal patches due to the new tariffs on Chinese imports into the United States, design changes in the pouch, and quality problems with material in the pouch, all of which resulted in manufacturing delays in meeting the first order for Best Choice. We solved the problem by delivering the patch in bulk and unpackaged, and Best Choice has the assembly of the patch completed in South Korea. Best Choice's purchases to date were for preliminary marketing activities. Best Choice has advised us that its preliminary marketing activities consisted of purchasing inventory in anticipation of obtaining regulatory approval, meeting with potential distributors and trying to build brand awareness through various marketing approaches most notably on social media. Until Best Choice has obtained the necessary regulatory approval, we do not anticipate generating any significant revenue from Best Choice. Our agreement with Best Choice agreement had an initial term which expired on April 30, 2019 and was extended to April 30, 2020. The agreement provides for an automatic renewal for three years and for five-year periods thereafter if certain minimum purchases are made. As of the date of this report, the minimum purchases for the current contract year have not been met.

#### **Acquisition of 4P Therapeutics**

Pursuant to an acquisition agreement dated April 5, 2018 between us and 4P Therapeutics, on August 1, 2018, we acquired all of the equity interest in 4P Therapeutics from Steven Damon, the owner of 4P Therapeutics. The purchase price of \$2,250,000, consisting of 62,500 shares of common stock, valued at \$1,850,000, and cash of \$400,000, and are to pay Mr. Damon a 6% royalty on any revenue we receive or derive from our utilization or sale of the abuse deterrent intellectual property that we acquired as a part of the assets 4P Therapeutics, including partner license milestones and development payments. The royalty is payable pursuant to the acquisition agreement and continues as long as we generate revenue from our utilization or sale of the abuse deterrent intellectual property we acquired as part of the acquisition of 4P Therapeutics. The 62,500 shares were issued to Mr. Damon (41,750 shares) and Dr. Alan Smith (20,750 shares). In connection with the acquisition, Mr. Damon retained any cash and accounts receivable and assumed any liabilities other than those relating to the ongoing business. Pursuant to the acquisition agreement, we appointed Mr. Damon to our board of directors in April 2018, when we signed the acquisition agreement, and we agreed to pay Mr. Damon the compensation received by independent board members.

#### **Our Organization**

We are a Nevada corporation, incorporated on January 4, 2016. In January 2016, we acquired Nutriband Ltd, an Irish company which was formed by Gareth Sheridan, our chief executive officer, in 2012 to enter the health and wellness market by marketing transdermal patches. Our corporate headquarters are located at 121 S. Orange Ave. Suite 1500, Orlando, Florida 32765, telephone (407) 377-6695. Our website is [www.nutriband.com](http://www.nutriband.com). Information contained on or available through our website or any other website does not constitute a portion of this annual report.

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## Implications of Being an Emerging Growth Company

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise generally applicable to public companies, although as a smaller reporting company we are taking advantage of reduced reporting requirements. In particular, as an emerging growth company, we:

- may present only two years of audited financial statements and related disclosure under Management’s Discussion and Analysis of Financial Condition and Results of Operations, or MD&A;
- are not required to provide a detailed narrative disclosure discussing our compensation principles, objectives and elements and analyzing how those elements fit with our principles and objectives, which is commonly referred to as “compensation discussion and analysis”;
- are not required to obtain an attestation and report from our auditors on our management’s assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- are not required to obtain a non-binding advisory vote from our stockholders on executive compensation or golden parachute arrangements (commonly referred to as the “say-on-pay,” “say-on frequency” and “say-on-golden-parachute” votes);
- are exempt from certain executive compensation disclosure provisions requiring a pay-for-performance graph and chief executive officer pay ratio disclosure;
- are not be required to conduct an evaluation of our internal control over financial reporting by our auditors.

We intend to take advantage of all of these reduced reporting requirements and exemptions. However, since we have already adopted certain new or revised accounting standards under §107 of the JOBS Act, we are not able to take advantage of the delayed phase in of the new or revised accounting standards.

Under the JOBS Act, we may take advantage of the above-described reduced reporting requirements and exemptions for up to five years after our initial sale of common equity pursuant to a registration statement declared effective under the Securities Act of 1933, as amended, or such earlier time that we no longer meet the definition of an emerging growth company. The JOBS Act provides that we would cease to be an “emerging growth company” if we have more than \$1.07 billion in annual revenues (as adjusted for inflation), have more than \$700 million in market value of our common stock held by non-affiliates, or issue more than \$1 billion in principal amount of non-convertible debt over a three-year period. Under current Securities and Exchange Commission, or SEC, rules however, we will continue to qualify as a “smaller reporting company” for so long as we have either (i) a public float (i.e., the market value of common equity held by non-affiliates) of less than \$250 million as of the last business day of our most recently completed second fiscal quarter or (ii) annual revenues of less than \$100 million and a public float of less than \$700 million.

## Effects of the COVID-19 Pandemic

Our business may be affected by the COVID-19 pandemic and the response to the pandemic. Factors which may affect our business include, but are not limited to, the following:

- Our ability to raise financing for our operations and to enter into a joint venture agreement may be affected by both the willingness and ability of potential financing sources and potential joint venture partners to invest in an undercapitalized business, particularly at a time when the potential financing source or joint venture partner may need to devote its resources to existing portfolio companies or joint ventures which may be in need of financing. decision by investors who would invest in early stage pharmaceutical companies to limit their financing efforts to companies that are dealing with products or services related to COVID-19 diagnosis or treatment.

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- The decision by investors who would invest in early stage pharmaceutical companies to limit their financing efforts to companies that are dealing with products or services related to COVID-19 diagnosis or treatment.
- The effect of recent stock market declines on the willingness of investors to make an investment in our securities.
- The financial health of our potential contract service customers.
- Our ability to perform contract services.
- Our ability to obtain any goods or services which we may need to perform contract services.
- The ability of our foreign distributors to obtain regulatory approval, which may be affected by the regulatory agencies giving a low priority to products such as our consumer patches.
- The financial health of Best Choice.
- If regulatory approval is obtained in South Korea, the extent to which consumers in South Korea purchase our products.
- The extent to which the purchase of our consumer products is a low priority item for a population whose disposable income may have decreased as a result of COVID-19 and the steps taken by the South Korean government to curb the spread of infection.

## Pharmaceutical Products in Development

We have a pipeline of transdermal pharmaceutical products that are primarily in the early, preclinical, stages of development. Our pipeline consists primarily of drug compounds which have been previously approved by the FDA and are now off-patent. In many cases, we are developing the first non-injectable version of the drug utilizing our transdermal technology which represents a new route of administration. In most cases, we plan to utilize the 505(b) (2) regulatory pathway provided by the FDA which allows us to reference the safety information on file at FDA for the approved drug or to reference the published literature instead of having to generate new safety information that would typically be required for new chemical entities. However, we cannot assure you that the FDA will concur with our approach or that we will be able to receive FDA approval to market any of products that we develop.

Our lead product under development is our abuse deterrent fentanyl transdermal system. As the United States faces an epidemic of opioid abuse, fentanyl transdermal patches have become an attractive target for recreational drug abusers due to the drug’s potency and its ease of abuse by the oral route. We are looking to utilize our proprietary approach to incorporate aversive agents into the transdermal patch to deter the abuse of fentanyl patches by the oral, buccal and inhaled routes, which represent as much as 70% of all transdermal fentanyl abuse. The technology is based on the incorporation of taste and sensory aversive agents into the patch. We believe that the aversive agents we selected have several advantages, such as their high potency, established safety, and the potential to prevent

accidental misuse by children and pets. The aversive agents are formulated in a controlled-release matrix that is coated onto the backing of a transdermal fentanyl patch. The controlled release aspect of the technology is designed so that the abuse deterrent properties are maintained after normal use and during attempts to separate the aversive agents from the fentanyl. We believe that this structure provides maximum exposure during oral abuse and during attempts to extract the drug, while preventing exposure of the patient to the aversive agents during transdermal wear. We believe that a key differentiating aspect of the technology is that the aversive agents are physically separated from the drug matrix, meaning that the aversive agents do not have to be formulated in the fentanyl drug matrix and do not contact the skin. In addition to the fentanyl patch, this technology has broad applicability to any therapeutic patch where deterring abuse and accidental misuse by children and pets are valuable attributes.

We believe that our abuse deterrent technology can be broadly applied to various transdermal products and our strategy is to follow the development of our abuse deterrent fentanyl transdermal system with the development of additional products for pharmaceuticals that have risks or history of abuse. For example, we believe that our technology can be utilized in other transdermal products to deter the abuse of other transdermal drugs such as buprenorphine, an opioid used to treat acute pain and chronic pain, and methylphenidate, a central nervous system stimulant.

Buprenorphine is an opioid used to treat opioid addiction, acute pain and chronic pain. It can be used under the tongue, by injection, as a skin patch, or as an implant. For opioid addiction, it is typically only started when withdrawal symptoms have begun and for the first two days of treatment under direct observation of a health care provider. For longer term treatment of addiction, a combination formulation of buprenorphine/naloxone is recommended to prevent misuse by injection.

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Methylphenidate, sold under various trade names, such as Ritalin in oral form, and in transdermal patch form known as Daytrana, is a central nervous system stimulant of the phenethylamine and Piperidine classes that is used in the treatment of attention deficit hyperactivity disorder and narcolepsy. We plan to follow up with transdermal delivery systems for buprenorphine and methylphenidate after we make significant progress on our abuse deterrent fentanyl transdermal system.

We are also exploring product applications for our transdermal technology to deliver proteins and peptides such as exenatide for type 2 diabetes and follicle stimulating hormone (FSH) for infertility. Presently, these products are only available by injection or oral routes. We believe that transdermal delivery has the potential to improve compliance, which can lead to improved therapeutic outcomes associated with these treatments.

Exenatide (exendin-4) is a glucagon-like peptide-1 (GLP-1) receptor agonist which is approved to improve glycemic control in patients with type 2 diabetes mellitus. Exenatide is currently approved as a twice-daily subcutaneous injection or as a once-weekly injection. However, many patients have a strong aversion to needles, resist initiation of injections even when oral agents are failing to control their diabetes and struggle with compliance after starting therapy. We have performed pre-clinical work on the development of a novel transdermal patch for administration of exenatide to match the therapeutic plasma levels achieved by subcutaneous injections of exenatide. However, we need substantial funds before we can continue these efforts. In addition to being needle-free, painless and easy-to-use, our proposed exenatide transdermal system is being designed to incorporate compliance tracking to help providers improve patient outcomes. We believe that the development of an exenatide patch matching the profile of exenatide injections will follow the 505(b)(2) NDA regulatory pathway, thereby limiting the extent of safety and efficacy trials required for FDA approval, although we cannot assure you that the FDA will agree. Transdermal exenatide is currently in the preclinical phase of development.

Follicle-stimulating hormone (FSH) is a gonadotropin, a glycoprotein polypeptide hormone that is synthesized and secreted by the gonadotropic cells of the anterior pituitary gland. Follicle stimulating hormone (FSH) is indicated for the treatment of infertility in women and is currently only approved and marketed as a subcutaneous injection. FSH is mainly used for ovarian hyperstimulation as part of an in vitro fertilization (IVF) regimen. There are several purified and recombinant FSH injections currently on the market. We are developing a novel transdermal patch to match the pharmacokinetic profile of FSH subcutaneous injection but without the need for painful injections. Transdermal FSH is intended to offer a painless, easy to use one-step application to improve patient compliance with FSH therapy. Transdermal FSH will be offered at multiple strengths to match the typical doses prescribed to treat infertility. We plan to conduct a Phase 1 clinical trial to demonstrate that the transdermal patch can match the pharmacokinetics of subcutaneous injection. Then we plan to conduct an irritation and sensitization study to demonstrate the skin safety of the product and a pivotal clinical efficacy trial to demonstrate that transdermal FSH is not inferior to subcutaneous injection. We intend to seek to utilize the 505(b)(2) NDA regulatory pathway to register the product with the FDA which allows us to reference the known safety of FSH on file at FDA for the reference listed drug and the safety information that has been published in the literature. We have not yet communicated with the FDA on our proposed development plan or registration plan and we cannot assure you that the FDA will agree to our use of the 505(b)(2) pathway. Transdermal FSH is currently in the preclinical phase of development.

In addition, we may seek to develop certain generic transdermal products where we think we can efficiently make an improvement to existing patches and potentially take significant market share with good profit margins. One example of such a product candidate is the development of a generic scopolamine patch.

Transdermal scopolamine (Transderm Scop®) was developed in the 1970s by Alza Corporation for Ciba-Geigy (now Novartis) for prevention of nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. The product was approved as the first modern transdermal therapeutic system by the FDA in 1979. A generic transdermal scopolamine product was approved in 2015 (Perrigo) but was not marketed until 2017. As of November 2018, there was only one generic transdermal scopolamine approved and marketed. We are looking to develop what we believe is an improved proprietary generic scopolamine patch. Product improvements include enhancements to the manufacturing processes to reduce the manufacturing cost and optimization of the adhesive formulation to reduce cold flow and increase patient acceptability. We have performed pre-clinical work on this proposed product, however, we cannot proceed further without significant funding. We plan to follow the FDA guidance on the product development of a generic transdermal scopolamine patch and plan on utilizing the ANDA regulatory pathway to obtain FDA approval for marketing. Transdermal scopolamine is currently in the preclinical phase of development.

We have not yet determined which product we will seek to develop after our abuse deterrent fentanyl transdermal system. The prioritization of our portfolio of product candidates will be reviewed on an ongoing basis and will take into account technical progress, market potential, available funding and commercial interest. Our ability to take any meaningful steps to the development of any of these products is determined by our ability to provide sufficient funding for such purchase. As stated above, without significant financing or a joint venture agreement we will not be able to take any steps to the development of any of these products.

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## **Consumer Products**

Our consumer transdermal product line consists of eleven product lines: an energy patch line, a weight management patch line, a multivitamin patch line, a children's multivitamin patch line, an amino acid patch line, an anti-wrinkle patch line, an insect repellent patch line, a detox patch line, a PMS patch line, a sleep patch line and a nausea and motion sickness patch line. These products require FDA or EPA (for the insect repellent line) approval in order to be sold in the United States. Since we have not received FDA or EPA approval and we have no plans to do so at this time, and we are limiting our marketing to countries in which we believe that these products can be sold without significant product development costs for clinical or nonclinical testing and product registration for government approval. Based on our initial in-house testing, we modified the formulation of our consumer patches to include non-synthetic ingredients to avoid any concerns regarding potential skin irritation.

## **Marketing**

Pursuant to an exclusive distribution dated April 13, 2018, we granted Best Choice exclusive distribution rights for all of our consumer products in South Korea, Taiwan (the Republic of China), the People's Republic of China and South Asia. Best Choice is presently marketing our products only in South Korea. The

agreement provides that it automatically renews for an additional three years and for each five year period thereafter if a minimum increase in sales of 10% per year or a cumulative equivalent or a year by year 10% increase is achieved by the end of the initial term and each extension period thereafter. The agreement, as extended, provides a minimum purchase requirement \$2.0 million for the initial term, which is the prior from the commencement date through April 30, 2020. The minimum purchase requirement increases by 10% each year after the initial term. The agreement provides that our price to Best Choice will be no greater than lowest price sold to anyone plus 5%. Best Choice has the right to purchase a minimum of 50% of our production capacity. We give Best Choice a warranty that we will replace or refund any product which is not in a marketable state, such as damaged packaging and missing product. The agreement may be terminated at any time by Best Choice with or without cause on 90 days' notice. The agreement may be terminated by us for cause, which includes Best Choice's failure to meet the minimum purchase requirements. While the agreement has minimum purchase requirements, it does not assure us that Best Choice will meet the minimum purchase requirements or that Best Choice will not terminate the agreement.

Best Choice has advised us that, subject to obtaining regulatory approval, it plans to market the energy patch line, vitamin patch line and weight management patch line products in South Korea. However, in order for Best Choice to market our products in South Korea, it needs to obtain approval from the MFDS. Although Best Choice has made modest purchases from us for its preliminary marketing activities, until it receives approval to market our product in South Korea, we will not generate significant revenue from our consumer products. Best Choice has advised us that its preliminary marketing activities consisted of purchasing inventory in anticipation of obtaining regulatory approval, meeting with potential distributors and trying to build brand awareness through various marketing approaches most notably on social media. We cannot assure you that we will generate significant revenue from Best Choice's activities in South Korea if it obtains regulatory clearance. At present, Best Choice has not received the necessary regulatory approval to market our consumer products in South Korea. Although Best Choice has advised us that it is working with the MFDS to obtain a classification, if it is unable to obtain a classification and complete the regulatory procedures, it will be unable to sell our products in South Korea.

If we obtain FDA approval for any of our pharmaceutical transdermal products, we will need to establish a distribution network in the United States. We do not anticipate that we will take any steps toward establishing such a distribution network until we are in the late stages of the FDA approval process.

## **Manufacturing**

We have an agreement with Pocono Coated Products LLC to manufacture our consumer transdermal products. Pocono manufactures coated film roll stock using a solvent coating process. These rolls are then sealed and shipped to South Korea for slitting, die-cutting and pouching of individual patches and then packaging in boxes of 30 packs or five packs.

Manufacturing of our pharmaceutical transdermal products will be performed for clinical trials during the development program and for manufacturing of commercial products prior to FDA approval and for sales and marketing. Clinical manufacturing for our early stage clinical trials will most likely be performed at our facilities at 4P Therapeutics. However, the manufacture of clinical products for later stage pivotal clinical trials and for commercial manufacturing may either be done by contract manufacturers or done in our commercial facilities. Manufacture of clinical and commercial product will be performed in compliance with current FDA Good Manufacturing Procedures (cGMP) and all applicable local regulations. All manufacturing processes will be subject to review by the FDA during development, prior to approval and during subsequent routine FDA inspections.

## **Government Regulations**

### ***United States***

The pharmaceutical business is subject to extensive government regulation. In the United States, we must comply with the rules and regulations of the FDA. In other countries we must comply with the laws and regulations of each country to legally market and sell our products. Obtaining FDA approval does not mean that the product will be approved in other countries. Each country may require that additional clinical and nonclinical studies be conducted prior to approval.

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The process required by the FDA to receive approval prior to marketing and distributing a drug in the United States generally involves the following. The definition of drug is broadly defined, and includes our pharmaceutical products and most of our consumer transdermal patches. Even though the drug used in each of our proposed products is currently approved by the FDA in oral or injectable dosage forms, we will still need to conduct a full development program including preclinical and clinical trials before we receive FDA marketing approval. The FDA also has a number of abbreviated approval pathways which, if we are eligible, could shorten the time for approval. However, we cannot be certain that we will be able to use any abbreviated approval pathway, in which event we will need to comply with the full regulatory pathway.

- **Preclinical phase.** Before a drug company can test an experimental treatment in humans, it must prove the drug is safe and effective in animals. Scientists run tests in various animals before presenting the data to the FDA as an investigational new drug application. For already approved drugs, an animal study may not be required prior to testing in humans. In most cases, the company must file an Investigational New Drug (IND) submission to get clearance to test the product in humans.
- **Phase one clinical trial.** In the first round of clinical trials, the drug company attempts to establish the drug's safety in humans. Drug researchers administer the treatment to healthy individuals — instead of patients suffering from the disease or condition the drug is intended to treat — and gradually increase the dose to see if the drug is toxic at higher levels or if any possible side effects occur. These drug trials are usually small, containing about 20 to 80 participants, according to the FDA. For drug delivery products incorporating already approved drugs, Phase 1 studies involve measuring blood levels of the drug to understand the pharmacokinetics for a new route of administration.
- **Phase two clinical trial.** In the second round of clinical trials, researchers give the treatment to patients who have the disease to assess the drug's efficacy. The trial is randomized, meaning half of the study participants receive the drug and half receive a placebo. These trials usually contain hundreds of participants, according to the FDA. There is about a 30 percent chance of a drug moving on to a phase three clinical trial, according to data from the biotech trade organization BIO. For already approved drugs, as is the case with drug delivery products, a Phase 2 trial may not be necessary as the therapeutic drug doses and blood concentrations are already known. However, a Phase 2 may be conducted to inform the design of the Phase 3 clinical trial in regards to the safety and efficacy of the product when used by patients.
- **Phase three clinical trial.** In the third phase of clinical trials, researchers work with the FDA to design a larger trial to test the drug's ideal dosage, patient population and other factors that could decide whether the drug is approved, according to the report. These trials usually contain a few hundred to thousands of participants. In the case of drug delivery products that utilize an approved drug, Phase 3 trials will typically include a comparison to the already approved reference product. For example a transdermal patch may be compared to an injection.
- **New drug application.** Once a drug company collects and analyzes all data from the clinical trials, it submits a new drug application to the FDA. The application includes trial data, preclinical information and details on the drug's manufacturing process. If the FDA accepts the application for review, the agency has ten months — or six months if the drug has priority review status — to make a decision, according to the report. The FDA can hold an advisory committee meeting where independent experts assess the data and recommend whether to approve the drug. From there, the FDA will either approve the drug or give the applicant a complete response letter, which explains why the drug did not get approved and what steps the applicant must take before resubmitting the application for approval.

The FDA may also require Human Abuse Liability or Human Abuse Potential clinical studies to evaluate the abuse liability or abuse potential of a new chemical entity for drugs that affect the central nervous system. If the abuse deterrent technology renders a product less desirable than conventional formulations, it is said to convey abuse deterrent properties and can include specific label language indicating this difference.

In other instances, sponsors are required to evaluate the effectiveness of an Abuse Deterrent Formulation. For Abuse Deterrent Formulation trials, the objective is to assess the ability of the new formulation to be tampered with and abused, and is often pursuant to a 505(b)(2) strategy.

Before approving an NDA, the FDA may inspect the facilities where the product is being manufactured or facilities that are significantly involved in the product development and distribution process and will not approve the product unless compliance with current good manufacturing processes is satisfactory. The FDA may deny approval of an NDA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. In pursuing FDA approval there may be various delays and it is possible that approval may never be granted. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

If a product is approved, the FDA may impose limitations on the indications for use for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies or trials be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or impose other limitations.

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Once a product receives FDA approval, marketing the product for other indicated uses or making certain manufacturing or other changes related to the product will require FDA review and approval of a supplemental NDA or a new NDA, which may require additional clinical safety and efficacy data and may require additional review fees. In addition, further post-marketing testing and surveillance to monitor the safety or efficacy of a product may be required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing.

With respect to the labeling for our abuse deterrent transdermal fentanyl system or any other opioid transdermal patch we develop, it is likely that we will need to disclose the risks of improper use or abuse using language required by the FDA.

