

Risk Factors Comparison 2024-02-14 to 2023-01-30 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

Risks Related to Our Business and Industry We **have a present need for additional funding, which raises questions about our ability to continue as a going concern. We may be unable to raise capital when needed, which would force us to delay, reduce or eliminate aspects of our business or cause our business to fail. As of October 31, 2023, we had cash and cash equivalents of only approximately \$ 0.5 million. We believe that based on our current operating plan, our existing cash and cash equivalents will only be sufficient to enable us to fund our operations and our debt and other obligations for a very limited period. See “ Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.”** Moreover, we will need significant additional funds to satisfy our outstanding payables, fund our working capital, and fully implement our business plan as we seek to grow our revenues and ultimately achieve positive cash flow and profitability. In addition, our ability to continue as a going concern is adversely affected by the uncertainty surrounding Bidi’s PMTA process with FDA and outcome of Bidi petition with the 11th Circuit Court of Appeals regarding the FDA’s January 2024 MDO relating to Classic Bidi® Stick as well as our negative cash flows from operations, significant recurring losses and present need for additional funding. All of these factors raise substantial doubt regarding our ability to continue as a going concern. There is therefore a material risk that we will be unable to generate sufficient revenues to pay our expenses, and if our existing sources of cash and cash flows are insufficient to fund our activities, we will need to raise additional funds. Additional equity or debt financing may not be available on acceptable terms, if at all, particularly in the current economic environment. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our new products in development. Until such time, if ever, we can generate substantial product revenues, we will be required to finance our cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements. If we elect to raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we may raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to generate cash flow positive operations or achieve profitability, and if we are unable to raise additional funds on commercially reasonable terms or at all, we may be required to significantly reduce or cease our operations, declare bankruptcy or our business could fail, which could result in the loss to investors of their investment in our securities. We currently rely exclusively on Bidi as the supplier of the ~~Bidi Products-products~~ **our Products-products** that we distribute. The loss of this relationship, or any negative impacts on Bidi’s ability to manufacture the ~~Bidi Products-products~~, would severely harm our business. Pursuant to the A & R Distribution Agreement between us and Bidi, Bidi has engaged us to act as the sole distributor of the ENDS products and related components, including the BIDI® Stick, manufactured by Bidi. Any failure by Bidi to fulfil its obligation under the A & R Distribution Agreement could have a material adverse effect on our revenue and operating results and operating cash flows; and could impair the strength of our brand. In addition, because of our dependence on Bidi as the exclusive supplier of ~~our Products-products~~, any loss of our relationship with Bidi, or any adverse change in the financial health of Bidi that would affect its ability to perform its obligations under the A & R Distribution Agreement, would have a material adverse effect on our revenue, operating results, and ability to run our business. Further, Bidi is subject to supply shortages and interruptions, long lead times, and act-of-God events such as global pandemics, weather related catastrophes, or conflict, any of which could disrupt the operations of Bidi and have a material adverse impact on our results of operations. We may be unable to identify or contract with new suppliers or producers in the event of a disruption to our supply and could experience a material adverse effect on our revenue, operating results, and ability to run our business. The terms of our agreements with Bidi, including our A & R Distribution Agreement, may not always be as favorable to us as the terms that may be obtained by arms’ length negotiation. We currently are, and we anticipate that we will continue to be, substantially dependent on our relationships with our affiliated entities, including Bidi. We believe that our current arrangement with Bidi provides our business with stability and transparency. Although we believe that the terms of the A & R Distribution Agreement are as favorable to us as what we could have obtained in an arm’s length transaction, there can be no assurance that this arrangement or any future agreements that we enter with Bidi, or any other affiliated entity, will be as favorable to us as we may be able to negotiate with unaffiliated parties. ~~Our~~ **We rely primarily on Bidi for access to our key intellectual property rights, and any change in our** relationship with Bidi is subject ~~could adversely alter such rights or our access to change them~~. We currently