#### *FDA Approval Pathways*

The FDA has several pathways that can be followed to obtain FDA approval.

- A stand-alone NDA is an application submitted under Section 505(b)(1) of the Food, Drug and Cosmetic Act (“FD&C Act”) and approved under Section 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness that were conducted by or for the applicant or for which the applicant has a right of reference or use. This is typically the pathway used for new chemical entities.
- A 505(b)(2) application is an NDA submitted under Section 505(b)(1) and approved under Section 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. This is the pathway typically taken for off-patent drugs that are being development into alternate dosage forms or routes of administration.
- An ANDA is an application for a duplicate of a previously approved drug product that was submitted and approved under Section 505(j) of the FD&C Act. An ANDA relies on the FDA’s finding that the previously approved drug product is safe and effective. An ANDA generally must contain information to show that the proposed generic product (1) is the same as the drug with respect to the active ingredients, conditions of use, route of administration, dosage form, strength and labeling (with certain permissible differences) and (2) is bioequivalent to the referenced drug. An ANDA may not be submitted if studies are necessary to establish the safety and effectiveness of the proposed product. This is the pathway taken for generic drugs.

We cannot assure you that we will be able to take advantage of any of the available abbreviated approval pathways for any of our proposed products.

#### *Post-approval requirements*

Any drug products for which we receive FDA approval will be subject to continuing regulation by the FDA. Certain requirements include, among other things, record-keeping requirements, reporting of adverse events with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or patient populations that are not described in the drug’s approved labeling, known as “off-label use,” and other promotional activities, such as those considered to be false or misleading. Failure to comply with FDA regulations can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Such enforcement may also lead to scrutiny and enforcement by other government and regulatory bodies.

Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not encourage, market or promote such off-label uses. As a result, “off-label promotion” has formed the basis for litigation under the Federal False Claims Act, violations of which are subject to significant civil fines and penalties. In addition, manufacturers of prescription products are required to disclose annually to the Center for Medicaid and Medicare any payments made to physicians and teaching hospitals in the U.S. under the federal Physician Payment Sunshine Act. Reportable payments may be direct or indirect, in cash or kind, for any reason, and are required to be disclosed even if the payments are not related to the approved product. Failure to fully disclose or not in time reporting could lead to penalties up to \$1.15 million per year.

The manufacturing of any of our products will be required to comply with the FDA’s current good manufacturing process (cGMP) regulations. These regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register with the FDA their establishments and list any products they make and to comply with related requirements in certain states. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current good manufacturing processes and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer or holder of an approved NDA, as well as lead to potential market disruptions. These restrictions may include recalls, suspension of a product until the FDA is assured that quality standards can be met, and continuing oversight of manufacturing by the FDA under a “consent decree,” which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, or Phase IV testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of our products.

#### *Other Government Regulations*



We are subject to government regulations that are applicable to businesses generally, including those relating to workers' health and safety, environmental and waste disposal, wage and hour and labor practices, including sexual harassment laws and regulations, and anti-discrimination laws and regulations.

In addition, we must comply with the laws and regulations governing the research and manufacture of products containing controlled substances such as fentanyl and other opioids. We must be licensed by the Drug Enforcement Agency (DEA) and the state(s) in which we conduct research and development activities. We currently hold a DEA license and a Georgia State Board of Pharmacy license to support our current research activities at our facility in Georgia. As a result we have been inspected by the DEA and the Georgia Board of Pharmacy. As we enter the manufacturing phase of development we will need to obtain a DEA manufacturing license and a Georgia Board of Pharmacy manufacturing license and obtain production quota from the DEA to allocate sufficient amounts of controlled substances to us to conduct our development program. There is no guarantee that we will be able to obtain sufficient production quota from the DEA to support our manufacturing operations.

### ***South Korea***

We do not sell products in South Korea. We sell our products to Best Choice and, subject to our extending our agreement with Best Choice, Best Choice will sell the products in South Korea upon receipt of regulatory approval. Food and drug products are regulated in South Korea by the MFDS. In order to market the products in Korea, Best Choice needs to obtain a permit or complete the filing of a report with the MFDS. It is difficult to determine the classification of the products, and Best Choice has advised us that it is working with the MFDS to determine a classification for our products. It would be necessary to determine whether our products would be treated as health functional foods, quasi-drugs, over-the-counter drugs or prescription drug. Each category has a specific approval process, with health functional foods requiring the least amount of data and prescription drugs requiring the most data. Health functional foods refer to "foods" manufactured with functional raw materials or ingredients beneficial to the human body and "functionality" means controlling nutrients for the structure or functions of the human body or providing beneficial effects to health purposes, such as physiological effects. "Quasi-drugs" refer to any of the following: fibers, rubber products or similar products used for the purpose of treating, alleviating, or preventing human or animal diseases; non-appliance, non-machinery or similar articles that have insignificant influences on or do not directly act upon human bodies; and preparations used for sterilization, insecticide, and uses similar thereto for the purpose of preventing infectious diseases. An over-the-counter drug is a drug, the misuse or abuse of which is of little concern, and the safety and efficacy of which may be expected even when used without a prescription by a physician or a dentist; or a drug that may be used to cure a disease without a physician's or dentist's professional knowledge; or a drug that has a relatively small side effect on human bodies in light of the dosage form and pharmacological action. A prescription drug means a drug that is not an OTC drug.

Regardless of efficacy in pharmacological actions, based on the overall judgment of the ingredients, shape (container, packaging, design, etc.), name, indicated purpose of use, efficacy, effects, administration methods, dosage, advertising or explanation for sale, in case it is perceived to be used for as a health functional food, quasi-drug or prescription drugs, the aforementioned purpose or demonstrated to have medicinal effects in the perspective of the general public, they all are drugs that are subject to the Pharmaceutical Affairs Act. Therefore, in case the products are sold without obtaining the required approval, it will be deemed an act of selling drugs without obtaining an approval, which is a criminal offense by the person selling without authorization in South Korea.

### ***Europe and Other Countries***

If we market our products in any countries other than the United States, we would be subject to the laws of those countries. In order to obtain market our products in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products.

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The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 31 countries in the European Economic Area, the European Commission and the European Medicines Agency. All medicines must be authorized before they can be placed on the market in the European Union. The European system offers different routes for authorization. A centralized procedure allows the marketing of a medicine on the basis of a single European Union assessment and marketing authorization which is valid throughout the European Union. However, a majority of medicines authorized in the European Union do not fall within the scope of the centralized procedure, and we do not know whether our proposed products will fall within the centralized authorization. We also do not know how the withdrawal of Great Britain from the European Union will affect the procedure for approval of medicines in the United Kingdom. If we are not able to use the centralized procedure, we would need to use one of the following procedures. One method is the decentralized procedure where we would apply for the simultaneous authorization in more than one European Union member. The second method is the mutual-recognition procedure where we would have a medicine authorized in one European Union country apply for authorization to be recognized in other European Union countries. In either case, we would be required to complete clinical trials to demonstrate the safety and efficacy of the medicine and show that the medicine is manufactured in accordance with good manufacturing practice based upon European Union standards.

In countries other than the United States and the European Union, we would be required to comply with the applicable laws of those countries, which may require us to perform additional clinical testing.

Failure to obtain regulatory approval in any country would prevent our product candidates from being marketed in those countries. In order to market and sell our products in jurisdictions other than the United States and the European Union, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The regulatory approval process outside the United States and the European Union generally includes all of the risks associated with obtaining FDA and European Union approval, but can involve additional testing.

In addition, in many countries worldwide, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Even if we were to receive approval in the United States or the European Union, approval by the FDA or the European Medicines Agency does not ensure approval by regulatory authorities in other countries or jurisdictions. Similarly, approval by one regulatory authority outside the United States would not ensure approval by regulatory authorities in other countries or jurisdictions. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in other foreign jurisdictions, the commercial prospects of those product candidates may be significantly diminished and our business prospects could decline.

Outside the United States, particularly in member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations or the successful completion of health technology assessment procedures with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Certain countries allow companies to fix their own prices for medicines, but monitor the pricing.

In addition to regulations in the United States, if we market outside of the United States, we will be subject to a variety of regulations governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries.

### **Intellectual Property Rights**

4P Therapeutics filed an international patent application under the Patent Cooperation Treaty for worldwide prosecution of the abuse deterrent transdermal technology patent used in our lead product, an abuse deterrent fentanyl transdermal system. The patent is being prosecuted in the United States and in other countries. The European Patent Office and the patent offices for Japan, Australia and Russia had granted patent protection for the patent application filed by 4P

Therapeutics for its abuse deterrent transdermal technology and the patent office of Mexico has granted a notice of allowance. We have received any response from the United States Patent and Trademark Office. In addition to applying the technology to developing an abuse deterrent fentanyl transdermal system, we believe that the abuse deterrent patch technology can be applied to other opioids and pain medication patches where there is risk of abuse and overdose, as well as other transdermal pharmaceuticals where we believe our technology can help prevent abuse or accidental misuse.

We have received a trademark for the name Nutriband.

## **Competition**

Since our proposed pharmaceutical products deliver a drug which is off patent and presently available, we will compete with a number of companies who are presently selling the drug which is generally taken by injection. In addition, there are a number of companies that market generic transdermal patches, including fentanyl transdermal patches, and we will compete against those companies that make products with the same drug. Further, as transdermal patches become more popular, other companies, many of which have significantly greater resources and existing relationships with physicians and medical personnel, may use their resources to develop improved transdermal delivery systems for the drugs that are in our pipeline. We believe that competition is based on such factors as price, insurance/Medicaid and Medicare reimbursement rates and policies, safety and efficacy, side effects or reduction in side effects and the reliability of the supplier or manufacturer. Since we are developing our products to meet the needs of the patients, physicians, and the payers, we need to demonstrate advantages in terms of safety, efficacy, compliance and cost. If we obtain regulatory approval to market our products, we cannot assure you that we will be successful in the marketplace.

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## **ITEM 1A. RISK FACTORS**

*An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information included in this annual report before making an investment decision with regard to our securities. The statements contained in this annual report include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those set forth in or implied by forward-looking statements. The risks set forth below are not the only risks facing us. Additional risks and uncertainties may exist that could also adversely affect our business, prospects or operations. If any of the following risks actually occurs, our business, financial condition or results of operations could be harmed. In that case, the trading price of our common stock could decline, and you may lose all or a significant part of your investment.*

### **Risks Concerning our Business**

***Because of a lack of funds, we have suspended our product development operations.***

Our business is the development of transdermal systems for the delivery of pharmaceuticals. The development of pharmaceutical products is highly cash intensive, and many early stage drug development companies are unable to raise sufficient cash to complete the development and testing of their products and obtain regulatory approval, with the result that they either obtain funding on very unfavorable terms, cease to conduct business or sell or license their intellectual property on unfavorable terms. At January 31, 2020, we had a working capital deficiency of approximately \$1.9 million, and cash of approximately \$10,000. Because of our lack of cash and the absence of any significant financing, we have suspended our development activities relating to our transdermal pharmaceutical products. Because of the anticipated lack of revenues until we have an approved product that we can market and the time required to obtain FDA approval, which can take many years, we must rely on our ability to raise money in the private or public equity market or enter into a joint venture relationship with a company that has the funds, the willingness and the ability to fund or obtain funds for the project that is the subject of the joint venture. In March 2020, we withdrew a registration statement relating to a proposed public offering. If we are able to raise funds or enter into a joint venture, it is likely that the term will not be favourable to us. We cannot assure you that we will be able to raise funds in a public or private financing or a joint venture, and, if we are unable to do so, we may cease operations..

***Because we are an early-stage company with minimal revenue and a history of losses and we expect to continue to incur substantial losses for the foreseeable future, we cannot assure you that we can or will be able to operate profitably.***

We did not generate any revenue prior to the quarter ended October 31, 2018, we have incurred losses since our organization, 4P Therapeutics generated only modest revenue from contract research and development services which are not related to our pharmaceutical transdermal patch business. Although we anticipate that, for the near term, we will continue to perform research and development services for third parties, we do not expect to generate significant revenue from performing contract research and development services for our clients and we have generated losses from operations from this business. During the year ended January 31, 2020, we experienced a significant decline in revenue from 4P Therapeutics' largest customer. We generated a negative gross margin and negative cash flow from operations for the years ended January 31, 2020 and 2019. We are subject to the risks common to start-up, pre-revenue enterprises, including, among other factors, undercapitalization, cash shortages, limitations with respect to personnel, financial and other resources and lack of revenues. Drug development companies typically incur substantial losses during the product development and FDA testing phase of the business and do not generate revenues until after the drug has received FDA approval, which cannot be assured, and until the company has started to sell the product. We can give no assurance that we can or will ever be successful in achieving profitability and the likelihood of our success must be considered in light of our early stage of operations. We cannot assure you that we will be able to operate profitably or generate positive cash flow. If we cannot achieve profitability, we may be forced to cease operations and you may suffer a total loss of your investment.

***Our auditors' report includes a going concern paragraph.***

Our financial statements include a going-concern qualification from our auditors, which expresses doubt about our ability to continue as a going concern. We have operated at a loss since inception. Our ability to operate profitable is dependent upon, among other things, obtaining substantial financing, developing our products, completing FDA clinical testing, obtaining FDA approval and implementing a marketing program for our products. These factors, among others, raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments that take into consideration the uncertainty of our ability to continue operations.

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***Our business will be likely be adversely affected by the COVID-19 pandemic.***

The COVID-19 pandemic and the response to the pandemic will affect our business in a number of ways, including, but are not limited to, the following:

- Our ability to raise financing for our operations and to enter into a joint venture agreement may be affected by both the willingness and ability of potential financing sources and potential joint venture partners to invest in an undercapitalized business, particularly at a time when the potential financing source or joint venture partner may need to devote its resources to existing portfolio companies or joint ventures which may be in need of financing.
- The decision by investors who would invest in early stage pharmaceutical companies to limit their financing efforts to companies that are dealing with products or services related to COVID-19 diagnosis or treatment.
- The effect of recent stock market decline on the willingness of investors to make an investment in our securities.

- The financial health of our potential contract service customers.
- Our ability to perform contract services.
- Our ability to obtain any goods or services which we may need to perform contract services.
- The ability of our foreign distributors to obtain regulatory approval, which may be affected by the regulatory agencies giving a low priority to products such as our consumer patches.
- The financial health of Best Choice.
- If regulatory approval is obtained in South Korea, the extent to which consumers in South Korea purchase our products.
- The extent to which the purchase of our consumer products is a low priority item for a population whose disposable income may have decreased as a result of COVID-19 and the steps taken by the South Korean government to curb the spread of infection.

***Because we do not have a product we can market in the United States, we cannot predict when or whether we will operate profitably.***

We have not completed the development of our lead product, which is our abuse deterrent fentanyl transdermal system, and we do not have any product that we can market in the United States. Because of the numerous risks and uncertainties associated with product development, we cannot assure you that we will be able to develop and market any products or achieve or attain profitability. If we are able to obtain financing for our operations, we expect that we will incur substantial expenses as we continue with our product development and clinical trials. Further, if we are required by applicable regulatory authorities, including the FDA as well as the comparable regulatory agencies in other countries in which we may seek to market product, to perform studies in addition to those we currently anticipate, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. As a result, we expect to continue to incur substantial losses and negative cash flow for the foreseeable future.

A number of factors, including, but not limited to the following, may affect our ability to develop our business and operate profitably:

- our ability to obtain necessary funding to develop our proposed products;
- the success of clinical trials for our products;
- our ability to obtain FDA approval for us to market any proposed product in our pipeline in the United States;
- any delays in regulatory review and approval of product in development;
- if we obtain FDA approval to market our product, our ability to establish manufacturing and distribution operations or entering into manufacturing and distribution agreements with qualified third parties;
- market acceptance of our products;
- our ability to establish an effective sales and marketing infrastructure;
- our ability to protect our intellectual property;
- competition from existing products or new products that may emerge;

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- the ability to commercialize our products;
- potential product liability claims and adverse events;
- our ability to adequately support future growth; and
- our ability to attract and retain key personnel to manage our business effectively.

***Our failure to develop our abuse deterrent fentanyl transdermal system will impair our ability to continue in business.***

Our lead product is our abuse deterrent fentanyl transdermal system, and we are devoting our resources primarily to developing this product, and, if we complete the development of this product, we will conduct the clinical trials necessary to enable us to obtain FDA approval and to market the product. If we are not able to obtain necessary financing to develop, obtain FDA marketing approval and market this product successfully, we may not have the resources to develop additional products, and we may not be able to continue in business.

***Before we can market in the United States any product which is classified by the FDA as a drug, we must obtain FDA marketing approval.***

Our proposed transdermal products are drug-device combinations that are considered by the FDA to be drugs, which require approval by the FDA. In order to obtain FDA approval, it is necessary to conduct a series of preclinical and clinical tests to confirm that the product is safe and effective. Even though the medication that is being delivered through our transdermal patch may have already received FDA approval, because we are delivering the medication through the skin, we will need to complete, to the FDA's satisfaction, all of the required clinical testing steps to demonstrate safety and efficacy. At any point, the FDA could ask us to perform additional tests or to refine and redo a test that we had previously completed. The process of obtaining FDA approval could take many years, with no assurance that the FDA will approve the product. The FDA also will need to approve the manufacturing process and the manufacturing facility.

***We may need to rely on a third party contract research organization to conduct our preclinical and clinical trials.***

Although we believe that we, through 4P Therapeutics, have the capabilities to conduct preclinical studies and early stage clinical studies in house, we may need to rely on third party contract research organizations to conduct our pivotal preclinical and clinical trials. Our failure or the failure of the contract research organization to conduct the trials in compliance with FDA regulations could possibly derail our obtaining FDA approval, and could require us to redo any preclinical or clinical trials which we or the organization administered.

***We may encounter delays in completing clinical trials, which would increase our costs and delay market entry.***

We may experience delays in completing the clinical trials necessary for FDA approval. These delays may result from a number of factors which could prevent us from starting the trial on time or completing the study in a timely manner, which may include factors out of our control. Since we may need to rely on third parties for supplying us with the drug and transdermal patches used in the trials, there may be various reasons for us to experience a delay in obtaining the clinical materials required to start each clinical trial, which may include factors out of our control. Clinical trials can be delayed or terminated for a number of reasons, including delay

or failure to:

- obtain necessary financing;
- obtain regulatory approval to commence a trial;
- reach agreement on acceptable terms with prospective contract research organizations, investigators and clinical trial sites, the terms of which may be subject to extensive negotiation and vary significantly among different research organizations and trial sites;
- obtain institutional review board approval at each site;
- enlist suitable patients to participate in a trial;
- have patients complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of the product candidate for use in clinical trials.

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Patient enrolment is also a significant factor in the timely completion of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including any new drugs or treatments that may be approved for the indications we are investigating.

We may also encounter delays if a clinical trial is suspended or terminated by us, by the independent review boards of the institutions in which such trials are being conducted, by the trial's data safety monitoring board, or by the FDA. Such authorities may suspend or terminate one or more of our clinical trials due to a number of factors, including our failure to conduct the clinical trial in accordance with relevant regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in carrying out or completing preclinical or clinical trials for any product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***Our ability to finance our operations and generate revenues depends on the clinical and commercial success of our abuse deterrent fentanyl transdermal system and our other product candidates and failure to achieve such success will negatively impact our business.***

Our prospects, including our ability to finance our operations and generate revenues, depend on the successful development, regulatory approval and commercialization of our abuse deterrent fentanyl transdermal system, which itself requires substantial financing, as well as our other product candidates. The clinical and commercial success of our product candidates depends on a number of factors, many of which are beyond our control, including:

- the FDA's acceptance of our parameters for regulatory approval relating to our product candidates, including our proposed indications, primary endpoint assessments, primary endpoint measurements and regulatory pathways;
- the FDA's acceptance of the number, design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from preclinical studies or clinical trials;
- the FDA's acceptance of the sufficiency of the data we collect from our preclinical studies and pivotal clinical trials to support the submission of a New Drug Application, known as an NDA, without requiring additional preclinical or clinical trials;
- the FDA's acceptance of our abuse deterrent labelling relating to our products, including our abuse deterrent fentanyl transdermal system;
- when we submit our NDA upon completion of our clinical trials, the FDA's willingness to schedule an advisory committee meeting, if applicable, in a timely manner to evaluate and decide on the approval of our NDA;
- the recommendation of the FDA's advisory committee, if applicable, to approve our application without limiting the approved labelling, specifications, distribution or use of the products, or imposing other restrictions;
- our ability to satisfy any issues raised by the FDA in response to our test data;
- the FDA's satisfaction with the safety and efficacy of our product candidates;
- the prevalence and severity of adverse events associated with our product candidates;
- the timely and satisfactory performance by third party contractors of their obligations in relation to our clinical trials;
- if we receive FDA approval, our success in educating physicians and patients about the benefits, administration and use of our product candidates;
- our ability to raise additional capital on acceptable terms in order to achieve conduct the necessary clinical trials;
- the availability, perceived advantages and relative cost of alternative and competing treatments;
- the effectiveness of our marketing, sales and distribution strategy and operations;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices;

- our ability to obtain, protect and enforce our intellectual property rights;
- our ability to bring an action timely for patent infringement arising out of the filing of ANDAs by generic companies seeking approval to market generic versions of our products, if applicable, before the expiry of our patents; and
- our ability to avoid third party claims of patent infringement or intellectual property violations.

If we fail to achieve these objectives or to overcome the challenges presented above, many of which are beyond our control, in a timely manner, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, even if we obtain FDA approval to market our products, we may not be able to generate sufficient revenues through the sale of our products to enable us to continue our business.

***Since we do not have commercial manufacturing capability, if we are unable to establish manufacturing facilities, we may have to enter into a manufacturing agreement with a manufacturer that has been approved by the FDA.***

Any commercial manufacturer of our products and the manufacturing facilities where we make our commercial products will be subject to FDA approval. Part of the process of seeking FDA approval to market our products is the FDA's approval of the manufacturing process and facility. Although we plan to establish our own manufacturing facilities, the establishment of a manufacturing facility is very costly, and, unless we obtain funding for that purpose, it would be necessary for us to engage a third party who has experience in manufacturing transdermal patches for FDA approved products. By relying on a third party manufacturer, we will be dependent upon the manufacturer, whose interests may be different from ours. Any third party contract manufacturer will be responsible for quality control and for meeting our requirements. If the manufacturer does not meet our quality standards and delivers products that do not meet our specifications, we may both incur liability for breach of our warranty to our customer, as well as liability for any damage, including death, that may result from the use, abuse or accidental misuse of the product. Regardless of whether we are able to make a claim against the manufacturer, our reputation may be impaired and we may lose business as a result. Further, the contract manufacturer may have other customers and may allocate its resources based on the contract manufacturer's interest rather than our interest. Furthermore, we may not be able to assure ourselves that we will get favorable pricing. We have previously had problems with our manufacturer of our consumer over-the-counter transdermal patches, and we cannot assure you that we will not have the same, similar or other problems with the manufacturer of our FDA approved products.