have no intellectual property rights (other than the intellectual property assets we acquired in May 2023 from GoFire and our trademarks KAIVAL BRANDS and KAIVAL LABS) ~~and~~, **We** rely on the intellectual property rights, including logos, trademarks, and trade names, of Bidi that were granted to us pursuant to the A & R Distribution Agreement to be used in connection with the marketing, advertisement, and sale of the ~~Bidi Products-products~~. We also indirectly rely on Bidi’s intellectual property rights related to the ~~Bidi Products-products~~, such as patents. We have from time to time considered, and discussed with Bidi, potential alterations to this arrangement, including a potential acquisition by us of all or a portion of the intellectual property owned by Bidi and related to ~~the Bidi Products-products~~. Should we pursue such a transaction, it would be a “ related party transaction,” as defined by the listing

rules of ~~The Nasdaq Stock Market, LLC (the “Nasdaq”)~~ and, thus, subject to the review of the Audit Committee of our Board **(or, if deemed appropriate, a special Board committee comprised of disinterested directors)**. Further, should we undertake such a transaction, then we would become responsible to respond if a third-party challenged Bidi’s patents, or infringed upon such rights, in which case our business could be materially adversely affected. We outsource key sales and marketing and other key functions to QuikfillRx, and the loss of this relationship would damage our business. We conduct our sales and marketing activities in close coordination with our consultant QuikfillRx. Pursuant to our agreement with QuikfillRx (most recently amended in November 2022), QuikfillRx provides key services to us. We are therefore reliant on our relationship with QuikfillRx, and the loss of that relationship for any reason would significantly damage our ability to ~~operation~~ **operate** our business. We have a limited operating history, and our historical operating and financial results may not be indicative of future performance, which, along with the relative early stage of the ENDS industry, makes it difficult to predict our future business prospects and financial performance. Our current business model is relatively new, and so business and prospects may be difficult to evaluate. Our limited operating history makes it difficult to evaluate both our operating history and our future potential. We have yet to demonstrate a consistent ability to generate revenue, and are still subject to many of the risks common to early-stage companies operating in the nicotine and non-nicotine delivery system products sector, including the uncertainty as to our ability to implement our business plan, market acceptance of business plan, under-capitalization, cash shortages, limitations with respect to personnel, financing and other resources and uncertainty of our ability to generate revenues. There is therefore a significant risk that our activities will not result in any material revenues or profit, and the likelihood of our business viability and long-term prospects must be considered in light of the stage of our development. There can be no assurance that we will be able to fulfill our stated business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results of operations in our current business model for investors to use to identify historical trends. Investors should consider our prospects considering the risk, expenses and difficulties we will encounter as an early-stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are therefore subject to the risk that we will be unable to address these risks, and our inability to address these risks could lead to the failure of our business. **Moreover, Our business is rapidly evolving and is particularly at risk given the FDA’s January 2024 MDO for Classic BIDI® Stick or in the event that Bidi’s pending PMTA for non-tobacco flavored BIDI® Sticks is denied or delayed. The ENDS industry is relatively new and is rapidly evolving, and the FDA has been aggressive in its oversight of the ENDS industry.** Changes in existing laws, regulations and policies and the issuance of new laws, regulations, policies, **as well as the FDA’s actions on ENDS-related PMTAs (including Bidi’s)** and any other entry barriers in relation to the ENDS industry may materially and adversely affect our **ability to conduct** business **and our results of** operations. Bidi was among the many companies that received a MDO for its non-tobacco flavored BIDI® Sticks. On August 23, 2022, the U. S. Court of Appeals for the Eleventh Circuit set aside (i. e., vacated) the MDO issued to the non-tobacco flavored BIDI® Sticks and remanded Bidi’s ~~Premarket Tobacco Product Application (“PMTA”)~~ back to FDA for further review. Specifically, the Court held that the MDO was “arbitrary and capricious” in violation of the Administrative Procedure Act (“APA”) because the FDA failed to consider the relevant evidence before it, specifically Bidi’s aggressive and comprehensive marketing and sales-access-restrictions plans designed to prevent youth appeal and access. The opinion further indicated that the FDA did not properly review the data and evidence that it has long made clear are critical to the “appropriate for the protection of the public