***If we or any third-party manufacturer fails to comply with FDA current good manufacturing practices, we may not be able to sell our products until and unless the manufacture becomes compliant.***

All FDA approved drugs, including our proposed transdermal products, must be manufactured in accordance with good manufacturing practices. All manufacturing facilities are inspected by the FDA as a matter of routine inspection or for a specific cause. If a manufacturer fails to comply with all applicable regulations, the FDA can prohibit us from distributing products manufactured in those facilities, whether they are a contract manufacturer or own facility. A failure to be in compliance with good manufacturing practices could result in the FDA closing the facilities or limiting our use of the facilities.

***If the FDA implements Risk Evaluation and Mitigation Strategies policies for any of our proposed products, we will need to comply with such policies before we can obtain FDA approval or the product.***

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. The FDA has issued a Risk Evaluation Mitigation Strategy for a fentanyl iontophoretic transdermal system. Before we can receive FDA approval for any product for which the FDA has issued a Risk Evaluation Mitigation Strategy, we must satisfy the FDA that we have complied with the Risk Evaluation Mitigation Strategy. If one of our products becomes subject to a Risk Evaluation and Mitigation Strategy policy after receiving FDA approval, it will need to comply with such policy.

***Our products will continue to be subject to FDA review after FDA approval is given.***

Discovery of previously unknown problems with our products or unanticipated problems with the manufacturing processes and facilities, even after FDA and other regulatory approvals of the product for commercial sale, may result in the imposition of significant restrictions, including withdrawal of the product from the market.

The FDA and other regulatory agencies continue to review products even after the products receive agency approval. If and when the FDA approves one of our products, its manufacture and marketing will be subject to ongoing regulation, which could include compliance with current good manufacturing practices, adverse event reporting requirements and general prohibitions against promoting products for unapproved or "off-label" uses. We are also subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Any enforcement action resulting from the failure, even by inadvertence, to comply with these requirements could affect the manufacture and marketing of our products. In addition, the FDA or other regulatory agencies could withdraw a previously approved product from the market upon receipt of newly discovered information. The FDA or another regulatory agency could also require us to conduct additional, and potentially expensive, studies in areas outside our approved indicated uses.

***We must continually monitor the safety of our products once approved and marketed for potential adverse events which could jeopardize our ability to continue marketing the products.***

As with all medical products, the use of our products could sometimes produce undesirable side effects or adverse reactions or events (referred to cumulatively as adverse events). Our consumer products initially caused skin irritation because of certain of the ingredients in the patch, which we corrected by reformulating the patches. For the most part, we expect these adverse events to be known and occur at some predicted frequency based on our experience in the clinical development program. When adverse events are reported to us, we are required to investigate each event and the circumstances surrounding it to determine whether it was caused by our product and whether a previously unrecognized safety issue exists. We will also be required to periodically report summaries of these events to the applicable regulatory authorities. If the adverse effects are significant, we may be required to recall our product. We cannot assure you that our medical products will not cause skin irritation or other adverse events. Our ability to market our products may be impaired by unanticipated adverse events and any recall of our product. Because we are an early-stage company, our reputation, and our ability to market products, could be affected more severely than a major pharmaceutical company.

In addition, the use of our products could be associated with serious and unexpected adverse events, or with less serious reactions at a greater than expected frequency. Such issues may arise when our products are used in critically ill or otherwise compromised patient populations. When unexpected events are reported to us, we are required to make a thorough investigation to determine causality and the implications for product safety. These events must also be specifically reported to the applicable regulatory authorities. If our evaluation concludes, or regulatory authorities perceive, that there is an unreasonable risk associated with the product, we would be obligated to withdraw the impacted lot(s) of that product or recall the product and discontinue marketing until all problems are satisfactorily resolved. Furthermore, an unexpected adverse event of a new product could be recognized only after extensive use of the product, which could expose us to product liability risks, enforcement action by regulatory authorities and damage to our reputation and public image.

A serious adverse finding concerning the risk of any of our products by any regulatory authority could adversely affect our reputation, business and financial results.

***If we obtain FDA approval to market our products, we expect to spend considerable time and money complying with federal and state laws and regulations governing their sale, and, if we are unable to fully comply with such laws and regulations, we could face substantial penalties.***

Health care providers, physicians and others will play a primary role in the recommendation and prescription of our proposed products. Further, if we use third-party sales and marketing providers, they may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products. Applicable federal and state health care laws and regulations are expected to include, but not be limited to, the following:

- The federal anti-kickback statute is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid;
- The federal False Claims Act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false claim for payment of government funds. Penalties include three times the government's damages plus civil penalties of \$5,500 to \$11,000 per false claim. In addition, the False Claims Act permits a person with knowledge of fraud, referred to as a qui tam plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud, and, if the action is successful, the qui tam plaintiff is rewarded with a percentage of the recovery;
- Health Insurance Portability and Accountability Act, known as HIPAA, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- The Social Security Act contains numerous provisions allowing the imposition of a civil money penalty, a monetary assessment, exclusion from the Medicare and Medicaid programs, or some combination of these penalties; and
- Many states have analogous state laws and regulations, such as state anti-kickback and false claims laws. In some cases, these state laws impose more strict requirements than the federal laws. Some state laws also require pharmaceutical companies to comply with certain price reporting and other compliance requirements.

Our failure to comply with any of these federal and state health care laws and regulations, or health care laws in foreign jurisdictions, could have a material adverse effect on our business, financial condition, result of operations and cash flows.

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***Best Choice may not obtain approval to market our consumer products in South Korea.***

Although Best Choice has made modest purchases of our consumer products in South Korea in connection with its preliminary marketing activities, Best Choice requires regulatory approval by the MFDS before it can market our consumer products in South Korea. Although Best Choice has advised us it is working with the MFDS to determine a classification for our products, which is necessary before it can obtain authorization to market the products in South Korea, we cannot assure you that it will obtain the necessary authorization. The sale of products that require authorization without the required authorization is a criminal offense. We cannot assure you that Best Choice will be able to obtain the necessary approval, and if it unable to obtain the necessary approval, it will not be able sell our consumer products in South Korea.

***We may not be able to continue our relationship with Best Choice, which is the only distributor for our consumer products.***

Our agreement with Best Choice has an initial term which, as a result of an extension dated May 26, 2019, will expire on April 30, 2020. The agreement provides for an automatic renewal for three years and for five-year periods thereafter if certain minimum purchases are made. Best Choice did not meet the initial conditions for the continuation of the agreement and we extended the period during which Best Choice must meet the initial purchase requirement from April 30, 2019 to April 30, 2020. As of the date of this annual report, Best Choice has not met the initial purchase requirements. We cannot assure you that Best Choice will meet the minimum purchase requirements for the extended initial term and that the agreement will not terminate if Best Choice fail to make such purchases. However, we cannot assure you that, if the agreement with Best Choice terminates, we will be able to enter into an agreement with another distributor who would be willing and able to obtain necessary regulatory approval and sell our product in the international market. Our failure to have any international distributor will materially impair our ability to generate revenue from our consumer products in the South Korean or any other international market.

***Before we can market our product outside of the United States, we will need to obtain regulatory approval in each country in which we propose to sell our products.***

In order to market and sell our products in jurisdictions other than the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA and can involve additional testing.

In addition, in many countries worldwide, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Even if we were to receive approval in the United States, approval by the FDA does not ensure approval by regulatory authorities in other countries. Similarly, approval by one regulatory authority outside the United States would not ensure approval by regulatory authorities in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in foreign jurisdictions, the commercial prospects of those product candidates may be significantly diminished and our business prospects could be impaired.

Outside the United States, particularly in member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations or the successful completion of health technology assessment procedures with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Certain countries allow companies to fix their own prices for medicines but monitor the pricing.

In addition to regulations in the United States, if we market outside of the United States, we will be subject to a variety of regulations governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries.

***If we do not have sufficient product liability insurance, we may be subject to claims that are in excess of our net worth.***

Before we market any pharmaceutical product, we will need to purchase significant product liability insurance. However, in the event of major claims from the use of our products, it is possible that our product liability insurance will not be sufficient to cover claims against us. We cannot assure you that we will not face liability arising out of the use of our products which is significantly in excess of the limits of our product liability insurance. In such event, if we do not have the funds or access to the funds necessary to satisfy such liability, we may be unable to continue in business.

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***Because some of the patches we are developing, such as our abuse deterrent fentanyl patch, have potential severe side effects, we may face liability in the event patients suffer serious, possibly life-threatening, side effects from our products.***

Fentanyl patches have known side effects and may cause serious or life-threatening breathing problems due to opioid-induced respiratory depression. In addition, taking certain medications with fentanyl may increase the risk of serious or life-threatening breathing problems, sedation or coma. Because of the seriousness of the side effects, fentanyl patches should only be used in accordance with labeling approved by the FDA or by the applicable regulatory authorities outside of the United States. Fentanyl patches are only indicated for the treatment of people who are tolerant to opioid medications because they have taken this type of medication for at least one week and should not be used to treat mild or moderate pain, short-term pain, pain after an operation or medical or dental procedure, or pain that can be controlled by medication that is taken on an as-needed basis. Although we will include all warnings on the packaging that are required by the FDA or foreign regulatory authorities, claims may be made against us in the event that death or serious side effects result from the use of our abuse deterrent fentanyl transdermal system, even if prescribed for a patient for whom fentanyl patches should not be prescribed. We cannot assure you that we will not face significant liability as a result of such side effects and we may not have sufficient product liability insurance to cover any damages that may be assessed against us.

***Because of our lack of funds, we may have to enter into a joint venture or strategic relationship or licensing agreement with a third party to develop and seek to obtain FDA approval of our potential products.***

Our present efforts are directed to developing and seeking FDA approval for our pipeline of transdermal pharmaceutical products including our lead product, the abuse deterrent fentanyl transdermal system. The development of pharmaceutical products including a new delivery system for an already approved drug, is very expensive with no assurance of obtaining FDA approval. Because of the costs involved, we may need to enter into a joint venture or strategic alliance or licensing or similar agreement with a third party to bring our products to market, in which event we would have to give up a significant percentage of the equity in or rights to the product and require the other party to provide the necessary financing and personnel and to take a significant role in making the decisions relating to the development, testing, marketing and manufacturing of the product. The third party may have interests which are different from, and possibly in conflict with, our own. If we are unable to attract competent parties to distribute and market any product which we may develop, or if such parties' efforts are inadequate, we will not be able to implement our business strategy and may have to cease operations. We cannot assure you that we will be successful in entering into joint ventures or other strategic relationships or that any relationship into which we may enter will develop a marketable product or that we will generate any revenue or net income from such a venture.

***We may decide not to continue developing or commercializing any products at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.***

We may decide to discontinue the development of our abuse deterrent fentanyl transdermal system or any other product in our pipeline or not to continue to commercialize any potential product for a variety of reasons, such as the appearance of new technologies that make our product less commercially viable, an increase in competition, changes in or failure to comply with applicable regulatory requirements, the discovery of unforeseen side effects during clinical development or after the approved product has been marketed or the occurrence of adverse events at a rate or severity level that is greater than experienced in prior clinical trials. If we discontinue a program in which we have invested significant resources, we will not receive any return on our investment.

***If any of our potential products are approved for marketing but fail to achieve the broad degree of physician or market acceptance necessary for commercial success, our operating results and financial condition will be adversely affected.***

If any of the products in our pipeline receives FDA approval for us to market the product in the United States, it will be necessary for us to generate acceptance of our product for the indications covered by the FDA approval. In order to generate acceptance in the marketplace, we will need to demonstrate to physicians that our product provides a distinct advantage or better outcome at a price that reflects the value of our product as compared with existing products. We will need to develop and implement a marketing program directed at both physicians and the general public. Since we do not presently have the resources necessary to develop or implement an in-house marketing program and we may not have the funds to do so if and when we obtain FDA approval to market our product, we will need to establish a distribution network through license and distribution agreements with third parties who have the capability to market our product to physicians and emergency service organizations, and we will be dependent upon the ability of these third parties to market our products effectively. We cannot assure you that we will be able to negotiate license and distribution agreements with terms that are acceptable to us. Since we do not have an established track record and our product pipeline is relatively small, we may be at a disadvantage in negotiating the terms of license and distribution agreements. Further, we may have little control over the development and implementation of our licensee's marketing program, and our licensees may have interests that are inconsistent with ours with respect to the allocation of resources and implementation of the marketing program. We cannot assure you that a marketing program for any of our products can or will be implemented effectively or that we will be successful in developing physician and emergency service acceptance of our products.

***If we seek to market any products in our pipeline in countries other than the United States, we will need to comply with the regulations of each country in which we seek to market our products.***

None of our pharmaceutical products are currently approved for sale by any government authority in any jurisdiction. If we fail to comply with regulatory requirements in any market we decide to enter, or to obtain and maintain required approvals, or if regulatory approvals in the relevant markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed. Marketing approval in one jurisdiction, including the United States, does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory process in others. Failure to obtain a marketing approval in countries in which we seek to market our products or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for any of our products.

***The drug delivery industry is subject to rapid technological change and, our failure to keep up with technological developments may impair our ability to market our products.***

Our products use technology which we developed for the transdermal delivery of drugs. The field of drug delivery is subject to rapid technological changes. Our future success will depend upon our ability to keep abreast of the latest developments in the industry and to keep pace with advances in technology and changing customer requirements. If we cannot keep pace with such changes and advances, our proposed products could be rendered obsolete, which would result in our having to cease its operations.

***If we obtain FDA approval, we will face significant competition from better known and better capitalized companies.***

If we obtain FDA approval for any of our products, we expect to face significant competition from existing companies, which are better known and already have developed relationships with physicians within the healthcare system. Any product we may develop will compete with existing medications performing the same medicinal functions, which may include transdermal patches. We cannot assure you that we will be able to compete successfully. In addition, even if we are able to commercialize our product candidates, we may not be able to price them competitively with current standard of care products or their price may drop considerably due to factors outside our control. If this happens or the price of materials and manufacture increases dramatically, our ability to continue to operate our business would be materially harmed and we may be unable to commercialize any products successfully. In addition, other pharmaceutical companies may be engaged in developing, patenting, manufacturing and marketing products that compete with those that we are developing. These potential competitors may include large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and

marketing resources, greater brand recognition and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities.

***Healthcare reforms by governmental authorities, court decisions affecting health care policies and related reductions in pharmaceutical pricing, reimbursement and coverage by third-party payors may adversely affect our business.***

We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a result of healthcare reform, which could adversely affect third-party coverage of our proposed products and how much or under what circumstances healthcare providers will prescribe or administer our products, if approved.

In both the U.S. and other countries, sales of our products, if approved for marketing, will depend in part upon the availability of reimbursement from third-party payors, which include governmental authorities, managed care organizations and other private health insurers. Third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the United States healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. Any reduction in reimbursement that results from federal legislation or regulation may also result in a similar reduction in payments from private payors, since private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates.

Significant developments that may adversely affect pricing in the United States include the enactment of federal healthcare reform laws and regulations, including the Affordable Care Act, or ACA, which is popularly known as Obamacare, and the Medicare Prescription Drug Improvement and Modernization Act of 2003. A recent district court decision which struck down Obamacare, if upheld, could have a material adverse effect upon reimbursement and payment for products such as our proposed products. Changes to the healthcare system enacted as part of any healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third-party payors. Regulatory changes which have the effect of decreasing the use of opioids has resulted in a decrease in the size of the market for opioid products, including fentanyl, could impact the market for our abuse deterrent fentanyl transdermal system or any other opioid-based transdermal product we may develop.

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In 2017, a new administration, which had promised to repeal and replace the ACA, took office in the United States. Although we cannot predict the form any such replacement of the ACA may take or the full effect on our business of the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers prescribe or administer our products. This could materially and adversely affect our business by reducing our ability to generate revenues, raise capital, obtain licensees and market our products. In addition, we believe the increasing emphasis on managed care in the United States, has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

It will be difficult for us to profitably sell any of our products if reimbursement for these products is limited by government authorities and third-party payor policies.

***It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.***

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our technology which is incorporated in our products as well as successfully defending these patents against third-party challenges, should any be brought. 4P Therapeutics originally filed an international patent application under the Patent Cooperation Treaty for worldwide prosecution of the abuse deterrent transdermal technology patent used in our lead product, the abuse deterrent fentanyl transdermal system. The patent is being prosecuted in the United States and in other countries. Although the European Patent Office and the Japan patent office have approved our patent application, we have not yet received any response from the United States Patent and Trademark Office. Our ability to stop third parties from making, using, selling, offering to sell or importing products utilizing our proprietary or patented technology is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot assure you that a patent will be granted in the United States or in any country in which the patent is being prosecuted. The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States varies from country to country and is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in any patents we may be granted. Further, if any patents are granted and are subsequently deemed invalid and unenforceable, it could impact our ability to license our technology and, as noted previously, fend off competitive challenges. Patent litigation is very expensive and we may not have sufficient funds to defend our proprietary technology from infringement, either as a plaintiff in an action seeking to stop infringers from using our technology, or as a defendant in an action against us alleging infringement by us.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compositions or formulations that are similar to our products but that are not covered by the claims of our patents;
- other persons may have filed patents covering inventions, technology or processes that we use, with the result that we may infringe upon the prior patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- our pending patent applications may not result in the grant of patents;
- any patents which may be issued may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- our inability to fund any litigation to defend our proprietary rights, either in defense of an action against us or a plaintiff to seek to prevent infringement.
- our failure to develop additional proprietary technologies that are patentable.

***If we seek to expand our business through acquisition, we may not be successful in identifying acquisition targets or integrating their businesses with our existing business.***

We have recently expanded our business by acquisition, and we may make acquisitions in the future. In 2017, we issued 1,250,000 shares of common stock, valued at \$2,500,000, in connection with our proposed acquisition of Advanced Health Brands, Inc., but the stock of Advanced Health Brands was never transferred to us and



the value of the intellectual property we were to have acquired did not have the value we anticipated, with the result that we incurred a \$2,500,000 impairment loss in the year ended January 31, 2018. In September 2018, we entered into an agreement to acquire Carmel Biosciences Inc., and in November 2018, we terminated the agreement. We previously entered into another acquisition agreement which was rescinded shortly after the agreement was executed. We cannot assure you that any acquisition we complete will be successful or that any acquisition agreement we may enter into will result in an acquisition. An acquisition can be unsuccessful for a number of reasons, including the following:

- We may incur significant expenses and devote significant management time to the acquisition and we may be unable to consummate the acquisition on acceptable terms.

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- If we identify a potential acquisition, we may face competition from other companies in the industry or from financial buyers in seeking to make the acquisition.
- The integration of any acquisition with our existing business may be difficult and, if we are not able to integrate the business successfully, we may not only be unable to operate the business profitably, but management may be unable to devote the necessary time to the development of our existing business;
- The key employees who operated the acquired business successfully prior to the acquisition may not be happy working for us and may resign, thus leaving the business without the necessary continuity of management.
- Even if the business is successful, our senior executive officers may need to devote significant time to the acquired business, which may distract them from their other management activities.
- If the business does not operate as we expect, we may incur an impairment charge based on the value of the assets acquired.
- The products or proposed products of the acquired company may have regulatory problems with the FDA or any other regulatory agency, including the need for additional and unanticipated testing or the need for a recall or a change in labeling.
- We may have difficulty maintaining the necessary quality control over the acquired business and its products and services.
- To the extent that an acquired company operates at a loss prior to our acquisition, we may not be able to develop profitable operations following the acquisition.
- Problems and claims relating to the acquired business that were not disclosed at the time of the acquisition may result in increased costs and may impair our ability to operate the acquired company.
- The acquired company may have liabilities or obligations which were not disclosed to us, or the acquired assets, including any intellectual property, may not have the value we anticipated.
- The assets, including intellectual property, of the acquired company may not have the value that we anticipated.
- The products may not perform as anticipated.
- We may not be able to fund the development of any assets we may acquire.
- The products may be subject to recall or the FDA may require additional trials for the product.
- Components or ingredients for the product may become subject to tariffs which may increase manufacturing costs.
- We may require significant capital both to acquire and to operate the business, and the capital requirements of the business may be greater than we anticipated. Our failure to obtain funds on reasonable terms may impair the value of the acquisition.
- The acquired company may not operate at the revenue level or with the gross margin shown in the financial statements or projections.
- The acquired company may have granted rights to its intellectual property which decrease the value of the intellectual property to us.
- Patents may not be granted for patent applications which the acquired company filed or patents may be successfully challenged.
- There may be conflicts in management styles that prevent us from integrating the acquired company with us.
- The former equity owners or officers may compete in violation of their non-competition covenants or the non-competition covenants may be held to be unenforceable.
- The business of the acquired company may have problems of which management was unaware and which do not become evident until after the acquisition and we may require significant funding to remedy the problem.
- The indemnification obligations of the seller under the purchase agreement, if any, may be inadequate to compensate us for any loss, damage or expense which we may sustain, including undisclosed claims or liabilities.
- To the extent that the acquired company is dependent upon its management to maintain relationships with existing customers, we may have difficulty in retaining the business of these customers if there is a change in management.
- Government agencies may seek damages after we make the acquisition for conduct which occurred prior to the acquisition and we may not have adequate recourse against the seller.

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- The acquired company may have operated in violation of laws which results significant expenditures for us to remedy as well as potential penalties for the violations.
- We may have difficult collecting the acquired company's accounts receivable and in selling the acquired company's inventory.
- The sellers of the acquired company may be in breach of their representations and warranties and we may not be able to recover damages.

If any of the foregoing or any other events which we do not contemplate happen, we may incur significant expenses, which we may not be able to cover, and the development of our business can be impaired. We cannot assure you that any acquisition we will make will be successful.