health” (“APPH”) standard for PMTAs set forth in the Tobacco Control Act including, in Bidi’s case, “product information, scientific safety testing, literature reviews, consumer insight surveys, and details about the company’s youth access prevention measures, distribution channels, and adult-focused marketing practices,” which “target only existing adult vapor product users, including current adult smokers,” as well as **our the Company’s** retailer monitoring program and state-of-the-art anti-counterfeit authentication system. Because ~~a~~ **an** MDO must be based on a consideration of the relevant factors, such as the marketing and sales-access-restrictions plans, the denial order was deemed arbitrary and capricious, and vacated by the FDA. The FDA did not appeal the 11th Circuit’s decision. ~~The Agency had until October 7, 2022 (45 days from the August 23, 2022 decision) to either request a panel rehearing or a rehearing “en banc” (a review by the entire 11th Circuit, not just the 3-judge panel that issued the decision), and until November 21, 2022 (90 days after the decision) to seek review of the decision by the U. S. Supreme Court. No request for a rehearing was filed, and no petition for a writ of certiorari was made to the Supreme Court.~~ In the meantime, we anticipate that Bidi will be **has been** able to continue marketing and selling the non-tobacco flavored BIDI® Sticks, subject to FDA’s enforcement discretion, for the duration of the PMTA scientific review. FDA has indicated that it is prioritizing enforcement of unauthorized ENDS against companies (1) that never submitted PMTAs, (2) whose PMTAs have been refused acceptance or filing by the FDA, (3) whose PMTAs remain subject to MDOs, and (4) that are continuing to market unauthorized synthetic nicotine products after the July 13, 2022, cutoff. As none of these scenarios apply to Bidi, we believe the risk of FDA enforcement is low. **However, there is a risk that Bidi’s PMTA for non-tobacco flavored BIDI® Sticks will be denied, which would have a significant adverse affect on our business and could lead to our bankruptcy or the failure of our business entirely.** Separately, on or about May 13, 2022, FDA placed the tobacco-flavored Classic BIDI® Stick into the final Phase III scientific review. ~~If~~ **In March 2023, FDA issued a deficiency letter regarding the Classic BIDI® Stick PMTA, to which Bidi submitted a timely response in June 2023. Subsequently, on January 22, 2024, FDA issued a MDO for the Classic BIDI® Stick, which Bidi is contesting via a petition for review with the 11th Circuit. The January 2024 MDO regarding Classic BIDI® Stick has had an adverse impact on our business, and the outcome of Bidi’s planned PMTA-11th Circuit petition is uncertain and will likely take many months for-** ~~or the tobacco-derived nicotine-based formulation of the longer to resolve. Our continuing inability to sell Classic BIDI® Stick could continue Pouch is not submitted to cause material impediments to~~ **or our ability** authorized by the FDA, we will not be able to **operate our business and cause** sell the BIDI® Pouch in the United States. We are currently planning to initiate distribution of the BIDI®

Pouch initially outside the United States. Bidi is also planning to submit a **material adverse affect on our results of operations** PMTA for a BIDI ® Pouch manufactured using a tobacco- derived nicotine formula. The BIDI ® Pouch cannot be distributed in the United States unless the PMTA is authorized. If it is determined or perceived that the usage of ENDS products poses long- term health risks, the use of ENDS products may decline significantly, which may materially and adversely affect our business, financial condition, and results of operations. Negative publicity on the health consequences of ENDS products or other similar devices may also adversely affect the usage of ENDS products. For example, the FDA and the United States Centers for Disease Control and Prevention (“ CDC ”) issued a joint statement on August 30, 2019, linking a number of cases of respiratory illnesses to ENDS product use. On November 8, 2019, the CDC announced that it had preliminarily linked cases of severe respiratory illness to the presence of Vitamin E acetate, which was found in certain Tetrahydrocannabinol (THC)- containing ENDS cartridges for non- electronic nicotine delivery systems (non- ENDS) products that may have been obtained illegally. However, evidence is not sufficient to rule out the contribution of other chemicals of concern, including chemicals in either THC or non- THC products **(THC is the principal psychoactive constituent of cannabis)**. In January 2020, after further research, the FDA and CDC recommended against the use of THC- containing ENDS products, especially those from unofficial sources, and that the underage, pregnant women and adults who do not currently use tobacco products should not start using ENDS products. On February 25, 2020, the CDC issued a final update, stating that the number of cases of severe respiratory illnesses had declined to single digits as of February 9, 2020. The CDC also reconfirmed that (i) Vitamin E acetate, which was found in some THC- containing ENDS cartridges for non- ENDS ENDS products that were mostly obtained illegally, was strongly linked to and indicated to be the primary cause of the severe respiratory illnesses, and (ii) THC- containing ENDS products from informal sources were linked to most cases of severe respiratory illnesses. Furthermore, there have been recent claims that users of ENDS products may suffer a greater risk of more serious COVID- 19 complications. However, it remains unclear whether the exposure to toxic chemicals through ENDS product usage will increase the risk of COVID- 19. Research regarding the actual causes of these illnesses is still ongoing. If ENDS product usage is determined or perceived to pose long- term health risks or to be linked to illnesses, the usage of ENDS products may significantly decline, which would have a material adverse effect on our business, financial condition, and results of operations. Although we currently do not offer products containing THC, any perceived correlation between THC and Vitamin E acetate may adversely affect the public’ s perception of ENDS products in general, regardless of whether such products contain THC and / or Vitamin E. We **do not expect the assets acquired from GoFire will generate immediate revenue for us, and we may never be able to develop these assets into revenue generating products. We purchased a certain vaporizer and inhalation- related patent portfolio from GoFire in May 2023 with the goal of diversifying our business and lessening our dependence on Bidi. We do not expect that the acquired assets will generate immediate revenue for us. While we will seek to monetize the acquired intellectual property, including through third- party licensing opportunities, we can give no assurances at this time that either (i) the patent applications we acquired will result in issued patents or (ii) we will be able to successfully monetize these assets. Our failure to capitalize on our GoFire assets would materially impair our strategy of diversifying our product offerings, leaving us even more reliant on the products we distribute for Bidi.** We may not be successful in maintaining the consumer brand recognition and loyalty of our ~~Products~~ **products** and face intense competition and may fail to compete effectively. We compete in a market that relies on innovation and the ability to react to evolving consumer preferences and, thus, are subject to significant competition in the ENDS market, and larger tobacco industry and compete against companies in such market and industry that have access to significant resources in terms of technology, relationships with suppliers and distributors and access to cash flow and financial markets. Consumer perceptions of the overall safety of tobacco ~~and~~ , nicotine , **cannabis, and hemp / CBD - based-related** products is likely to continue to shift, and our success depends, in part, on our ability to anticipate these shifting tastes and the rapidity with which the markets in which we compete will evolve in response to these changes on a timely and affordable basis. If we are unable to respond effectively and efficiently to changing consumer preferences, the demand for our ~~Products~~ **products** may decline, which could have a material adverse effect on our business, results of operations, and financial condition. Regulations may be enacted in the future, particularly considering increasing restrictions on the form and content of marketing of tobacco products, that would make it more difficult to appeal to our consumers or to leverage existing recognition of the Bidi brand, or other brands that we own or license in the future. Furthermore, even if we can continue to distinguish our ~~Products~~ **products**, there can be no assurance that the sales, marketing, and distribution efforts of our competitors will not be successful in persuading consumers of our ~~Products~~ **products** to switch to their products. Many of our competitors have greater access to resources than we do, which better positions them to conduct market research in relation to branding strategies or to launch costly marketing campaigns. Any loss of consumer brand loyalty to our ~~Products~~ **products** or reduction of our ability to effectively brand our ~~Products~~ **products** in a recognizable way will have a material effect on our ability to continue to sell our ~~Products~~ **products** and maintain our market share, which could have a material adverse effect on our business, results of operations, and financial condition. The competitive environment and our competitive position are also significantly influenced by economic conditions, the state of consumer confidence, competitors’ introduction of low- priced products or innovative products, higher taxes, higher absolute prices, and larger gaps between price categories and product regulation that diminishes the consumer’ s ability to differentiate tobacco products. Due to the impact of these factors, as well as higher state and local excise taxes and the market share of deep discount brands, the tobacco industry has become increasingly price competitive. As we seek to adapt to the price competitive environment, our competitors that are better capitalized may be able to sustain price discounts for long periods of time by spreading the loss across their expansive portfolios, with which we are not positioned to compete. “ Big tobacco ” has also established its presence in the ENDS market and has begun to make investments in the alternative space. There can be no assurance that our ~~Products~~ **products** will be able to compete successfully against these companies or any of our other competitors, some of which have far greater resources, capital, experience, market penetration, sales and distribution channels than do we. Our distribution efforts rely in