***We may not be able to recover the 1,200,000 shares of common stock we issued in connection with our proposed acquisition of Advanced Health Brands.***

On May 22, 2017, we entered into an agreement to acquire Advanced Health Brands, which held six provisional patents for transdermal products. Pursuant to the agreement, we were to issue 1,250,000 shares of common stock, valued at \$2,500,000, in exchange for the stock of Advanced Health Brands and a related corporation. In August 2017, when we issued the shares to the Advanced Health Brands stockholders, the Advanced Health Brands stock had not been transferred to us. Although we did not have title to the shares of Advanced Health Brands stock, we treated the transaction as completed and we announced that we had acquired Advanced Health Brands, relying on the stockholders' obligation to transfer the shares to us. We had appointed two of the Advanced Health Brands stockholders as directors and executive officers. In January 2018, we recognized an impairment loss of \$2,500,000 based on both our failure to obtain title to the Advanced Health Brands stock and our conclusion that the provisional patents that were held by Advanced Health Brands did not have any value to us. In December 2018 50,000 shares were returned by one of the defendants. We have commenced legal actions against Advanced Health Brands and its stockholders in Florida and New York. In the Florida action, the court ruled against us. On February 1, 2019, we appealed the court's order. Pursuant to a settlement agreement with one of the defendants, that defendant returned the 50,000 shares which had been issued to her, and the shares were cancelled as of January 31, 2019. On March 20, 2020, the Florida district court of appeal reversed the lower court ruling in the Florida state court action that dismissed our complaint with prejudice, and gave us leave to file an amended complaint. The New York action was recently commenced against the stockholders of Advanced Health Brands, and the defendants have filed a motion to dismiss the action. See "Business — Legal Proceedings." We cannot assure you that we will prevail in either action, that we will be able to recover either the 1,200,000 shares of common stock or any monetary damages from the Advanced Health Brands stockholders or that we will not incur any liability as a result of either our issuance of the shares or our failure to provide the necessary documentation to permit the Advanced Health Brands stockholders to sell their shares pursuant to Rule 144 or from our treating and announcing the acquisition as completed or based on other claims.

***We are dependent on third party distributors for the marketing of our consumer products and complying with applicable laws.***

We do not currently sell or market our consumer transdermal products directly, and we rely on distributors to sell and market these products. We cannot market our consumer transdermal patch products in the United States without first obtaining FDA approval. We do not plan to seek FDA approval or market these products in the United States at this time. We plan to sell our transdermal consumer products to distributors in those countries in which the products can be sold in compliance with all applicable regulations without our spending significant monies for preclinical and clinical studies to obtain regulatory approval. At present we have one distribution agreement, which is our agreement with Best Choice that covers certain countries in Asia. At present, Best Choice is planning to market three of our product lines in South Korea pending receipt of necessary regulatory approval, and we cannot assure you that we will generate any significant revenue from Best Choice or that Best Choice will be able to sell our products in any country, including South Korea. Best Choice is responsible for compliance with all applicable government regulations relating to our products in the countries in which it sells our products. The failure of Best Choice or any other international distributor to comply with applicable government regulations could impair our ability to derive revenue from those countries and could result in actions against us as the supplier of the products regardless of whether we were involved in the conduct which violated applicable laws.

***We have had difficulty in having our consumer transdermal products manufactured for us; and we cannot assure you that we will not have problems with the manufacture of any other products we may develop.***

Our consumer transdermal products have been manufactured by a domestic contract manufacturer since 2016. However, our supplier ran into supply problems for certain foil components due to the new tariffs on Chinese imports into the United States, design changes in the pouch, and quality problems with material in the pouch, all of which resulted in manufacturing delays in meeting the first order for Best Choice, which was for product to be used for preliminary marketing activities. Our current arrangement is to have the manufacturer manufacture coated film roll stock and ship sealed rolls to Best Choice in South Korea for slitting, die-cutting and packaging individual patches in foil pouches. We cannot assure you that we will not have difficulty manufacturing any transdermal products in the future. Our failure to establish reliable manufacturing for our products may impair our ability to generate revenue from our products. Further, we will be responsible for the performance of the products we sell, regardless of whether or not we manufacture the products ourselves or manufacture them with a contract manufacturer. In addition, while we intend to require any manufacturer to maintain sufficient product liability insurance to protect us against any liability we may incur as a result of defects in manufacturing, we cannot assure you that any product liability insurance the manufacturer may obtain will be sufficient to protect us against liability.

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***We are dependent upon our chief executive officer and our chief operating officer.***

We are dependent upon Gareth Sheridan, our chief executive officer, and Dr. Alan Smith, our chief operating officer who is president of 4P Therapeutics. Although Mr. Sheridan has an employment agreement with us, the employment agreement does not guarantee that he will continue with us. We do not have an employment agreement with Dr. Smith. The loss of Mr. Sheridan or Dr. Smith would materially impair our ability to conduct our business.

***If we are unable to attract, train and retain technical and financial personnel, our business may be materially and adversely affected.***

Our future success depends, to a significant extent, on our ability to attract, train and retain key management, technical, regulatory and financial personnel. Recruiting and retaining capable personnel with experience in pharmaceutical product development is vital to our success. There is substantial competition for qualified personnel, and, competition is likely to increase. We cannot assure you we will be able to attract or retain the personnel we require. Our financial condition is likely to impair our ability to attract qualified candidates. If we are unable to attract and retain qualified employees, our business may be materially and adversely affected.

**Risks Concerning our Securities**

***We and our senior executive officers settled an SEC investigation, which may affect the market for and the market price of our common stock and warrants and our ability to list on a stock exchange.***

Following an investigation into the accuracy of statements in our Form 10 registration statement filed June 2, 2016, as amended, and our Form 10-K annual report filed May 8, 2017 that did not accurately reflect the FDA's jurisdiction over our consumer products and did not disclose that we could not legally market these products in the United States, a Wells notice which we, our chief executive officer and our chief financial officer received on August 10, 2017 and a Wells submission which we and the officers submitted in response to the Wells notice, the SEC, on December 26, 2018, announced that it has accepted our settlement offer and instituted settled an administrative cease-and-desist proceeding against us and our chief executive officer and chief financial officer. The SEC's administrative order, dated December 26, 2018, finds that we and the officers consented – without admitting or denying any findings by the SEC – to cease-and-desist orders against them for violations by us of Sections 12(g) and 13(a) of the Securities Exchange Act of 1934 and Rules 12b-20 and 13a-1 thereunder, which require issuers to file accurate registration statements and annual reports with the Commission; violations by the officers for causing our violations of the above issuer reporting provisions; and violations by the officers of Rule 13a-14 of the Exchange Act, which requires each principal executive and principal financial officer of issuers to attest that annual reports filed with the SEC do not contain any untrue statements of material fact. In addition to consenting to the cease-and-desist orders, the officers have each agreed to pay a \$25,000 civil penalty to resolve the investigation. The administrative order does not impose a civil penalty or any other monetary relief against us. The settlement may affect the market for and the market price of our common stock and warrants.

***Our lack of internal controls over financial reporting may affect the market for and price of our common stock and warrants.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to file a report by our management on our internal control over financial reporting. Our disclosure

controls and our internal controls over financial reporting are not effective. We do not have the financial resources or personnel to develop or implement systems that would provide us with the necessary information on a timely basis so as to be able to implement financial controls. Our financial condition together with the fact that we recently acquired 4P Therapeutics, which was a privately owned company prior to our acquisition and did not have any internal controls over financial reporting in effect, makes it difficult for us to implement a system of internal controls over financial reporting, and we cannot assure you that we will be able to develop and implement the necessary controls. The absence of internal controls over financial reporting may inhibit investors from purchasing our stock and may make it more difficult for us to raise capital or borrow money. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in developing or maintaining internal control.

If we are unable to conclude that we have effective internal controls over financial reporting, investors may lose confidence in our operating results, the price of the common stock and warrants could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, our common stock and warrants may not be able to remain listed on the NASDAQ Capital Market.

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***The market price for our common stock and warrants may be volatile and your investment in our common stock and warrants could suffer a decline in value.***

The trading volume in our stock is low, which may result in volatility in our stock price. As a result, any reported prices may not reflect the price at which you would be able to sell shares of common stock or warrants if you want to sell any shares or warrants you own or buy shares or warrants if you wish to buy shares or warrants. Further, stocks with a low trading volume may be more subject to manipulation than a stock that has a significant public float and is actively traded. The price of our stock and warrants may fluctuate significantly in response to a number of factors, many of which are beyond our control. These factors include, but are not limited to, the following, in addition to the risks described above and general market and economic conditions:

- concern about the effects of the recent SEC settlement;
- the market's reaction to our financial condition and its perception of our ability to raise necessary funding or enter into a joint venture, given the economic environment resulting from the COVID-19 pandemic, as well as its perception of the possible terms of any financing or joint venture;
- the market's perception as to our ability to generate positive cash flow or earnings;
- changes in our or any securities analysts' estimate of our financial performance;
- the perception of our ability to raise the necessary financing to complete the product development activities including preclinical and clinical testing required for FDA approval and our ability to generate revenue and cash flow from our products;
- the anticipated or actual results of our operations;
- changes in market valuations of other companies in our industry;
- litigation or changes in regulations and insurance company reimbursement policies affecting prescription drugs;
- concern that our internal controls are ineffective;
- any discrepancy between anticipated or projected results and actual results of our operations;
- actions by third parties to either sell or purchase stock in quantities which would have a significant effect on our stock price; and
- other factors not within our control.

***Because of our executive officers' stock ownership, they have the power to elect all directors and to approve any action requiring stockholder approval.***

Our officers and directors as a group beneficially own approximately 61% of our common stock. As a result, they have the effective power to elect all of our directors and to approve any action requiring stockholder approval.

***Raising funds by issuing equity or convertible debt securities could dilute the net tangible book value of the common stock and impose restrictions on our working capital.***

We anticipate that we will require funds in addition to the net proceeds from this offering for our business. If we were to raise capital by issuing equity securities, either alone or in connection with a non-equity financing, the net tangible book value of the then outstanding common stock could decline. If the additional equity securities were issued at a per share price less than the market price, which is customary in the private placement of equity securities, the holders of the outstanding shares would suffer dilution, which could be significant. Further, if we are able to raise funds from the sale of debt securities, the lenders may impose restrictions on our operations and may impair our working capital as we service any such debt obligations.

***Stockholders may experience significant dilution as a result of future equity offerings and other issuances of our common stock or other securities.***

We will need to raise substantial funds in order to develop our products. In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not which is less than the market price and which may be based on a discount from market at the time of issuance. Stockholders will incur dilution upon exercise of any outstanding stock options, warrants or upon the issuance of shares of common stock under our present and future stock incentive programs. In addition, the sale of shares and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

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***We may issue preferred stock whose terms could adversely affect the voting power or value of our common stock.***

Our articles of incorporation authorize us to issue, without the approval of our stockholders, one or more classes or series of preferred stock having such designations, preferences, limitations and relative rights, including preferences over our common stock respecting dividends and distributions, as our board of directors may determine. The terms of one or more classes or series of preferred stock could adversely impact the voting power or value of our common stock. For example, we might grant holders of preferred stock the right to elect a number of our directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we might assign to holders of preferred stock could affect the

*For as long as we are an emerging growth company, we will not be required to comply with certain reporting requirements, including those relating to accounting standards and disclosure about our executive compensation, that apply to other public companies.*

We are classified as an “emerging growth company” under the JOBS Act. For as long as we are an emerging growth company, which may be up to five full fiscal years, we will not be required to, among other things, (i) provide an auditor’s attestation report on management’s assessment of the effectiveness of our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, (ii) comply with any new requirements adopted by the PCAOB requiring mandatory audit firm rotation or a supplement to the auditor’s report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, (iii) provide certain disclosure regarding executive compensation, or (iv) hold nonbinding advisory votes on executive compensation. We will remain an emerging growth company for up to five years, although we will lose that status sooner if we have more than \$1.07 billion of revenues in a fiscal year, have more than \$700 million in market value of our common stock held by non-affiliates, or issue more than \$1.07 billion of non-convertible debt over a three-year period. To the extent that we rely on any of the exemptions available to emerging growth companies, you will receive less information about our executive compensation and internal control over financial reporting than issuers that are not emerging growth companies. If some investors find our common stock to be less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

*We do not intend to pay any cash dividends in the foreseeable future.*

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future.

## **ITEM 2. PROPERTIES**

We do not own any real property. We lease approximately 200 square feet of office space in Orlando, Florida pursuant to a one-year lease which expires in July 2020. The current annual rental is \$20,640. We have the right to renew, at a rent to be determined. With the office lease, we have access to board rooms, kitchen facilities and administrative support services.

## **ITEM 3. LEGAL PROCEEDINGS**

On August 10, 2018, we, our chief executive officer and our chief financial officer received a Wells notice from the enforcement division staff of the Miami Regional Office of the SEC in connection with an investigation into the accuracy of certain statements in our Form 10 registration statement filed June 2, 2016, as amended, and our Form 10-K annual report filed May 8, 2017. The staff’s inquiry was focused on our disclosure language in those filings relating to the FDA requirements for our consumer transdermal patch products in that our filings did not accurately reflect the FDA’s jurisdiction over our consumer products and did not disclose that we could not legally market these products in the United States. On September 7, 2018, we and the officers filed a Wells submission in response. After engaging in settlement discussions with the staff about the matters under investigation, we and the officers submitted an offer of settlement to resolve the investigation without admitting or denying any violations of the federal securities laws.

On December 26, 2018, the SEC announced that it has accepted the settlement offer and instituted settled administrative cease-and-desist proceedings against us and the named officers. The SEC’s administrative order, dated December 26, 2018, finds that we and the officers consented – without admitting or denying any findings by the SEC – to cease-and-desist orders against them for violations by us of Sections 12(g) and 13(a) of the Exchange Act 1934 and Rules 12b-20 and 13a-1 thereunder, which require issuers to file accurate registration statements and annual reports with the SEC; violations by the officers for causing our violations of the above issuer reporting provisions; and violations by the officers of Rule 13a-14 of the Exchange Act, which requires each principal executive and principal financial officer of issuers to attest that annual reports filed with the SEC do not contain any untrue statements of material fact. In addition to consenting to the cease-and-desist orders, the officers have each agreed to pay a \$25,000 civil penalty to resolve the investigation. The administrative order does not impose a civil penalty or any other monetary relief against us.

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On July 27, 2018, we commenced an action in the Circuit Court of the Ninth Judicial Circuit in and for Orange County, Florida, against Advanced Health Brands, Inc., Raymond Kalmar, Paul Murphy, Michelle Polly-Murphy, Laura Fillman and John Baker, together with a Motion for Temporary Injunction Without Notice and a Motion for Prejudgment Writ of Replevin arising from our decision to seek to rescind for misrepresentation the agreement by which we acquired advanced Health Brands, Inc. for 1,250,000 shares of common stock valued at \$2,500,000 and seek return of the shares. On August 2, 2018, the court entered a Temporary Injunction Without Notice and an Order to Show Cause against the defendants. Defendants Kalmar, Murphy, Polly-Murphy, and Baker filed a Motion to Dismiss our Verified Complaint, Motion to Dissolve Temporary Injunction Without Notice and Response to Order to Show Cause, and Motion to Compel Arbitration. On January 4, 2019, the court dismissed our complaint with prejudice, and directed the defendants to assign to us within 30 days, the six patents never duly transferred to us. On February 1, 2019, we appealed the court’s order. Pursuant to a settlement agreement with one of the defendants, that defendant returned the 50,000 shares which had been issued to her, and the shares were cancelled as of January 31, 2019. On June 7, 2019, the individual defendants (other than the defendant whom we have a settlement agreement), filed a motion for sanctions and civil contempt against us, which generally claimed that we failed to comply with the Court’s January 4, 2019 order by refusing to issue the Ruling 144 letters that would allow the defendants to transfer their shares of common stock. On October 29, 2019, the Court denied the defendants motion. On March 20, 2020, the Florida district court of appeal reversed the lower court ruling in the Florida state court action that dismissed our complaint with prejudice, and gave us leave to file an amended complaint.

On August 22, 2018, four of the defendants in the Florida action described in the previous paragraph filed a complaint against us in the Franklin County, Ohio Court of Common Pleas seeking a declaratory judgment permitting them to sell the shares of common stock they received pursuant to the acquisition agreement. The parties have agreed to a stay pending the outcome of the Florida litigation.

On April 29, 2019, we filed a securities fraud action in the U.S. District Court for the Eastern District of New York against Raymond Kalmar, Paul Murphy, Michelle Polly-Murphy, Advanced Health Brands and TD Therapeutic, Inc. In the complaint we allege that in 2017, the defendants fraudulently and deceitfully obtained 1,250,000 shares of common stock by orchestrating a months-long scheme to defraud us. We are seeking the return of the 1,200,000 shares of common stock and monetary damages resulting from the defendants’ fraudulent conduct. The defendants filed a motion to dismiss on August 23, 2019, and we filed our response on September 13, 2019.

## **ITEM 4. MINE SAFETY DISCLOSURES.**

Not Applicable

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## **PART II**

### **ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our common stock has been traded on the OTCQB market under the symbol NTRB since November 30, 2017. Any over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transaction.

As of April 10, 2020 we had 68 holders of record of our common stock.

The transfer agent for the common stock is American Stock Transfer & Trust Company, LLC, 6201 15th Ave, Brooklyn, NY 11219, telephone (800) 937-5449.

On January 31, 2020, we issued 8,572 shares of common stock to each of Sean Gallagher, president and a director, and Strategic Pharmaceutical Consulting LLC, which is controlled by Jeff Patrick, chief scientific officer, pursuant employment agreements with Mr. Gallagher and Dr. Patrick. The employment agreements provide that each of Mr. Gallagher and Dr. Patrick receive annual compensation of \$60,000, which may be paid in cash or stock. The shares were issued as compensation of \$120,000 for the years ended January 31, 2020 and 2019. The shares were exempt from the registration requirements of the Securities Act pursuant to Section 4(a)(2).

We do not have any equity plans, except to the extent that our employment agreements with Mr. Gallagher and Dr. Patrick may be deemed equity incentive plans since they give us the right to pay their compensation in shares of common stock.

#### **ITEM 6. SELECTED FINANCIAL DATA**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

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#### **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis of financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. See "Note Regarding Forward-Looking Statements." Our actual results could differ materially from those anticipated in the forward-looking statements as a result of certain factors discussed in "Risk Factors" and elsewhere in this report.*

It should be noted that current public health threats could adversely affect our ongoing or planned business operations. In particular, the novel coronavirus (COVID-19) has resulted in quarantines, restrictions on travel and other business and economic disruptions. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the partners and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and adversely impacted. The measures being taken by service providers and government agencies to suppress the spread of COVID-19 infection may delay time to production of our planned abuse deterrent fentanyl transdermal system product and therefor delay the time of filing with FDA for approval.

##### **Overview**

Our primary business is the development of a portfolio of transdermal pharmaceutical products. Our lead product is our abuse deterrent fentanyl transdermal system which we are developing to provide clinicians and patients with an extended-release transdermal fentanyl product for use in managing chronic pain requiring around the clock opioid therapy combined with properties designed to help combat the opioid crisis by deterring the abuse and misuse of fentanyl patches. We believe that our abuse deterrent technology can be broadly applied to various transdermal products and our strategy is to follow the development of our abuse deterrent fentanyl transdermal system with the development of additional transdermal prescription products for pharmaceuticals that have risks or a history of abuse. In addition, we are developing a portfolio of transdermal pharmaceutical products to deliver commercially available drugs or biologics that are typically delivered by injection but with the potential to improve compliance and therapeutic outcomes.

Because of our financial position, we have put our development efforts with respect to these products on hold, and our only business is the performance of contract services for a small number of customers. Because of both our financial position and the effects of the COVID-19 pandemic, our contract service business has also been scaled back. The description of our business in this annual report is based on our ability to raise significant financing or enter into a joint venture agreement with a third party that has the financial ability to fund the joint venture's operations. We cannot assure you that we will be able to obtain necessary financing or enter into a joint venture agreement on reasonable, if any, terms. If we are not able to continue obtain financing or enter into a joint venture agreement, we may not be able to continue in business.

Through July 31, 2018, our business was the development of a line of consumer and health products that are delivered through a transdermal patch which we plan to sell internationally. Consumer products are products that are sold over the counter and do not require a prescription. Most of our consumer products require FDA approval for sale in the United States, and we have not sought to obtain, and we do not plan to seek to obtain, FDA approval to market these product in the United States at this time. Presently our efforts with respect to our consumer transdermal products is limited to our distribution agreement with Best Choice, which is planning to market our consumer products in South Korea. Through January 31, 2020, we generated modest revenue from the sale of our consumer products to Best Choice, which is conducting preliminary marketing activities in South Korea pending obtaining the necessary regulatory approvals necessary to market the products to consumers in South Korea. Since Best Choice has not yet obtained the necessary regulatory approval to market our consumer products in South Korea, we do not anticipate generating any significant revenue from Best Choice during the year ending January 31, 2020. We cannot assure you that Best Choice will obtain necessary regulatory approval in South Korea or in any other country in which it has distribution rights or that, if it does obtain the necessary approval, that we will generate any significant revenue from Best Choice.

With our acquisition of 4P Therapeutics on August 1, 2018, our focus changed, and we are seeking to develop and seek FDA approval on a number of transdermal pharmaceutical products under development by 4P Therapeutics. As a result of the acquisition of 4P Therapeutics, we have pipeline of potential products.

4P Therapeutics has not generated any revenue from any of its products under development. Rather, prior to our acquisition, 4P Therapeutics generated revenue to provide cash for its operations through contract research and development and related services for a small number of clients in the life sciences field on an as-needed basis. We are, for the near term, continuing this activity, although we do not anticipate that it will generate significant revenues and, since our acquisition, it has generated a negative gross margin. We have no long-term contractual obligations, and either party can terminate at any time.

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With the change in our focus, our capital requirement have increased substantially. The process of developing pharmaceutical products and submitting them for FDA approval is both time consuming and expensive, with no assurance of obtaining approval from the FDA to market our product in the United States. We have budgeted \$5.0 million for research and development of our abuse deterrent fentanyl transdermal system, including clinical manufacturing and clinical trials that need to be completed in order to obtain FDA approval. However, the total cost could be substantially in excess of that amount. We do not presently have the funds to enable us to develop our lead product, and we are seeking funding from this offering for this purpose. In the event that we are not able to complete this offering, we may be unable to raise the funds necessary to develop our lead product.

On March 2020, we issued in a private placement 46,828 units at a price of \$11 per unit. Each unit consisted of one share of common stock and a warrant to purchase one share of common stock at an exercise price of \$14 per share. The warrants expire April 30, 2023. We issued a total of 46,828 shares of common stock and warrants to purchase 46,828 shares of common stock. We received proceeds of \$515,113.

On March 25, 2020, we paid off the convertible notes in the principal amount of \$270,000 from the proceeds of the private placement. The total payments, including the prepayment penalty and accrued interest, was \$345,656.24. The payment was made from the proceeds of the private placement. As a result of the payment of the notes, the derivative liability, which was \$928,774 at January 31, 2020, was reduced to zero. As a result of the terms of the private placement, the warrants, which were issued to the holders of the convertible debt, to purchase 50,000 shares of common stock at the lesser of (a) \$20.90 or (b) if the Company completes a private offering, 110% of the initial offering price of the common stock in the public offering, became warrant to purchase 95,000 shares at \$11 per share, subject to adjustment pursuant to the antidilution provisions of the warrant.

In March 27, 2020, a minority stockholder who had previously made loans to us in the total amount of \$215,000, made an additional loan to us in the amount of \$60,000, increasing the total loans from the stockholder to \$275,000. On March 27, 2020, we issued 25,000 shares of common stock upon conversion of the notes.

## Results of Operations

### *Years Ended January 31, 2020 and 2019*

For the year ended January 31, 2020, we generated revenue of \$370,647 and our costs of revenue were \$549,107, resulting in negative gross profit of \$178,460. For the year ended January 31, 2019, we generated revenue of \$245,285 and our costs of revenue were \$288,301, resulting in negative gross margin of \$43,016. Our revenue for January 31, 2020 was derived from two sources – a continuation of research and development contracts of the type 4P Therapeutics performed prior to our acquisition, which accounted for \$245,679, and \$124,968 from sales of our consumer transdermal product to or South Korean distributor for its preliminary marketing efforts since the product has not obtained regulatory approval for retail sales in South Korea. Since we do not have the funds for development of our lead product, the 4P Therapeutics fixed costs are allocated to the contract services that we perform for clients. Our cost of revenue for our contract research and development services represents basically our labor cost plus a modest amount of material costs which we passed on to the client. In connection with our consumer transdermal products, our suppliers ran into supply problems for certain foil components used in the transdermal patches due to the tariffs on Chinese imports into the United States which resulted in manufacturing delays in meeting the first order from Best Choice, and it was necessary for Best Choice to perform at our cost, some of the manufacturing functions in South Korea. We have worked to resolve these manufacturing problems.

For the year ended January 31, 2020, our selling, general and administrative expenses were \$1,790,980 primarily legal, accounting and payroll expense. Of this amount, \$252,700 was stock-based compensation comprised of a warrant granted to Dr. Jeff Patrick, our scientific officer, which expired unexercised, and \$120,000 representing the value of shares of common stock issued to our president, Sean Gallagher, and to an entity controlled by Dr. Patrick as compensation for services during the year ended January 31, 2020 pursuant to employment agreements with Mr. Gallagher and Dr. Patrick. The agreements provide for annual compensation of \$60,000 to each of them, which may be paid in stock or cash, and the shares were issued for services rendered in the years ended January 31, 2020 and 2019. For the year ended January 31, 2019, our operating expenses were \$3,288,224, of which \$1,763,950 represented stock-based compensation, consisting of \$1,374,500 of executive compensation, including compensation for services to a company affiliated with an officer, \$74,000 of compensation to our scientific advisory board member who is not an officer, \$222,000 of fees paid to our independent directors, and \$93,450 paid for consulting and related services, of which \$44,800 was paid to an affiliate of an officer for services rendered prior to the date he became an officer. Other selling, general and administrative expenses were \$1,524,274, primarily professional fees, marketing expenses, and compensation.

During the year ended January 31, 2020, we incurred derivative expense of \$767,650 and a gain on change in fair value of derivatives of \$88,876 in connection with our October 30, 2019 financing in which we raised gross proceeds of \$250,000 and net proceeds of \$203,000 from the sale of convertible notes and warrants. We had no derivative expense during the year ended January 31, 2019.

We incurred interest expense of \$73,413 for the year ended January 31, 2020. We had no interest expense for the year ended January 31, 2019.

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As a result of the foregoing, we sustained a net loss of \$2,721,627 or \$(0.50) per share (basic and diluted) for the year ended January 31, 2020, compared with a loss of \$3,331,240, or \$(0.62) per share (basic and diluted) for the year ended January 31, 2019.

### *Liquidity and Capital Resources*

For the year ended January 31, 2020, we used \$894,470 in our operations. The principal adjustment to our net loss of \$2,721,627 were stock-based compensation of \$252,700, derivative expense of \$767,650 a loss on change in fair value of derivatives of \$88,876 an increase in accounts payable and accrued expenses of \$720,150, a decrease in prepaid expenses of \$82,558, depreciation and amortization of \$72,188, offset by a decrease in customer deposits of \$71,225.

For the year ended January 31, 2019, we used cash of \$1,105,466 in operations. The principal adjustments to our net loss of \$3,331,240 were stock-based compensation of \$1,763,950, an increase in accounts payable and accrued expenses of \$273,352, a decrease in prepaid expenses of \$57,778 and depreciation and amortization of \$36,616 and an increase in expenses paid on our behalf by an officer of \$24,300.

For the year ended January 31, 2020, we had no cash flow from investing activities. For the year ended January 31, 2019, our cash flow from investing activities consisted of a \$400,000 payment in connection with the acquisition of 4P Therapeutics and \$4,163 for the purchase of equipment.

For the year ended January 31, 2020, we had cash flows from financing activities of \$430,250 primarily \$175,000 from non-interest bearing loan from a minority stockholder and gross proceeds of \$250,000 from the sale of convertible debt in the principal amount of \$270,000 and warrants to purchase common stock.

For the year ended January 31, 2019, our cash flows from financing activities of \$1,983,888 consisted primarily of \$1,500,000 from the sale of common stock and \$500,000 from the exercise of warrants.

### **Off Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **Critical Accounting Policies**

#### *Going Concern*

Our consolidated financial statements for the year ended January 31, 2020 have been prepared on a going concern basis which contemplates the realization of assets and settlement of liabilities in the normal course of business. We did not generate any revenue prior to the quarter ended October 31, 2018. For the year ended January 31, 2020, we generated revenue of \$370,647 on which we recorded cost of sales of \$549,107 and a loss from operations of \$2,014,440. Subsequent to January 31, 2020, because of the lack of available cash and the decline in business resulting in part from the effects of the COVID-19 pandemic, we temporarily closed our operations, and do not expect that we will be able to commence operations relating to the development of our transdermal pharmaceutical products until we received substantial funding. Successful business operations and our transition to attaining profitability are dependent upon obtaining significant financing and achieving a level of revenue to support its cost structure, developing our products and obtaining FDA approval to market any product we develop and implementing a marketing program for such products. These factors raise substantial doubt about our ability to continue as a going concern. Without such financing, we may not be able to continue in business.

#### *Use of Estimates*

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates including, but not limited to, those related to such items as income tax exposures, accruals, depreciable/useful lives, allowance for doubtful accounts and valuation allowances. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

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### *Revenue Recognition*

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which amends the accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled when products are transferred to a customer. We adopted the guidance under the new revenue standards using the modified retrospective method effective February 1, 2018 and determined no cumulative effect adjusted to retained earnings was necessary upon adoption. Topic 606 requires the Company to recognize revenues when control of the promised goods or services and receipt of payment is probable. The Company recognizes revenue based on the five criteria for revenue recognition established under Topic 606: 1) identify the contract, 2) identify separate performance obligations, 3) determine the transaction price, 4) allocate the transaction price among the performance obligations, and 5) revenue is recognized when the performance obligations are satisfied.

### *Revenue Types*

The following is a description of the Company's revenue types, which include professional services and sales of consumer products:

- Professional services include the contract of research and development related services with our clients in the life sciences field on an as-needed basis. Deliverables primarily consist of detailed findings and conclusion reports provided to the client for each given research project engaged.
- Sales revenues are generated from the sale of our products. Upon the receipt of a purchase order, we have the order filled and shipped.

### *Contracts with Customer.*

A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods or services to be transferred and identifies the payment terms related to these goods or services, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

### *Performance Obligations*

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in the new revenue standard. The contract transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. For our different revenue service types, the performance obligation is satisfied at different times. Our performance obligations include providing products and professional services in the area of research. We recognize product revenue performance obligations in most cases when the product has shipped to the customer. When we perform professional service work, we recognize revenue when we have the right to invoice the customer for the work completed, which typically occurs on a monthly basis for the work performed during that month.

All revenue recognized in the statement of operations is considered to be revenue from contracts with customers.

### *Intangible Assets*

Intangible assets include patents, intellectual property and other intangible assets acquired through business combinations. We account for Other Intangible Assets under the guidance of ASC 350, "Intangibles-Goodwill and Other." We capitalize certain costs related to patent technology, as a substantial portion of the purchase price related to our acquisition has been assigned to the intellectual property and other intangibles of the acquired entity. Under the guidance, other intangible assets with definite lives are amortized over their estimated useful lives. Intangible assets with indefinite lives are tested annually for impairment. Patents and intellectual property are being amortized over their useful lives of ten years.

### *Goodwill*

Goodwill represents the difference between the total purchase price and the fair value of assets (tangible and intangible) and liabilities at the date of acquisition. Goodwill is reviewed for impairment annually, and more frequently as circumstances warrant, and written down only in the period in which the recorded value of such assets exceed their fair value. We do not amortize goodwill in accordance with ASC 350.

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### *Long-lived Assets*

Management reviews long-lived assets for potential impairment whenever significant events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment exists when the carrying amount of the long-lived asset is not recoverable and exceeds its fair value. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the estimated undiscounted cash flows expected to result from the use and eventual disposition of the asset. If an impairment exists, the resulting write-down would be the difference between fair market value of the long-lived asset and the related net book value.

### *Stock-Based Compensation*

ASC 718, "Compensation - Stock Compensation," prescribes accounting and reporting standards for all share-based payment transactions in which employee services, and, since February 1, 2019, non-employees, are acquired. Transactions include incurring liabilities, or issuing or offering to issue shares, options and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the financial statements based on their fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period).

### *Business Combinations*

We recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquired entity at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the accounting literature. In accordance with this guidance, acquisition-related costs, including restructuring costs, must be recognized separately from the acquisition and will generally be expensed as incurred. That replaces the cost-allocation process detailed in previous accounting literature, which required the cost of an acquisition to be allocated to the individual assets acquired and liabilities assumed based on their estimated fair

*Recent Accounting Standards*

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for nonemployee share-based payment transactions by expanding the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. Under the new standard, most of the guidance on stock compensation payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. This standard became effective for us on February 1, 2019. The adoption of this standard did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, “Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement.” ASU 2018-13 modifies the fair value measurements disclosures with the primary focus to improve effectiveness of disclosures in the notes to the financial statements that is most important to the users. The new guidance modifies the required disclosures related to the valuation techniques and inputs used, uncertainty in measurement, and changes in measurements applied. ASU 2018-13 will be effective for the Company for its fiscal year beginning after December 15, 2019 and each quarterly period thereafter. Early adoption is permitted. The Company is currently assessing the impact this new guidance may have on the Company’s consolidated financial statements and footnote disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. This ASU removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This ASU is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. We are currently assessing the impact of this standard on our combined financial statements.

In January 2017, the FASB issued ASU 2017-04, “Simplifying the Test for Goodwill Impairment,” which removes Step 2 from the goodwill impairment test and replaces the qualitative assessment. Impairment will be measured using the difference between the carrying amount and the fair value of the reporting unit. Under this revised guidance, failing Step 1 will always result in a goodwill impairment. The amendments in this update should be applied prospectively for annual and interim periods in fiscal years beginning after December 15, 2019. The Company early adopted ASU 2018-07 on February 1, 2019. The Company’s adoption of ASU 2018-07 has had no impact on its consolidated financial statements or disclosures.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. ASU No. 2017-01 clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of a business or as acquisitions (or disposals) of assets. ASU No. 2017-01 is effective for annual periods beginning after December 15, 2018, with early adoption permitted under certain circumstances. The amendments of ASU No. 2017-01 were adopted by the Company effective February 1, 2019. The adoption of this standard had no impact on our consolidated financial position or results of operations.

The Company has reviewed all other FASB-issued ASU accounting pronouncements and interpretations thereof that have effective dates during the period reported and in future periods. The Company has carefully considered the new pronouncements that alter previous GAAP and does not believe that any new or modified principles will have a material impact on the company’s reported financial position or operations in the near term. The applicability of any standard is subject to the formal review of the Company’s financial management and certain standards are under consideration.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements start on Page F-1.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES****Management’s Conclusions Regarding Effectiveness of Disclosure Controls and Procedures**

We conducted an evaluation of the effectiveness of our disclosure controls and procedures, as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of January 31, 2020, the end of the period covered by this annual report. The disclosure controls evaluation was done under the supervision and with the participation of management, including our chief executive officer and chief financial officer, who are two of our three full-time employees. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon this evaluation, our chief executive officer and chief financial officer concluded that, due to our limited internal audit function, our very limited staff, and our recent acquisition of 4P Therapeutics, which is principally responsible for our business and was privately owned when we acquired it, were not effective as of January 31, 2020, such that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (ii) accumulated and communicated to the chief executive officer/chief financial officer, as appropriate to allow timely decisions regarding disclosure.

**Management’s Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act. Our management is also required to assess and report on the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 (“Section 404”). Management assessed the effectiveness of our internal control over financial reporting as of January 31, 2020. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. During our assessment of the effectiveness of internal control over financial reporting as of January 31, 2020, management identified material weaknesses related to (i) our internal audit functions (ii) inadequate levels of review of the financial statements and (iii) a lack of segregation of duties within accounting functions. Therefore, our internal controls over financial reporting were not effective as of January 31, 2020.

Management has determined that our internal controls contain material weaknesses due to the absence of segregation of duties, as well as lack of qualified accounting personnel, excessive reliance on third party consultants for accounting, financial reporting and related activities, and the lack of any separation of duties. Because of our financial condition it is unlikely that we will be able to implement effective internal controls over financial reporting in the near future.

Until we generate significantly greater revenues and employ accounting personnel, it is doubtful that we will be able implement any system which provides us with any degree of internal controls over financial reporting. Due to the nature of this material weakness in our internal control over financial reporting, there is more than a remote likelihood that misstatements which could be material to our annual or interim financial statements could not be prevented or detected.

A material weakness (within the meaning of PCAOB Auditing Standard No. 5) is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of our financial reporting.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness



to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

### Changes in Internal Control over Financial Reporting.

During the quarterly period ended January 31, 2020, there was no change in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### ITEM 9B. OTHER INFORMATION

None.

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## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### Executive Officers and Directors

Set forth below is certain information with respect to our directors and executive officers:

Name	Age	Position
Gareth Sheridan	30	Chief executive officer and director
Sean Gallagher	57	President and director
Serguei Melnik	47	Chief financial officer and director
Gerald Goodman	71	Chief accounting officer
Alan Smith, Ph.D.	54	Chief operating officer and president of 4P Therapeutics
Patrick Ryan	33	Chief technical officer
Jeff Patrick, Pharm.D.	50	Chief scientific officer
Larry Dillaha, MD	56	Chief medical officer
Radu Bujoreanu <sup>3</sup>	49	Director
Thomas Cooney	56	Director
Steven P. Damon	64	Director
Michael Doron <sup>2</sup>	58	Director
Mark Hamilton <sup>1,2,3</sup>	34	Director
Stefan Mancas <sup>1</sup>	43	Director
Jay Moore <sup>1</sup>	46	Director

1 Member of the Audit Committee

2 Member of the Compensation Committee

3 Member of the Nominating and Corporate Governance Committee

Gareth Sheridan, our founder, has been chief executive officer and a director since our organization in 2016. In 2012, Mr. Sheridan founded Nutriband Ltd., an Irish company which we acquired in 2016. Mr. Sheridan was named Ireland's 'Young Entrepreneur of the Year' in 2014 in the National Bank of Ireland Startup Awards for establishing Nutriband Ltd. Mr. Sheridan has further business awards from S. Dublin's Best Young Entrepreneur and Nutriband Ltd as S. Dublin's Best Startup Company. Mr. Sheridan has also worked as a Business Mentor with 100 Minds, a social enterprise founded in 2013, that brings together some of Ireland's top college students and connects them with one cause to achieve large charitable goals in a short space of time. Mr. Sheridan is also a past Nissan Generation Next Ambassador, receiving the acknowledgement in 2015 by Nissan Ireland as one of Ireland's future generational leaders. Mr. Sheridan received a B.Sc. in Business and Management from Dublin Institute of Technology in 2012 where he concentrated on international economics, venture creation and entrepreneurship.

Sean Gallagher has been president since February 2018 and a director since July 2018. Mr. Gallagher's business ventures include serving as chief executive officer of a commercial real estate company, Clyde Real Estate, which he founded in 2014, Ireland's largest home technology company, Smarthomes, which he founded in 2000, and a director of Team Horizon, a pharmaceutical engineering company, since 2015. Mr. Gallagher also stood, as an Independent candidate, and was runner up, in the 2011 Irish Presidential Election. From 1994 to 2000, he was vice chief executive officer of one of Ireland's Government Enterprise Agencies and has spent more than 20 years training and mentoring hundreds of start-ups and emerging entrepreneurs. Mr. Gallagher qualified with an MBA from the University of Ulster. Mr. Gallagher works for us on a part-time basis.

Serguei Melnik has been our chief financial officer and a director since January 2016. Mr. Melnik has been involved in general business consulting for companies in the U.S. financial markets and setting up the legal and financial framework for operations of foreign companies in the U.S. During the last twenty years Mr. Melnik, through his consulting company Wolf Blitz Inc., consulted on multiple international trade deals with the clients from Ecuador, Ukraine, Moldova, and Romania. Mr. Melnik received his law degree from Moldova State University.

Gerald Goodman has been our chief accounting officer since July 31, 2018. Mr. Goodman is a certified public accountant and, since 2014, has practiced with his own firm, Gerald Goodman CPA P.C. From January 1, 2010 until December 31, 2014, Mr. Goodman practiced with Madsen & Associates, CPA's Inc., Murray, Utah, and was a non-equity partner and managed the firm's SEC practice. Mr. Goodman is a director of Lifestyle Medical Network, Inc., which provides management services to healthcare providers. From 1971 to 2010, Mr. Goodman was a partner in the accounting firm of Wiener, Goodman & Company P.C. Mr. Goodman is a 1970 graduate of Pennsylvania State University where he received a B.S. Degree in Accounting. Mr. Goodman works for us on a part-time basis.

Alan Smith, Ph.D. has been our chief operating officer and president of 4P Therapeutics since December 2018. He served as our vice president, clinical, regulatory, quality, and operations from April 2018, when we signed the agreement to acquire 4P Therapeutics. Dr. Smith co-founded 4P Therapeutics in 2011. From 2000 until 2011, Dr. Smith was with Altea Therapeutics, most recently serving as vice president, product development and head of clinical research and development, regulatory affairs, and project management. At Altea, he led major research and development programs with pharmaceutical companies such as Eli Lilly, Amylin, Hospira, Elan, and Novartis. Dr. Smith has more than 20 years of experience in the research and development of transdermal drug and biologic delivery systems, as well as diagnostics and medical devices for treatment and management of diabetes, chronic pain and cardiovascular disease. Prior to joining Altea Therapeutics, he led the development of transdermal glucose monitoring systems at SpectRx, Inc., a publicly traded noninvasive diagnostics company. Dr. Smith received Ph.D. and M.S. degrees in biomedical engineering from Rutgers University and the University of Medicine and Dentistry of New Jersey. He currently serves on the Editorial Advisory Board of the journal Expert Opinion on Drug Delivery.

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Patrick Ryan has been chief technical officer since February 2018. Mr. Ryan also is also director of digital consultancy agency Trigger Media. From 2016 to September 2017, he was general manager of CRS Events. From 2013 to 2016, Mr. Ryan worked as an online security analyst with Paddy Power Betfair Plc. Mr. Ryan serves as technical advisor for sports media brand, Pundit Arena, where he has advised on technical development since 2012 and as a digital consultant for Irish Aid Charity,

Bóthar, where he works on the development of the charity's plans. Mr. Ryan has been involved in general technical consulting for startups and companies in Ireland for more than ten years. Mr. Ryan graduated with a Bachelors in Engineering from University College Dublin is working towards his masters in data analytics from National College of Ireland. Mr. Ryan works for us on a part-time basis.

Jeff Patrick, Pharm.D. has been our chief scientific officer since May 2018. He is also head of our scientific advisory board. Dr. Patrick has served as director of the Drug Development Institute at the Ohio State University Comprehensive Cancer Center since February 2017. Dr. Patrick served as chief scientific officer for New Haven Pharmaceuticals, Inc., a specialty pharmaceutical company, from October 2014 to February 2017. Dr. Patrick was global vice president of professional affairs at Mallinckrodt Pharmaceuticals, Inc. from April 2010 to August 2014. Dr. Patrick is a residency-trained clinical pharmacist with approximately 20 years of pharmaceutical industry experience. Dr. Patrick earned his B.S. and Pharm.D. degrees from the University of Tennessee. Dr. Patrick also completed the Wharton School of Business Pharmaceutical Executive Program. Dr. Patrick devotes only a portion of his time to our business. Dr. Patrick works for us on a part-time basis.

Larry Dillaha, M.D. has been our chief medical officer since August 2018. Dr. Dillaha also serves as a member of our scientific advisory board. Dr. Dillaha was chief executive officer of Repros Therapeutics, a development stage biopharmaceutical company focused on the development of oral small molecule drugs, from February 2017 to February 2018 and the chief executive officer of CavtheRx, an inception stage biotechnology company, from June 2016 to February 2017, and chief operating officer and chief medical officer of New Haven Pharmaceuticals, a specialty pharmaceutical company from April 2014 to January 2017. He also served as chief medical officer of Insys Therapeutics from March 2010 to March 2014. Dr. Dillaha received an M.D. degree from the University of Tennessee, Memphis. Dr. Dillaha works for us on a part-time basis.

Radu Bujoreanu has been a director since June 2019. Mr. Bujoreanu has been the owner and executive director of Consular Assistance, Inc., which provides assistance in obtaining visas for the Republic of Moldova and related services since December 2002, and he has been a real estate agent with Keller Williams Realty, Inc. since May 2019. Mr. Bujoreanu received his Bachelor in International Public Law from the University of Moldova.

Thomas Cooney has been a director since July 2018. Mr. Cooney is Professor of Entrepreneurship at the Dublin Institute of Technology, Academic Director of the DIT Institute for Minority Entrepreneurship, Adjunct Professor at the University of Turku (Finland) and Editor of the journal Small Enterprise Research. He is a former president of the International Council for Small Business (2012-13) and of the European Council for Small Business (2009-11), and was chair of the ICSB 2014 World Entrepreneurship Conference. He is a policy advisor to governments, European commission, OECD and other international organizations. He was a founding director of Startup Ireland and is a director of several businesses, and he works in various capacities with a range of commercial and not-for-profit enterprises. He has researched and published widely on the topic of entrepreneurship. Dr. Cooney received a B.Comm. from University College Cork, Ireland and an M.B.A from University of Bradford, England and his Ph.D. in 2001 from Trinity College, Ireland.

Steven P. Damon has been a director since April 2018, when we signed the agreement to acquire 4P Therapeutics. Mr. Damon is a co-founder of 4P Therapeutics, which was formed in 2011, and he has more than 20 years of experience with various business roles in the medical and pharmaceutical industries. Before founding 4P Therapeutics, Mr. Damon led the business development team at Altea Therapeutics as the company's senior vice president of business development. Mr. Damon is a director of Georgia BIO, a non-profit trade association that promotes Georgia's life science industry. Mr. Damon received his Bachelors in Business Administration and Associate in accounting from Colorado Mesa University.

Michael Doron, a director since July 2018, is the co-founding partner at Cidron Ventures AB. Cidron Ventures, a venture capital funds specializing in Series A and B financings of disruptive technology companies across the Nordic region. The fund's core focus is on capital efficient and B2B software propositions. Previously, Mr. Doron served on non-profit boards for more than 11 years while being active in several community service organizations. Mr. Doron attended The University of Maryland and American University.

Mark Hamilton, a director since July 2018, has been at BDO Ireland, a major accounting firm, for more than nine years, held positions in Corporate Finance, Corporate Advisory, Restructuring and Recovery, Client management and in his current role in Business Development. Mr. Hamilton is a Chartered Accountant and a member of the Association of Chartered Accountants (ACA) qualifying in 2012. He is a chartered accountant and has been a member of the Association of Chartered Accountants since 2012. Mr. Hamilton's accounting background and experience in corporate finance, corporate advisory and insolvency assists us in his role as an independent board member. Mr. Hamilton received a B.Sc. in Business and Management from Dublin Institute of Technology in 2008 and subsequently received 1st class honours in his postgraduate degree specializing in Accountancy in 2009.

Stefan Mancas, a director since July 2018, received a Ph.D. in Applied Mathematics from the University of Central Florida in May 2007 under the supervision of Dr. Roy S. Choudhury, with the dissertation topic "Dissipative Solitons in the cubic-quintic Complex Ginzburg Landau equation: Bifurcations and Spatiotemporal Structure" for which he received the Outstanding Dissertation Award in 2008. Dr. Mancas is a professor and associate chair in the department of mathematics at Embry-Riddle Aeronautical University. He is the co-founder of the nonlinear Waves Lab which contains a 10 m. long water tank used for research in water waves, solitons in shallow water, vortex solitons, soliton ships, surface waves and wind-wave interaction, microcavitation, design and optimization, submarine currents, autonomous underwater vehicles, tractor beams, etc. He is also the organizer of national and international conferences in applied mathematics, and has published more than 40 articles in refereed journals.

Jay Moore, a director since July 2018, is a marketing executive with more than 20 years of accomplishments in Internet technologies, web services, professional sports, and entertainment. He is currently the vice president of marketing for StackPath, a global platform of secure edge services, a position he has held since February 2017. From October 2007 to February 2017, Mr. Moore was vice president of marketing for Highwinds Network Group, Inc., a content delivery network. Mr. Moore holds a Bachelor's Degree in Communication Studies from the University of California, Santa Barbara and a Master's Degree in Sports Administration from Florida State University.

#### **Committees of the Board of Directors**

The board of directors has created two committees - the audit committee and the compensation committee. The board intends to create a nominating and corporate governance committee. Each of the committees will have a charter which meets the NASDAQ requirements and will be composed of three independent directors.

##### *Audit Committee*

The audit committee is comprised of Mr. Hamilton, as chairman, Dr. Mancas and Mr. Moore. We do not have an "audit committee financial expert." The audit committee oversees, reviews, acts on and reports on various auditing and accounting matters to the board, including: the selection of our independent accountants, the scope of our annual audits, fees to be paid to the independent accountants, the performance of our independent accountants and our accounting practices, all as set forth in our audit committee charter.

##### *Compensation Committee*

The compensation committee is comprised of Michael Doron and Mark Hamilton. The compensation committee oversees the compensation of our chief executive officer and our other executive officers and reviews our overall compensation policies for employees generally as set forth in the audit committee charter. If so authorized by the board, the compensation committee may also serve as the granting and administrative committee under any option or other equity-based compensation plans which we may adopt. The compensation committee will not delegate its authority to fix compensation; however, as to officers who report to the chief executive officer, the compensation committee will consult with the chief executive officer, who may make recommendations to the compensation committee. Any recommendations by the chief executive officer are accompanied by an analysis of the basis for the recommendations. The committee will also discuss with the chief executive officer and other responsible officers the compensation policies for employees who are not officers. The compensation committee has the responsibilities and authority relating to the retention, compensation, oversight and funding of compensation consultants, legal counsel and other compensation advisers. The compensation committee members will consider the independence of such advisors before selecting or receiving advice from such



Sean Gallagher, President <sup>1</sup>	2020	-	-	\$ 60,000	-	-	-	-	60,000
	2019	-	-	462,500	-	-	-	-	462,500
Jeff Patrick Chief Scientific Officer <sup>1</sup>	2020	-	-	60,000	252,700	-	-	-	312,700
	2019	-	-	222,500	-	-	-	-	222,500

1 During the year ended January 31, 2020, we issued to Mr. Gallaher 8,572 shares of common stock, valued at \$120,000, representing his compensation for the years ended January 31, 2020 and 2019 pursuant to his employment agreement. During the year ended January 31, 2019, we issued to Mr. Gallagher 25,000 shares of common stock valued at \$402,500.

2 During the year ended January 31, 2020, we issued to Strategic Pharmaceutical Consulting LLC, a company controlled by Dr. Patrick 8,572 shares of common stock, valued at \$120,000, representing Dr. Patrick's compensation for the years ended January 31, 2020 and 2019. We also granted him to an option to purchase 25,000 shares of common stock at 75% of the market price. The option expired unexercised. During the year ended January 31, 2019, the Company issued to Mr. Patrick 12,500 shares of common stock valued at \$162,500.

### Employment Agreements

We have employment agreement with Gareth Sheridan and Sergei Melnik dated February 1, 2018 pursuant to which we agree to employ Mr. Sheridan as chief executive officer and Mr. Melnik as chief financial officer. The agreements also provide that the executive will continue as a director. The agreements provide that employment is ongoing, with no specific termination date. The agreement does not provide for any specific salary. Mr. Sheridan is currently receiving compensation at the annual rate of \$42,000, and Mr. Melnik is not currently receiving any compensation.

We have an employment agreement dated January 1, 2018 with Sean Gallagher pursuant to which we employed him as president for a term with no expiration date at an annual salary of \$60,000, which may be paid in stock or cash. The president serves on a part-time basis.

The Company has an employment agreement dated February 19, 2019 with its chief scientific officer pursuant to which the Company agrees to employ him as chief scientific officer for annual compensation of \$60,000, payable in cash or stock, as the Company may elect. The agreement has a term ending on February 13, 2021 and continues thereafter on a year to year basis unless terminated by either party on 30 days' notice. The chief scientific officer serves on a part-time basis.

### Director Compensation

During the year ended January 31, 2019, we issued 1,250 shares of common stock, valued at \$37,000, based on the market price on the date of issuance, as compensation to each of our independent directors – Thomas Cooney, Michael Davidov, Michael Doron, Mark Hamilton, Stefan Mancas and Jay Moore.

### Pension Benefits

We currently have no plans that provide for payments or other benefits at, following, or in connection with retirement of our officers.

### Outstanding Equity Awards at Fiscal Year-End

There are no outstanding equity awards at January 31, 2020.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table provides information as to shares of common stock beneficially owned as of April 10, 2020, by:

- Each director;
- Each current officer named in the summary compensation table;
- Each person owning of record or known by us, based on information provided to us by the persons named below, at least 5% of our common stock; and
- All directors and officers as a group.

For purposes of the following table, "beneficial ownership" means the sole or shared power to vote, or to direct the voting of, a security, or sole or shared investment power with respect to a security, or any combination thereof, and the right to acquire such power (for example, through the exercise of warrants granted by us) within 60 days of April 10, 2020. At April 10, 2020, 5,512,928 shares of common stock were outstanding.

Name and Address <sup>1</sup> of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage
Gareth Sheridan	1,500,000	27.21%
Vitalie Botgros	750,000	13.60%
Serguei Melnik <sup>2</sup>	707,500	12.83%
Steven Damon	41,750	*
Sean Gallagher	33,572	*
Dr. Larry Dillaha	12,500	*
Stefan Mancas	1,625	*
Thomas Cooney	1,250	*
Michael Doron	1,250	*
Mark Hamilton	1,250	*
Jay Moore	10,251	*
Radu Bujoreanu	-	*
Dr. Jeff Patrick <sup>3</sup>	21,072	*
Patrick Ryan	2,500	*
All officers and directors as a group (16 individuals) <sup>2,3</sup>	3,128,992	56.8%

\* Less than 1%

1 The address is c/o Nutriband, Inc., 121 South Orange Ave., Suite 1500, Orlando, FL 32801.

2 Includes 100,000 shares owned by Mr. Melnik's wife, as to which Mr. Melnik disclaims beneficial interest, and 100,000 shares owned by each of his two minor

children.

- 3 Includes 21,072 shares owned by Strategic Pharmaceutical Consulting, with respect to which Dr. Jeff Patrick, chief scientific officer, has the power to vote and dispose of the shares, and 2,500 shares owned by Trigger Movement, as to which Patrick Ryan, chief technical officer, has the power to vote and dispose of the shares.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

During the year ended January 31, 2020, Serguei Melnik, our chief financial officer, and Dr. Alan Smith, our chief operating officer, advanced us \$33,317, of which \$29,730 was repaid. As of January 31, 2020, the amounts due the officers was \$29,067, which is non-interest bearing.

On January 31, 2020, we issued 8,572 shares to each of Sean Gallagher and to Strategic Pharmaceutical Consulting LLC, which is controlled by Jeff Patrick, for services rendered by Mr. Gallaher and Dr. Patrick valued at \$120,000. These issuances were made pursuant to employment agreements with Mr. Gallagher and Dr. Patrick which provide for annual compensation of \$60,000 and represented compensation for the years ended December 31, 2019 and 2018.

#### Director Independence

Six of our directors, Radu Bujoreanu, Thomas Cooney, Michael Doron, Mark Hamilton, Stefan Mancas and Jay Moore, are independent directors based on the NASDAQ definition of independent director.

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### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the fees billed by our independent accountants, Sadler, Gibb & Associates, LLC, for each of our last two years for the categories of services indicated.

	Year Ended January 31	
	2020	2019
Audit fees	\$ 42,469	\$ 24,500
Audit – related fees	23,325	33,700
Tax fees	-	-
All other fees	-	-
Total Fees	\$ 65,794	\$ 58,200

Audit fees consist of fees related to professional services rendered in connection with the audit of our annual financial statements and review of our interim financial statements.

All other fees relate to professional services rendered in connection our proposed registration statement and acquisition audit.

Our policy is to pre-approve all audit and permissible non-audit services performed by the independent accountants. These services may include audit services, audit-related services, tax services and other services. Under our audit committee's policy, pre-approval is generally provided for particular services or categories of services, including planned services, project based services and routine consultations. In addition, the audit committee may also pre-approve particular services on a case-by-case basis. Our board approved all services that our independent accountants provided to us in the past two fiscal years.

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## PART IV

### ITEM 15. EXHIBITS

#### Exhibits

Exhibit Number	Description
3.1A	<a href="#">Articles of Incorporation. (Filed as Exhibit 3.1A to the the Company's registration statement on Form 10, which was filed with the Commission on June 2, 2016, and incorporated herein by reference.)</a>
3.1B	<a href="#">Amendment to Articles of Incorporation, filed May 12, 2016. 2(Filed as Exhibit 3.1B to the the Company's registration statement on Form 10, which was filed with the Commission on June 2, 2016, and incorporated herein by reference.)</a>
3.1	<a href="#">Certificate of Amendment filed January 22, 2020. (Filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed January 27, 2020).</a>
3.2	<a href="#">By-laws<sup>(1)</sup></a>
4.3	<a href="#">Securities purchase agreement dated October 29, 2019 among the Company, Jefferson Street Capital LLC and Platinum Point Capital LLC<sup>(7)</sup></a>
4.4	<a href="#">Form of convertible 6% promissory note issued pursuant to Exhibit 4.3<sup>(7)</sup></a>
10.1	<a href="#">Share exchange agreement dated January 15, 2016 by and among the Company, Nutriband Limited, an Ireland corporation, and Gareth Sheridan and/or his nominee<sup>(1)</sup></a>
10.2	<a href="#">Quality agreement, dated July 19, 2016, between Pocono Coated Products LLC and the Company.<sup>(1)</sup></a>
10.4	<a href="#">Acquisition agreement dated April 5, 2018 between the Company and 4P Thereapeutics LLC.<sup>(3)</sup></a>
10.5	<a href="#">Form of agreement with independent directors.<sup>(4)</sup></a>
10.6	<a href="#">Exclusive master distribution agreement dated April 13, 2018 between the Company and EMI-Korea (Best Choice), Inc.<sup>(4)</sup></a>
31	<a href="#">Certification of Chief Executive Officer and Financial Officers pursuant to Rule 13A-14(A)/15D-14(A) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002<sup>(6)</sup></a>
32	<a href="#">Certification of Chief Executive and Financial Officers Pursuant to 18 U.S.C. 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)<sup>(6)</sup></a>
99.1	<a href="#">Audit Committee Charter<sup>(4)</sup></a>
99.2	<a href="#">Compensation Committee Charter<sup>(4)</sup></a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema Document
101.CAL	XBRL Taxonomy Calculation Document
101.DEF	XBRL Taxonomy Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document

- (1) Filed as exhibit to the Company's registration statement on Form 10, which was filed with the Commission on June 2, 2016, and incorporated herein by reference.
- (2) Filed as an exhibit to the Company's report on Form 8-K, which was filed with the Commission on May 23, 2017 and incorporated herein by reference.
- (3) Filed as an exhibit to the Company's report on Form 8-K, which was filed with the Commission on April 10, 2018 and incorporated herein by reference.
- (4) Filed as an exhibit to the Company's annual report on Form 10-K for the year ended January 3, 2019 which was filed with the Commission on April 19, 2019, and incorporated herein by reference.
- (5)
- (6) Filed herewith.
- (7) Filed as an exhibit to the Company's report on Form 8-K, which was filed with the Commission on November 4, 2019.

#### ITEM 16. FORM 10-K SUMMARY

Not applicable.

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#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: April 14, 2020

#### NUTRIBAND INC

By: /s/ Gareth Sheridan

Name: Gareth Sheridan

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated. Each person whose signature appears below hereby authorizes Gareth Sheridan and Serguei Melnik, and each of them acting singly, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution for him or her and in his or her name, place and stead, in any and all capacities to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission.

Signature	Title	Date
<u>/s/ Gareth Sheridan</u> Gareth Sheridan	Chief executive officer and director (principal executive officer)	April 14, 2020
<u>/s/ Serguei Melnik</u> Serguei Melnik	Chief financial officer and director (principal financial officer)	April 14, 2020
<u>/s/ Gerald Goodman</u> Gerald Goodman	Chief accounting officer	April 14, 2020
<u>/s/ Steven P. Damon</u> Steven P. Damon	Director	April 14, 2020
<u>/s/ Thomas Cooney</u> Thomas Cooney	Director	April 14, 2020
<u>/s/ Radu Bujoreanu</u> Radu Bujoreanu	Director	April 14, 2020
<u>/s/ Michael Doron</u> Michael Doron	Director	April 14, 2020
<u>Sean Gallagher</u>	Director	April , 2020
<u>/s/ Mark Hamilton</u> Mark Hamilton	Director	April 14, 2020
<u>/s/ Stefan Mancas</u> Stefan Mancas	Director	April 14, 2020
<u>/s/ Jay Moore</u> Jay Moore	Director	April 14, 2020

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NUTRIBAND INC.  
January 31, 2019

<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheets at January 31, 2020 and 2019</a>	F-3
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the years ended January 31, 2020 and 2019</a>	F-4
<a href="#">Consolidated Statements of Changes in Stockholder's Equity (Deficit) for the years ended January 31, 2020 and 2019</a>	F-5
<a href="#">Consolidated Statements of Cash Flows for the years ended January 31, 2020 and 2019</a>	F-6
<a href="#">Notes to Consolidated Financial Statements</a>	F-7

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of Nutriband Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nutriband Inc. ("the Company") as of January 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended January 31, 2020 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of January 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended January 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has limited revenues. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Sadler, Gibb & Associates, LLC

We have served as the Company's auditor since 2016.

Salt Lake City, UT  
April 13, 2020

NUTRIBAND INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	January 31,	
	2020	2019
<u>ASSETS</u>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,181	\$ 474,653
Accounts receivable	12,833	13,088
Prepaid expenses	20,167	102,725
Total Current Assets	<u>43,181</u>	<u>590,466</u>
PROPERTY & EQUIPMENT-net	<u>111,029</u>	<u>146,147</u>
OTHER ASSETS:		
Goodwill	1,719,235	1,719,235
Right of use operating lease asset-net	9,610	-
Intangible assets-net	<u>314,700</u>	<u>351,770</u>
<b>TOTAL ASSETS</b>	<b><u>\$ 2,197,755</u></b>	<b><u>\$ 2,807,618</u></b>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 771,931	\$ 291,781
Customer deposits	-	71,225

Operating lease liability	10,050	-
Derivative liability	928,774	-
Notes payable-related party	29,067	-
Notes payable	215,000	40,000
Convertible debt- net of debt discount of \$202,500 and \$-0- as of January 31, 2020 and 2019, respectively	67,500	-
Total Current Liabilities	<u>2,022,322</u>	<u>403,006</u>
Commitments and Contingencies	-	-
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$.001 par value, 10,000,000 shares authorized, -0- outstanding	-	-
Common stock, \$.001 par value, 250,000,000 shares and 25,000,000 shares authorized; 5,441,100 and 5,423,956 shares issued and outstanding at January 31, 2020 and 2019, respectively	5,441	5,424
Additional paid-in-capital	9,072,573	8,579,890
Accumulated other comprehensive loss	(304)	(52)
Accumulated deficit	(8,902,277)	(6,180,650)
Total Stockholders' Equity	<u>175,433</u>	<u>2,404,612</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 2,197,755</u>	<u>\$ 2,807,618</u>

See notes to consolidated financial statements

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NUTRIBAND INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended January 31,	
	2020	2019
Revenue	\$ 370,647	\$ 245,285
Costs and expenses:		
Cost of revenues	549,107	288,301
Selling, general and administrative expenses	1,790,980	3,288,224
Total Operating Costs and Expenses	<u>2,340,087</u>	<u>3,576,525</u>
Loss from operations	(1,969,440)	(3,331,240)
Other income (expense)		
Derivative expense	(767,650)	-
Gain on change in fair value of derivative	88,876	-
Interest expense	(73,413)	-
Total other income (expense)	<u>(752,187)</u>	<u>-</u>
Loss from operations before provision for income taxes	(2,721,627)	(3,331,240)
Provision for income taxes	-	-
Net loss	<u>\$ (2,721,627)</u>	<u>\$ (3,331,240)</u>
Net loss per share of common stock-basic and diluted	<u>(0.50)</u>	<u>(0.62)</u>
Weighted average shares of common stock outstanding - basic and diluted	<u>5,423,956</u>	<u>5,352,321</u>
<b>Other Comprehensive Loss:</b>		
Net loss	\$ (2,721,627)	\$ (3,331,240)
Foreign currency translation adjustment	(252)	394
Total Comprehensive Loss	<u>\$ (2,721,879)</u>	<u>\$ (3,330,846)</u>

See notes to consolidated financial statements

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NUTRIBAND INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Total	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income(Loss)	Accumulated Deficit
		Number of shares	Amount			
Balance, February 1, 2018	\$ 121,508	5,219,275	\$ 5,219	\$ 2,966,145	\$ (446)	\$ (2,849,410)
Issuance of common stock for services	1,763,950	80,500	81	1,763,869	-	-



Sale of common stock for cash	1,500,000	80,431	80	1,499,920	-	-
Common stock issued on the exercise of warrants	500,000	31,250	31	499,969	-	-
Cancellation of common stock	-	(50,000)	(50)	50	-	-
Common stock issued for acquisition	1,850,000	62,500	63	1,849,937	-	-
Foreign currency translation adjustment	394	-	-	-	394	-
Net loss for the year ended January 31, 2019	<u>(3,331,240)</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(3,331,240)</u>
Balance, January 31, 2019	2,404,612	5,423,956	5,424	8,579,890	(52)	(6,180,650)
Issuance of warrants for services	252,700	-	-	252,700	-	-
Issuance of common stock for accounts payable	240,000	17,144	17	239,983	-	-
Net loss for the year ended January 31, 2020	<u>(2,721,627)</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(2,721,627)</u>
Foreign currency translation adjustment	(252)	-	-	-	(252)	-
Balance, January 31, 2020	<u>\$ 175,433</u>	<u>5,441,100</u>	<u>\$ 5,441</u>	<u>\$ 9,072,573</u>	<u>\$ (304)</u>	<u>\$ (8,902,277)</u>

See notes to consolidated financial statements

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NUTRIBAND INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended January 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (2,721,627)	\$ (3,331,240)
Adjustments to reconcile net loss to net cash used in operating activities:		
Expenses paid on behalf of the Company by related party	23,817	24,300
Depreciation and amortization	72,188	37,011
Derivative expense	767,650	-
Gain on change in fair value of derivative	(88,876)	-
Amortization of debt discount	67,500	-
Amortization of right of use asset	19,217	-
Stock-based compensation	252,700	1,763,950
Changes in operating assets and liabilities:		
Accounts receivable	255	(12,825)
Prepaid expenses	82,558	57,778
Inventories	-	4,133
Customer deposits	(71,225)	71,225
Operating lease liability	(18,777)	-
Accounts payable and accrued expenses	720,150	280,202
Net Cash Used In Operating Activities	<u>(894,470)</u>	<u>(1,105,466)</u>
Cash flows from investing activities:		
Payment on acquisition	-	(400,000)
Purchase of equipment	-	(4,163)
Net Cash Used in Investing Activities	<u>-</u>	<u>(404,163)</u>
Cash flows from financing activities:		
Payment of bank overdraft	-	(762)
Proceeds from sale of common stock	-	1,500,000
Proceeds from exercise of warrants	-	500,000
Proceeds from notes payable	175,000	25,000
Proceeds from convertible debt	250,000	-
Payment of notes payable	-	(1,820)
Proceeds from related parties	34,980	2,500
Payment of related party payables	(29,730)	(41,030)
Net Cash Provided by Financing Activities	<u>430,250</u>	<u>1,983,888</u>
Effect of exchange rate on cash	<u>(252)</u>	<u>394</u>
Net change in cash	<u>(464,472)</u>	<u>474,653</u>
Cash and cash equivalents - Beginning of period	<u>474,653</u>	<u>-</u>
Cash and cash equivalents - End of period	<u>\$ 10,181</u>	<u>\$ 474,653</u>
Supplementary information:		
Cash paid for:		

Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
Supplemental disclosure of non-cash investing and financing activities		
Common stock to be issued for services	\$ -	\$ 1,763,950
Adoption of ASC 842 Operating lease asset and liability	\$ 28,827	\$ -
Debt discount on convertible notes	\$ 270,000	\$ -
Common issued for services	\$ 240,000	\$ -
Details of Acquisition:		
Assets purchased		
Equipment	\$ -	\$ 160,065
Intangible Asset	-	2,089,935
	-	2,250,000
Liabilities assumed	-	-
Net assets purchased	-	2,250,000
Common stock issued	-	(1,850,000)
Cash paid	\$ -	\$ 400,000

See notes to consolidated financial statements

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NUTRIBAND INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
AS OF AND FOR THE YEARS ENDED JANUARY 31, 2020 AND 2019

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Nutriband Inc. (the “Company”) is a Nevada corporation, incorporated on January 4, 2016. In January 2016, the Company acquired Nutriband Ltd, an Irish company which was formed by the Company’s chief executive officer in 2012 to enter the health and wellness market by marketing transdermal patches. References to the Company relate to the Company and its subsidiaries unless the context indicates otherwise.

On August 1, 2018, the Company acquired 4P Therapeutics LLC (“4P Therapeutics”) for \$2,250,000, consisting of 250,000 shares of common stock, valued at \$1,850,000, and \$400,000, and a royalty of 6% on all revenue generated by the Company from the abuse deterrent intellectual property that had been developed by 4P Therapeutics payable to the former owner of 4P Therapeutics. The former owner of 4P Therapeutics has been a director of the Company since April 2018, when the Company entered into an agreement to acquire 4P Therapeutics.

4P Therapeutics is engaged in the development of a series of transdermal pharmaceutical products, that are in the preclinical stage of development. Prior to the acquisition of 4P Therapeutics, the Company’s business was the development and marketing of a range of transdermal consumer patches. Most of these products are considered drugs in the United States and cannot be marketed in the United States without approval by the Food and Drug Administration (the “FDA”). The Company is not presently taking any steps to seek FDA approval of its consumer transdermal products and its consumer products are not being marketed in the United States.

With the acquisition of 4P Therapeutics, 4P Therapeutics’ drug development business became the Company’s principal business. The Company’s approach is to use generic drugs that are off patent and incorporate them into the Company’s transdermal drug delivery system. Although these medications have received FDA approval in oral or injectable form, the Company needs to conduct a transdermal product development program which will include the preclinical and clinical trials that are necessary to receive FDA approval before we can market any of our pharmaceutical products.

Reverse Stock Split

On June 25, 2019, the Company effected one-for-four reverse split, pursuant to which each share of common stock became and was converted into 0.25 share of common stock. The reverse split became effective in the marketplace on July 24, 2019. All share and per share information in these financial statements retroactively reflect the reverse split.

Going Concern

The Company’s consolidated financial statements for the year ended January 31, 2020 have been prepared on a going concern basis which contemplates the realization of assets and settlement of liabilities in the normal course of business. The Company did not generate any revenue prior to the quarter ended October 31, 2018. For the year ended January 31, 2020, the Company generated revenue of \$370,647 on which it recorded cost of revenues of \$549,107 and a loss from operations of \$1,969,440. Subsequent to January 31, 2020, because of the lack of available cash and the decline in business resulting in part from the effects of the COVID-19 pandemic, the Company has temporarily closed its operations, and does not expect that it will be able to commence operations until it received substantial funding. Successful business operations and its transition to attaining profitability are dependent upon obtaining additional financing and achieving a level of revenue to support its cost structure, developing its products and obtaining FDA approval to market any product it develops and implementing a marketing program for such products. These factors raise substantial doubt about ability of the Company to continue as a going concern for a period of at least one year from the date of issuance of these financial statements. Without such financing, the Company may not be able to continue in business. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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The consolidated financial statements of the Company include the Company and its wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated. The operations of 4P Therapeutics are included in the Company's financial statements from the date of acquisition of August 1, 2018.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates including, but not limited to, those related to such items as income tax exposures, accruals, depreciable/useful lives, allowance for doubtful accounts and valuation allowances. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash equivalents include short-term investments in money-market funds and certificate of deposits with an original maturity of three months or less when purchased.

Foreign Currency Translation

The functional currency of the Company's Irish subsidiary is the Euro. The assets and liabilities of the subsidiary are translated into US dollars using the prevailing exchange rate as of the balance sheet date and income and expenses are translated into US dollars using the average exchange rate during the reporting period. Translation adjustments are recorded in other comprehensive income (loss).

Revenue Recognition

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which amends the accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled when products are transferred to a customer. The Company adopted the guidance under the new revenue standards using the modified retrospective method effective February 1, 2018 and determined no cumulative effect adjusted to retained earnings was necessary upon adoption. Topic 606 requires the Company to recognize revenues when control of the promised goods or services and receipt of payment is probable. The Company recognizes revenue based on the five criteria for revenue recognition established under Topic 606: 1) identify the contract, 2) identify separate performance obligations, 3) determine the transaction price, 4) allocate the transaction price among the performance obligations, and 5) recognize revenue as the performance obligations are satisfied.

Revenue Types

The following is a description of the Company's revenue types, which include professional services and sale of consumer products:

- Professional services include the contract of research and development related services with the Company's clients in the life sciences field on an as-needed basis. Deliverables primarily consist of detailed findings and conclusion reports provided to the client for each given research project engaged.
- Sales revenues are derived from the sale of the Company's consumer products. Upon the reception of a purchase order, we have the order filled and shipped.

Contracts with Customers

A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods or services to be transferred and identifies the payment terms related to these goods or services, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in the new revenue standard. The contract transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. For the Company's different revenue service types, the performance obligation is satisfied at different times. The Company's performance obligations include providing products and professional services in the area of research. The Company recognizes product revenue performance obligations in most cases when the product has shipped to the customer. When we perform professional service work, we recognize revenue when we have the right to invoice the customer for the work completed, which typically occurs on a monthly basis for the work performed during that month.

All revenue recognized in the income statement is considered to be revenue from contracts with customers.

Disaggregation of Revenues

The Company disaggregates its revenue from contracts with customers by service type and by geographical location. See the tables:

	Years Ended January 31,	
	2020	2019
Revenue by service type		
Sale of goods	\$ 124,958	\$ 49,000
Services	245,679	196,285
Total	\$ 370,637	\$ 245,285

	Years Ended January 31,	
	2020	2019
Revenue by geographical location		
United States	\$ 245,679	\$ 196,285
Non-United States	124,958	49,000
Total	\$ 370,637	\$ 245,285

### Accounts receivable

Trade accounts receivable are recorded at the net invoice value and are not interest bearing. The Company maintains allowances for doubtful accounts for estimated losses from the inability of its customers to make required payments. The Company determines its allowances by both specific identification of customer accounts where appropriate and the application of historical loss to non-specific accounts. For the years ended January 31, 2020 and 2019, the Company recorded no bad debt expense and no allowance for doubtful accounts related to accounts receivable.

### Inventories

Inventories are valued at the lower of cost and realizable value determined using the first-in, first-out (FIFO) method. Net realizable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses. The cost of finished goods and work in progress is comprised of material costs, direct labor costs and other direct costs and related production overheads (based on normal operating capacity).

### Property, Plant and Equipment

Property and equipment represent an important component of the Company's assets. The Company depreciates its plant and equipment on a straight-line basis over the estimated useful life of the assets. Property, plant and equipment is stated at historical cost. Expenditures for minor repairs, maintenance and replacement parts which do not increase the useful lives of the assets are charged to expense as incurred. All major additions and improvements are capitalized. Depreciation is computed using the straight-line method. The lives over which the fixed assets are depreciated range from 3 to 5 years as follows:

Lab Equipment	5 years
Furniture, fixtures and equipment	3 years

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### Intangible Assets

Intangible assets include trademarks, intellectual property and customer base acquired through business combinations. The Company accounts for Other Intangible Assets under the guidance of ASC 350, "Intangibles-Goodwill and Other." The Company capitalizes certain costs related to patent technology. A substantial component of the purchase price related to the Company's acquisition has also been assigned to intellectual property and other intangibles. Under the guidance, other intangible assets with definite lives are amortized over their estimated useful lives. Intangible assets with indefinite lives are tested annually for impairment. Trademarks, intellectual property and customer base are being amortized over their estimated useful lives of ten years.

### Goodwill

Goodwill represents the difference between the total purchase price and the fair value of assets (tangible and intangible) and liabilities at the date of acquisition. Goodwill is reviewed for impairment annually on January 31, and more frequently as circumstances warrant, and written down only in the period in which the recorded value of such assets exceed their fair value. The Company does not amortize goodwill in accordance with ASC 350.

### Long-lived Assets

Management reviews long-lived assets for potential impairment whenever significant events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment exists when the carrying amount of the long-lived asset is not recoverable and exceeds its fair value. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the estimated undiscounted cash flows expected to result from the use and eventual disposition of the asset. If an impairment exists, the resulting write-down would be the difference between fair market value of the long-lived asset and the related net book value.

### Stock-Based Compensation

ASC 718, "Compensation - Stock Compensation," prescribes accounting and reporting standards for all share-based payment transactions in which employee services, and, since February 1, 2019, non-employees, are acquired. Transactions include incurring liabilities, or issuing or offering to issue shares, options and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the financial statements based on their fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period). As of February 1, 2019, pursuant to ASC 2018-07, ASC 718 was applied to stock-based compensation for both employees and non-employees.

### Business Combinations

The Company recognizes the assets acquired, the liabilities assumed, and any non-controlling interest in the acquired entity at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the accounting literature. In accordance with this guidance, acquisition-related costs, including restructuring costs, must be recognized separately from the acquisition and will generally be expensed as incurred. That replaces the cost-allocation process detailed in previous accounting literature, which required the cost of an acquisition to be allocated to the individual assets acquired and liabilities assumed based on their estimated fair value.

### Leases

In February 2016, the FASB issued ASU 2016-02, "Leases" (Topic 842), to provide a new comprehensive model for lease accounting under this guidance, lessees and lessors should apply a "right-of-use" model in accounting for all leases (including subleases) and eliminate the concept of operating leases and off-balance-sheet leases. Recognition, measurement and presentation of expenses will depend on classification as a finance or operating lease. Similar modifications have been made to lessor accounting in-line with revenue recognition guidance.

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The Company adopted ASU 2016-02 as amended effective February 1, 2019 using the modified retrospective approach. In connection with the adoption, the Company elected to utilize the Comparative Under 840 Option whereby the Company will continue to present prior period financial statements and disclosures under ASC 840. In addition, the Company elected the transition package of three practical expedients permitted under the standard, which eliminates the requirements to reassess prior conclusions about lease identification, lease classification and initial direct costs. The Company completed the necessary changes to its accounting policies, processes, disclosure and internal control over financial reporting.

Adoption of the new standard resulted in the recording of right-to-use assets in the amount of \$28,827 and lease liabilities related to operating leases in the amount of \$28,827 on the Company's consolidated balance sheet as of February 1, 2019. See Note 11, Leases, for Topic 842 disclosures in connection with the

Research and Development

Research and developments costs are expensed as incurred.

Income Taxes

Taxes are calculated in accordance with taxation principles currently effective in the United States and Ireland.

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company records net deferred tax assets to the extent they believe these assets will more-likely-than-not be realized. In making such determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. In the event the Company was to determine that it would be able to realize its deferred income tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the valuation allowance which would reduce the provision for income taxes.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash.

The Company's cash and cash equivalents are concentrated primarily in banks. At times, such deposits could be in excess of insured limits. Management believes that the financial institutions that hold the Company's financial instruments are financially sound and, accordingly, minimal credit risk is believed to exist with respect to these financial instruments. As of and for the years ended January 31, 2020 and 2019, three customers accounted for 100% of the Company's revenues and two customers accounted for 100% of accounts receivable.

Earnings Per Share

Basic earnings per share of common stock is computed by dividing net earnings by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed by dividing net earnings by the weighted average number of shares of common stock and potential shares of common stock outstanding during the period. Potential shares of common stock consist of outstanding common stock purchase warrants. For the years ended January 31, 2020 and 2019 there were 83,116 and 182,500 potential shares of common stock that were not included in the calculation of diluted earnings per share as their effect would be anti-dilutive.

Fair Value Measurements

FASB ASC 820, "Fair Value Measurements and Disclosure" ("ASC 820"), defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be to measure fair value.

The Company utilizes the accounting guidance for fair value measurements and disclosures for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis during the reporting period. The fair value is an exit price, representing the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants based upon the best use of the asset or liability at the measurement date. The Company utilizes market data or assumptions that market participants would use in pricing the asset or liability. ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers are defined as follows:

Level 1 -Observable inputs such as quoted market prices in active markets.

Level 2 -Inputs other than quoted prices in active markets that are either directly or indirectly observable.

Level 3 -Unobservable inputs about which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The carrying value of the Company's financial instruments including cash and cash equivalents, accounts receivable, prepaid expenses, and accrued expenses approximate their fair value due to the short maturities of these financial instruments.

Derivative liabilities are determined based on "Level 3" inputs, which are significant and unobservable and have the lowest priority. The recorded values of all other financial instruments approximate their current fair value because of their nature and respective short maturity dates or durations.

The Company's financial assets and liabilities carried at fair value measured on a recurring basis as of January 31, 2020, consisted of the following:

Description:	Total fair value at January 31, 2020 \$	Quoted prices in active markets (Level 1) \$	Significant other observable inputs (Level 2) \$	Significant other unobservable inputs (Level 3) \$
Derivative liability (1)	928,774	-	-	928,774
Total	928,774	-	-	928,774

(1) The Company has estimated the fair value of this liability using the Monte Carlo Model.

Derivative Liabilities

The Company accounts for derivative instruments in accordance with ASC Topic 815, "Derivatives and Hedging" and all derivative instruments are reflected as either assets or liabilities at fair value on the balance sheet. The Company uses estimates at fair value to value its derivative instruments. Fair value is defined as the price to sell an asset or transfer a liability in an orderly transaction between willing and able market participants. In general, the Company's policy in

estimating fair values is to first look at observable market prices for identical assets and liabilities in active markets, when available. When these are not available, other inputs are used to model fair value such as prices of similar instruments, yield curves, volatilities, prepayment speeds, default rates and credit spreads, relying first on observable data from active markets. Depending on the availability of observable inputs and prices, different valuation models could produce materially different fair value estimates. The value presented may not represent future fair values and may not be reliable. The Company categorizes its fair value estimates in accordance with ASC 820 based on the hierarchical framework associated with the three levels of price transparency utilized in measuring financial instruments at fair value as discussed above. As of January 31, 2020, the Company had a \$928,774 derivative liability.

Fair value estimates are made at a specific point in time, based on relevant market information about the financial statement. These estimates are subjective in nature and involve uncertainties and matter of significant judgment and therefore cannot be determined with precision. Changes in assumptions could significantly affect the estimates.

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### Recent Accounting Standards

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for nonemployee share-based payment transactions by expanding the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. Under the new standard, most of the guidance on stock compensation payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. This standard became effective for us on February 1, 2019. The adoption of this standard did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement." ASU 2018-13 modifies the fair value measurements disclosures with the primary focus to improve effectiveness of disclosures in the notes to the financial statements that is most important to the users. The new guidance modifies the required disclosures related to the valuation techniques and inputs used, uncertainty in measurement, and changes in measurements applied. ASU 2018-13 will be effective for the Company for its fiscal year beginning after December 15, 2019 and each quarterly period thereafter. Early adoption is permitted. The Company is currently assessing the impact this new guidance may have on the Company's consolidated financial statements and footnote disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. This ASU removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This ASU is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. We are currently assessing the impact of this standard on our combined financial statements.

In January 2017, the FASB issued ASU 2017-04, "Simplifying the Test for Goodwill Impairment," which removes Step 2 from the goodwill impairment test and replaces the qualitative assessment. Impairment will be measured using the difference between the carrying amount and the fair value of the reporting unit. Under this revised guidance, failing Step 1 will always result in a goodwill impairment. The amendments in this update should be applied prospectively for annual and interim periods in fiscal years beginning after December 15, 2019. The Company early adopted ASU 2018-07 on February 1, 2019. The Company's adoption of ASU 2018-07 has had no impact on its consolidated financial statements or disclosures.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. ASU No. 2017-01 clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of a business or as acquisitions (or disposals) of assets. ASU No. 2017-01 is effective for annual periods beginning after December 15, 2018, with early adoption permitted under certain circumstances. The amendments of ASU No. 2017-01 were adopted by the Company effective February 1, 2019. The adoption of this standard had no impact on our consolidated financial position or results of operations.

The Company has reviewed all other FASB-issued ASU accounting pronouncements and interpretations thereof that have effective dates during the period reported and in future periods. The Company has carefully considered the new pronouncements that alter previous GAAP and does not believe that any new or modified principles will have a material impact on the company's reported financial position or operations in the near term. The applicability of any standard is subject to the formal review of the Company's financial management and certain standards are under consideration.

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## 2. PROPERTY AND EQUIPMENT

	January 31,	
	2020	2019
Lab equipment	\$ 144,585	\$ 144,585
Furniture, fixtures and equipment	19,643	19,643
	164,228	164,228
Less: Accumulated depreciation	(53,199)	(18,081)
Net Property and Equipment	\$ 111,029	\$ 146,147

Depreciation expense amounted to \$35,118 and \$18,081 for the years ended January 31, 2020 and 2019, respectively.

## 3. INCOME TAXES

The Company adopted the provisions of ASC 740, "Income Taxes, ("ASC 740"). As a result of the implementation of ASC 740, the Company recognized no adjustment in the net liability for unrecognized income tax benefits. The Company believes there are no potential uncertain tax positions and all tax returns are correct as filed. Should the Company recognize a liability for uncertain tax positions, the Company will separately recognize the liability for uncertain tax positions on its balance sheet. Included in any liability or uncertain tax positions, the Company will also setup a liability for interest and penalties. The Company's policy is to recognize interest and penalties related to uncertain tax positions as a component of the current provision for income taxes.

There is no U.S. tax provision due to losses from U.S. operations for the years ended January 31, 2020 and 2019. Deferred income taxes are provided for the temporary differences between the financial reporting and tax basis of the Company's assets and liabilities. The principal item giving rise to deferred taxes is the net operating loss carryforward in the U.S. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. The Company has set up a valuation allowance for losses for certain carryforwards that it believes may not be realized.

The provision for income taxes consist of the following:

Years Ended	
January 31,	
2020	2019

Current		
Federal	\$ -	\$ -
Foreign	-	-
	<u>-</u>	<u>-</u>
Deferred		
Federal	-	-
Foreign	-	-
	<u>\$ -</u>	<u>\$ -</u>

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A reconciliation of taxes on income computed at the federal statutory rate to amounts provided is as follows:

	Years Ended	
	January 31,	
	2020	2019
Book loss from operations	\$ (571,542)	\$ (699,560)
Common stock issued for services	52,931	370,430
Impairment expense	-	-
Unused operating losses	518,611	329,130
Income tax expense	<u>\$ -</u>	<u>\$ -</u>

As of January 31, 2020, the Company recorded a deferred tax asset associated with a net operating loss (“NOL”) carryforward of approximately \$4,340,328 that was fully offset by a valuation allowance due to the determination that it was more likely than not that the Company would be unable to utilize those benefits in the foreseeable future. The Company’s NOL expires in 2037. The valuation allowance increased by approximately \$581,000 during the year ended January 31, 2020. On December 22, 2017, the Tax Cuts and Jobs Act (the “Tax Act”) significantly revised U.S. corporate income tax law by, among other things, reducing the corporate rate from 34% to 21%. Because the Company recognizes a valuation allowance for the entire balance, there is no net impact to the Company’s balance sheet or results of operations.

The types of temporary differences between tax basis of assets and liabilities and their financial reporting amounts that give rise to the deferred tax liability and deferred tax asset and their approximate tax effects are as follows:

	January 31,	
	2020	2019
Net operating loss carry forwards (expire through 2037)	\$ (688,858)	\$ (170,247)
Stock issued for services	(436,904)	(383,973)
Intangible impairment expense	(525,000)	(525,000)
Valuation allowance	1,650,762	1,079,220
Net deferred taxes	<u>\$ -</u>	<u>\$ -</u>

#### 4. NOTES PAYABLE/CONVERTIBLE DEBT

On September 12, 2017, the Company borrowed \$15,000 on an interest-free basis from a minority stockholder. In April 2018, the Company borrowed an additional \$25,000 from the minority stockholder. During 2019, the Company borrowed an additional \$175,000. The loans are interest free and due upon demand. The balance due on such loans was \$215,000 on January 31, 2020, and \$40,000 on January 31, 2019, which is included in notes payable.

During the year ended January 31, 2019, the Company’s chief financial officer and chief operating officer advanced the Company \$34,980, paid \$23,817 expenses on behalf of the Company, of which \$29,730 was repaid as of January 31, 2020. The balance due to the officers as of January 31, 2020 was \$29,067.

On October 30, 2019, the Company entered into a securities purchase agreement with two investors pursuant to which the Company issued to the investors (i) 6% one-year convertible promissory notes in the principal amount of \$270,000 and (ii) three-year warrant to purchase 50,000 shares of common stock at an exercise price equal to the lesser of (i) \$20.90 or (ii) if the Company completes a public offering, 110% of the initial public offering price of the common stock in the public offering. The loans contained an original issue discount of \$20,000 resulting in gross cash proceeds from this financing were of \$250,000.

The notes are convertible at a conversion price equal to the lesser of (i) the per share price of common stock offered in a public offering or (ii) the variable conversion price, which is defined as 70% of the lowest trading price of the common stock during the 20 trading days preceding the date of conversion. The conversion price and the percentage of the trading price is subject to downward adjustment in the event the Company fails to comply with the obligations under the notes. The Company has the right to prepay the notes during the 180 days following the issuance of the notes at a premium of 115% of the outstanding principal and interest during the 60 days following the date of issuance of the note, which percentage increases to 125% during the remainder of the 180 day period. The Company is required to pay the notes one business day after the closing of the first to occur of (a) the next public offering of the Company’s securities or (b) the next private placement of the Company’s equity or debt securities in which the Borrower received net proceeds of at least \$1.0 million, (c) issuance of securities pursuant to an equity line of credit or (d) a financing with a bank or other institutional lender.

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The embedded conversion option qualified for derivative accounting and bifurcation of under ASC 815-15 Derivatives and Hedging. The initial fair value of the conversion feature was \$128,870 and the fair value of the warrants issued in connection with the notes were valued at \$888,780 and were recorded based on their relative fair values. A debt discount to the note payables of \$270,000 and an initial derivative expense of \$767,650 was recorded.

The debt discount will be amortized over the life of the note. Amortization of debt discount for the year ended January was \$67,500. As of January 31, 2020, the debt discount remaining was \$202,500.

Interest expense for the year ended January 31, 2020 including the amortization of the debt discount was \$71,550.

In March 2020, the Company repaid the \$270,000 convertible debt and recorded a loss on the extinguishment of debt of \$69,132.

#### 5. ACQUISITION OF BUSINESS

On August 1, 2018, the Company acquired 100% of the membership interests of 4P Therapeutics, pursuant to an agreement dated April 5, 2018, for \$2,250,000, consisting of 250,000 shares of common stock, valued at \$1,850,000, and \$400,000, and a royalty of 6% on all revenue generated by us from the abuse deterrent

intellectual property that had been developed by 4P Therapeutics payable to the former owner of 4P Therapeutics. The primary purpose of the acquisition is to acquire the intellectual property of 4P Therapeutics and complete the development and seek FDA approval, initially for 4P Therapeutics' lead product, its abuse deterrent fentanyl transdermal system, which is in the development stage. Acquisition costs, which were minimal, have been expensed as incurred in accordance with ASC 350.

Details of the net assets acquired are as follows:

	Fair Value Recognized On Acquisition
Equipment	\$ 160,065
Customer base	136,500
Intellectual Property	191,900
Trademark	42,300
Goodwill	1,719,235
Net assets acquired	<u>\$ 2,250,000</u>
Satisfied by:	
Common stock issued	(1,850,000)
Cash outflows on acquisition	<u>\$ (400,000)</u>

The following unaudited pro forma condensed financial information presents the combined results of operations of the Company and 4P Therapeutics as if the acquisition occurred as of the beginning of the year ended January 31, 2019. The unaudited pro forma condensed financial information is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition occurred at the beginning of the prior year period presented and should not be taken as being representation of the future consolidated results of operations of the Company. The pro forma results for the year ended January 31, 2020 are not included in the table below because the operating results 4P Therapeutics were included in our consolidated of operations and comprehensive income.

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	2019	
	As Reported	Pro Forma
Net revenue	\$ 245,285	\$ 577,149
Net loss	(3,331,240)	(3,307,614)
Loss per common share - basic and diluted	\$ (0.16)	\$ (0.16)

#### 6. INTANGIBLE ASSETS AND GOODWILL

At January 31, 2020 and 2019, intangible assets consisted of intellectual property, customer base and trademarks, net of amortization, as follows:

	January 31,	
	2020	2019
Customer base	\$ 136,500	\$ 136,500
Intellectual property	234,200	234,200
Goodwill	1,719,235	1,719,235
Total	<u>2,089,935</u>	<u>2,089,935</u>
Less: Accumulated amortization	(56,000)	(18,930)
Net Intangible Assets	<u>\$ 2,033,935</u>	<u>\$ 2,071,005</u>

The value of the intangible assets, consisting of intellectual property and customer base has been recorded at their fair value by the Company after completing a valuation and are being amortized over a period of ten years. Amortization expense for the years ended January 31, 2020 and 2019 was \$37,070 and \$18,930, respectively.

No value has been given to the potential royalty payable to the former owner since the royalty is contingent upon the Company generating revenue from any source and there is no marketable product and there are material uncertainties, including the need for FDA approval, as to whether or when any revenue will be generated from the intellectual property subject to the royalty. If any royalties are paid to the former owner of 4P Therapeutics, the royalties will be expensed as incurred and treated as an operating expense.

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	January 31,	
	2020	2019
Intellectual property	\$ 234,200	\$ 234,200
Accumulated amortization	(35,525)	(12,105)
Book value	<u>\$ 198,675</u>	<u>\$ 222,095</u>
Customer base	\$ 136,500	\$ 136,500
Accumulated amortization	(20,475)	(6,825)
Book value	<u>\$ 116,025</u>	<u>\$ 129,675</u>
Total Intangible Assets, Net	<u>\$ 314,700</u>	<u>\$ 351,770</u>

Estimated Amortization:

Trademarks



Year Ended January 31,	and		Total
	Intellectual Property	Customer Base	
2021	\$ 23,420	\$ 13,650	\$ 37,070
2022	\$ 23,420	\$ 13,650	37,070
2023	\$ 23,420	\$ 13,650	37,070
2024	\$ 23,420	\$ 13,650	37,070
2025	\$ 23,420	\$ 13,650	37,070
Thereafter	\$ 81,525	\$ 47,775	129,350

## 7. DERIVATIVE LIABILITIES

The embedded conversion option of the convertible debentures described in Note 4 contain conversion features that qualify for embedded derivative classification. The fair value of the liabilities will be re-measured at the end of every reporting period and the change in fair value will be reported in the statement of operations as a gain or loss on derivative financial instruments.

The table below sets forth a summary in the fair value of the Company's Level 3 financial liabilities:

Original discount limited to proceeds of notes	\$ 250,000
Fair value of derivative liabilities in excess of notes proceeds received	767,650
Change in value of embedded conversion option	(88,876)
	<u>\$ 928,774</u>

The Company uses Level 3 inputs for its valuation methodology for the embedded conversion option and warrant liabilities as their fair value were determined by using the Monte Carlo Model based on various assumptions.

At issuance, the expected volatility was 158.3%; risk-free interest rate of 1.58%; and expected term of one year. For the revaluation at January 31, 2020, the expected volatility was 184.4%; risk-free rate of return of 1.43%; and expected term of nine months.

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## 8. RELATED PARTY TRANSACTIONS

- a) An interest-free advance from the mother of the chief executive officer was \$10,230 at January 31, 2018. The advance was repaid in full May 2018.
- b) The chief financial officer made payments on behalf of the Company during the year ended January 31, 2019 in the total amount of \$34,800, all of which was repaid in May 2018. During the year ended January 31, 2020, the Company's chief financial officer and chief operating officer advanced the Company \$34,980, paid expenses on behalf of the Company of \$23,817, of which \$29,730 was repaid. As of January 31, 2020, the amounts due the officers were \$29,067 which is non-interest bearing.
- c) The former owner of 4P Therapeutics has been a director of the Company since April 2018, when the Company entered into an agreement to acquire 4P Therapeutics. See Note 6 in connection with the terms of the acquisition of 4P Therapeutics from the former owner and the royalty payable to the former. The former owner was not a director of the Company when the acquisition agreement was signed.
- d) During the year ended January 31, 2019, the Company issued 210,000 shares of common stock, valued at \$967,500, to executives of the Company based on the market price of the common stock on the date of issuance and (ii) 5,000 shares of common stock to each of the Company's six independent directors for a total of 30,000 shares valued at \$222,000, based on the market price on the date of issuance.
- e) On February 19, 2019, the Company granted an executive officer an option to purchase 25,000 shares of the Company's common stock at an exercise price equal to 75% of the market price on the date the Company receives notice of exercise. The fair value of the warrant on the date of grant using the Black Scholes model was \$252,700 and was expensed during the year ended January 31, 2020. The warrant expired unexercised on May 19, 2019.
- f) On January 31, 2020, the Company issued 8,572 shares common stock to each of its president, who is also a director, and to a limited liability company controlled by the Company's chief scientific officer for accrued salaries valued at \$120,000. These issuances were made pursuant to employment agreements with the president and chief scientific officer which provide for annual compensation of \$60,000 and represented compensation for the years ended January 31, 2020 and 2019.

## 9. STOCKHOLDERS' EQUITY

### Preferred Stock

On January 15, 2016, the board of directors of the company approved a certificate of amendment to the articles of incorporation and changed the authorized capital stock of the Company to include and authorize 10,000,000 shares of Preferred Stock, par value \$0.001 per share.

On May 24, 2019, the Board of Directors created a series of preferred stock consisting of 2,500,000 shares designated as the Series A Convertible Preferred Stock ("Series A Preferred Stock"). On June 20, 2019, the Series A preferred Stock was terminated and the 2,500,000 shares were restored to the status of authorized but unissued shares of Preferred Stock, without designation as to series, until such stock is once more designated as part of a particular series by the Board of Directors.

### Common Stock

On June 25, 2019, the Company effected a one-for-four reverse split, pursuant to which each share of common stock became converted into 0.25 shares of common stock, and the Company decreased its authorized common stock from 100,000,000 to 25,000,000 shares.

On January 27, 2020, the Company amended its articles of incorporation to increase its authorized common stock from 25,000,000 shares to 250,000,000 shares.

On January 31, 2020, the Company issued 8,572 shares to each of its president, who is also a director, and to a limited liability company controlled by the Company's chief scientific officer for services valued at \$120,000 pursuant to employment agreements with the president and chief scientific officer. The compensation related to services for the years ended January 31, 2020 and 2019. See Note 12.

During the year ended January 31, 2019, the Company issued a total of 80,500 shares for services valued at \$1,763,950 as follows:

- (i) 68,000 shares of common stock, valued at \$1,419,300, issued to executive officers and their affiliates;

(ii) 7,500 shares of common stock, valued at \$222,000, issued to the Company's independent directors;

(iii) 2,500 shares of common stock, valued at \$74,000, issued to the Company's advisory board member; and

(iv) 2,500 shares of common stock, valued at \$48,600, issued to a non-affiliated party for services.

On May 2, 2018, the Company sold to an unrelated party for \$1.0 million, 62,500 shares stock and 30-day warrants to purchase 62,500 shares of common stock at \$16.00 per share. On May 27, 2018, the unrelated party exercised warrants to purchase 31,250 shares of common stock for \$500,000. and on June 2, 2018, warrants to purchase 31,250 shares of common stock expired unexercised.

On July 31, 2018, the Company issued 62,500 shares of common stock valued at \$1,850,000 representing a portion of the purchase price for the equity of 4P Therapeutics. See Notes 4 and 6.

In November 2018, one of the defendants in the legal proceedings with Advanced Health Brands, Inc. (see Note 12), returned 50,000 shares of common stock that had been issued to her, and these shares were cancelled as of January 31, 2019.

On November 23, 2018, the Company sold 17,931 shares of its common stock to a minority stockholder for \$500,000.

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## 10. WARRANTS AND OPTIONS

The following table summarizes the changes in warrants outstanding and the related price of the shares of the Company's common stock issued to non-employees of the Company.

	Shares	Exercise Price	Remaining Life	Intrinsic Value
Outstanding, January 31, 2018	182,500	\$ 6.32	1.35 years	
Granted	62,500	16.00		-
Exercised	(31,250)	16.00	-	-
Expired/Cancelled	(31,250)	16.00	-	-
Outstanding, January 31, 2019	182,500	\$ 6.32	0.35 years	\$ 4,101,000
Issued	50,000	20.90	3.00 years	-
Expired/Cancelled	(162,500)	5.38	-	-
Exercised	-	-	-	-
Outstanding-period ending January 31, 2020	70,000	\$ 18.93	2.08 years	\$ -
Exercisable - period ending January 31, 2020	70,000	\$ 18.93	2.08 years	\$ -

The exercise price for these warrants to purchase 50,000 shares, which were issued in the year ended January 31, 2020 is the lesser of (i) \$20.90 or, (ii) if the Company completes its public offering of its common stock, 110% of the initial public offering price of the Common Stock in the next firm commitment public offering of the Company's securities. Since the Company has not completed a public offering since the issuance of the warrants, an exercise price of \$20.90 has been used in the in the foregoing table and table below. The exercise price and number of shares subject to the warrant is subject to adjustment in the event that the Company issues stock at a price or warrants, options or other convertible securities at an exercise or conversion price less than the then current exercise price of the warrant.

The following table summarizes additional information relating to the warrants outstanding at January 31, 2020:

Range of Exercise Prices	Number Outstanding	Remaining Contractual Life(Years)	Exercise Price for Shares Outstanding	Number Exercisable	Exercise Price for Shares Exercisable
\$ 20.90	50,000	2.75	\$ 20.90	50,000	\$ 20.90
\$ 14.00	20,000	0.41	\$ 14.00	20,000	\$ 14.00

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The following table summarizes the changes in options outstanding and the related price of the shares of the Company's common stock issued to non-employees of the Company.

	Shares	Exercise Price	Remaining Life	Intrinsic Value
Outstanding, January 31, 2019	-	\$ -	-	\$ -
Granted	25,000	34.20	0.05 years	232,750
Expired	(25,000)	34.20	-	-
Exercised	-	-	-	-
Outstanding-period ending January 31, 2020	-	\$ -	-	\$ -

## 11. LEASES

The Company has operating leases for its facilities used for research and development, sales and administration. These leases have remaining lease terms of less than one year. Certain of these leases contain options to extend the term of the lease and certain of these leases contain options to terminate the lease within a specified period of time. The options to extend or terminate a lease are included in the lease term when it is reasonably likely that the Company will elect that option. The Company is not a party to any material sublease arrangements.

The components of lease expense, which are included in cost of revenues and general and administrative expense, based on the underlying uses of the right of use asset, were as follows:

	Year Ended January 31, 2020
Amortization of right-of-use asset	\$ 19,652
Interest on lease liability	1,863
Operating lease costs	-
Total Lease Cost	<u>\$ 21,515</u>

Supplementary cash flow information related to leases are as follows:

	Year Ended January 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 9,610
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	\$ 28,827

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Supplementary balance sheet information related to leases are as follows:

	January 31, 2020
Operating Leases:	
Operating lease right-of-use assets	\$ 9,610
Operating lease liabilities	<u>10,050</u>
Weighted-Average Remaining Lease Term:	
Operating leases	0.50
Weighted-Average Discount Rate:	
Operating leases	4.40%

The discount rate is based on the Company's incremental borrowing rate.

Maturities of lease liabilities were as follows as of January 31, 2020:

Year Ending January 31,	Operating Leases
2021-remaining	<u>10,320</u>
Total undiscounted cash flows	10,320
Less: imputed interest	<u>(270)</u>
Present value of lease liabilities	<u>\$ 10,050</u>

Under ASC 840, approximate future minimum rental payments due under these leases as of January 31, 2020 would have been as follows:

Year Ended January 31,	
2021	\$ 10,320

## Operating Leases

The Company leases office space in Orlando, Florida at a monthly rental of \$1,720 which expires on July 31, 2019. For the year ended January 31, 2019 the Company had lease commitments of \$10,320.

The Company leased 7,201 square feet of manufacturing space in Norcross, Georgia. The lease was month-to-month at a monthly rate of \$13,637. The Company is downsizing its operations in Georgia and will relocate from this facility. The Company is in the process of finding a new location and will negotiate a new long-term lease.

## 12. COMMITMENTS AND CONTINGENCIES

*Legal Proceedings*

On July 27, 2018, the Company commenced an action in the Circuit Court of the Ninth Judicial Circuit in and for Orange County, Florida, against Advanced Health Brands, Inc., Raymond Kalmar, Paul Murphy, Michelle Polly-Murphy, Laura Fillman and John Baker, together with a Motion for Temporary Injunction Without Notice and a Motion for Prejudgment Writ of Replevin arising from the Company's decision to seek to rescind for misrepresentation the agreement by which the Company acquired advanced Health Brands, Inc. for 1,250,000 shares of common stock valued at \$2,500,000 and seek return of the shares. On August 2, 2018, the court entered a Temporary Injunction Without Notice and an Order to Show Cause against the defendants. Defendants Kalmar, Murphy, Polly-Murphy, and Baker filed a Motion to Dismiss the Company's Verified Complaint, Motion to Dissolve Temporary Injunction Without Notice and Response to Order to Show Cause, and Motion to Compel Arbitration. On January 4, 2019, the court dismissed the Company's complaint with prejudice, and directed the defendants to assign the Company within 30 days, the six patents never duly transferred to the Company. On February 1, 2019, the Company appealed the court's order. Pursuant to a settlement agreement with one of the defendants, that defendant returned the 50,000 shares which had been issued to her, and the

shares were cancelled as of January 31, 2019. On June 7, 2019, the individual defendants (other than the defendant whom the Company has a settlement agreement), filed a motion for sanctions and civil contempt against us, which generally claimed that we failed to comply with the Court's January 4, 2019 order by refusing to issue the Ruling 144 letters that would allow the defendants to transfer their shares of common stock. On October 29, 2019, the Court denied the defendants motion. On March 20, 2020, the Florida district court of appeal reversed the lower court ruling in the Florida state court action that dismissed our complaint with prejudice, and gave us leave to file an amended complaint

On August 22, 2018, four of the defendants in the Florida action described in the previous paragraph filed a complaint against the Company in the Franklin County, Ohio Court of Common Pleas seeking a declaratory judgment permitting them to sell the shares of common stock they received pursuant to the acquisition agreement. The parties have agreed to a stay pending the outcome of the Florida litigation.

On April 29, 2019, the Company filed a securities fraud action in the U.S. District Court for the Eastern District of New York against Raymond Kalmar, Paul Murphy, Michelle Polly-Murphy, Advanced Health Brands and TD Therapeutic, Inc. In the complaint the Company alleges that in 2017, the defendants fraudulently and deceitfully obtained 1,250,000 shares of common stock by orchestrating a months-long scheme to defraud the Company. The Company is seeking the return of the 1,200,000 shares of common stock and monetary damages resulting from the defendants' fraudulent conduct. The defendants filed a motion to dismiss on August 23, 2019, and the Company filed its response on September 13, 2019.

#### *Employment Agreements*

The Company has employment agreements with its chief executive officer and chief financial officer dated April 23, 2019 pursuant to which we agree to employ them as chief executive officer and chief financial officer, respectively. The agreement also provides that the Company will include each of them as our nominee for director. The agreements have a term ending on January 31, 2024, and continuing on a year-to-year basis thereafter unless terminated by either party on not less than 30 days' notice given prior to the expiration of the initial term or any one-year extension. Pursuant to the employment agreements at January 31, 2020, the chief executive officer is receiving compensation at an annual rate of \$42,000, and chief financial officer is not currently receiving any compensation. Commencing with the month in which the Company has raised at least \$2,500,000 from public or private financing of its equity securities, they will each receive salary at the annual rate of \$170,000.

The Company has an employment agreement May 16, 2018 with its president pursuant to which the Company employed him as president for a term with no expiration date at annual salary of \$60,000, which may be paid in stock or cash. The president serves on a part-time basis.

The Company has an employment agreement dated February 19, 2019 with its chief scientific officer pursuant to which the Company agrees to employ him as chief scientific officer for annual compensation of \$60,000, payable in cash or stock, as the Company may elect. The agreement has a term ending on January 31, 2021 and continues thereafter on a quarter-to-quarter basis unless terminated by either party on 30 days' notice. The chief scientific officer serves on a part-time basis.

### 13. SUBSEQUENT EVENTS

In December 2019, COVID-19 emerged and has subsequently spread world-wide. The World Health Organization has declared COVID-19 a pandemic resulting in federal, state and local governments and private entities mediating various restrictions, including travel restrictions, restrictions on public gatherings, stay at home orders, and advisories and quarantining people who may have been exposed to the virus. The effect of these orders, government imposed quarantines and measures the Company would take, such as work-at-home policies, may negatively impact productivity, disrupt our business and could delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. Further, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain.

On March 22, 2020, the Company issued in a private placement 46,828 units at a price of \$11 per unit. Each unit consisted of one share of common stock and a warrant to purchase one share of common stock at an exercise price of \$14 per share. The warrants expire April 30, 2023. The Company issued a total of 46,828 shares of common stock and warrants to purchase 46,828 shares of common stock. The Company received proceeds of \$515,113.

In March 2020, a minority stockholder who had previously made loans of \$215,000, made an additional loan to the Company in the amount of \$60,000, increasing the total loans from the stockholder to \$275,000. See Note 4. On March 27, 2020, the Company issued 25,000 shares upon conversion of the notes in the principal balance of \$275,000.

On March 21, 2020, the Company prepaid the convertible notes in the principal amount of \$270,000 from the proceeds of the private placement. The total payments, including the prepayment penalty and accrued interest, was \$345,565. As a result of the payment of the notes, the derivative liability, which was \$928,774 at January 31, 2020, was reduced to zero. As a result of the terms of the private placement, the warrants to purchase 50,000 shares at lesser of (a) \$20.90 or (b) if the Company completes a private offering, 110% of the initial offering price of the common stock in the public offering, became a warrant to purchase 95,000 shares at \$11 per share, subject to adjustment pursuant to the antidilution provisions of the warrant. See Notes 4 and 10.

On March 20, 2020, the Florida district court of appeal reversed the lower court ruling in the Florida state court action that dismissed the Company's complaint with prejudice against Advanced Health Brands, Inc., Raymond Kalmer, Paul Murphy, Michelle Polly-Murphy and John Baker, and gave the Company leave to file an amended complaint. See Note 12.

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002  
CERTIFICATION

The undersigned, Gareth Sheridan and Serguei Melnik, certify that:

1. I have reviewed this Annual Report on Form 10-K of Nutriband Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements

made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting;

DATE: April 14, 2020

/s/ Gareth Sheridan

Gareth Sheridan, President, Chief Executive Officer

/s/ Serguei Melnik

Chief Financial Officer

EX-32 3 f10k2020ex32\_nutriband.htm CERTIFICATION OF CHIEF EXECUTIVE AND FINANCIAL OFFICERS PURSUANT TO 18 U.S.C. 1350 (SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002) (6)

**Exhibit 32**

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Nutriband Inc. (the "Company") on Form 10-K for the year ended January 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gareth Sheridan, President and Chief Executive Officer of the Company, and I Serguei Melnik, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge: (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Gareth Sheridan

Gareth Sheridan, President, Chief Executive Officer  
and Principal Financial Officer

/s/ Serguei Melnik

Chief Financial Officer

DATE: April 14, 2020