part on our ability to leverage relationships with large retailers and national chains. Our distribution efforts rely in part on our ability to leverage relationships with large retailers and national chains to sell and promote our **Products-products**, which is dependent upon the strength of the Bidi brand name and, in the future, any brand names that we may own or license, and our salesforce effectiveness. To maintain these relationships, we must continue to supply products that will bring steady business to these retailers and national chains. We may not be able to sustain these relationships or establish other relationships with such entities, which could have a material adverse effect on our ability to execute our branding strategies, our ability to access the end- user markets with our **Products-products**, or our ability to maintain our relationships with the manufacturer and sub-distributors of our **Products-products**. For example, if we are unable to meet benchmarking provisions in certain of our contracts or if we are unable to maintain and leverage our retail relationships on a scale sufficient to make us an attractive distributor, it would have a material adverse effect on our ability to act as sole distributor for Bidi, and on our business, results of operations and financial condition. In addition, there are factors beyond our control that may prevent us from leveraging existing relationships, such as industry consolidation. If we are unable to develop and sustain relationships with large retailers and national chains or are unable to leverage those relationships due to factors such as a decline in the role of brick- and- mortar retailers in the North American economy, our capacity to maintain and grow brand and product recognition and increase sales volume will be significantly undermined. In such an event, we may ultimately be forced to pursue and rely on local and more fragmented sales channels, which will have a material adverse effect on our business, results of operations and financial condition. Competition from illicit sources may have an adverse effect on our overall sales volume, restricting the ability to increase selling prices and damaging brand equity. Illicit trade and tobacco trafficking in the form of counterfeit products, smuggled genuine products, and locally manufactured products on which applicable taxes or regulatory requirements are evaded, represent a significant and growing threat to the legitimate tobacco industry **and significant, and unfair, competition that we are faced with**. Moreover, **Factors-factors** such as increasing tax regimes, regulatory restrictions, and compliance requirements are encouraging more consumers to switch to illegal, cheaper tobacco- related products, and providing greater rewards for smugglers. **All of these factors based on Illicit-illicit trade can has had and may continue to** have an adverse effect on our overall sales volume, **may** restrict the ability to increase selling prices, damage **our** brand equity, and may lead to commoditization of our **Products-products**. Although **If we combat counterfeiting of our Products are unable to manage the risks posed by illicit competition engaging in certain tactics**, such as requiring all sales force personnel to randomly collect **our results of operation and overall business may suffer**. **Our** Products from retailers in order to be tested by our quality control team, maintaining a quality control group that is responsible for identifying counterfeit products and surveillance of retailers we suspect are selling counterfeit Products through our own secret shopper force, no assurance can be given that we will be able to detect or stop sales of all counterfeit products. In addition, we have in the past and will continue to bring suits against retailers and distributors that sell certain counterfeit products. While we have been successful in securing financial recoveries from and helping to obtain criminal convictions of counterfeiters in the past, no assurance can be given that we will be successful in any such suits or that such suits will be successful in stopping other retailers or distributors from selling counterfeit products. Even if we are successful, such suits could consume a significant amount of management' s time and could also result in significant expenses to us. Any failure to track and prevent counterfeiting of our Products could have a material adverse effect on our ability to maintain or effectively compete for our Products we distribute under the Bidi brand names, which would have a material adverse effect on our business, results of operations and financial condition. Our Products are regulated by the FDA, which has broad regulatory powers. Increases in tobacco- related taxes have been proposed or enacted and are likely to continue to be proposed or enacted in numerous jurisdictions. Tobacco products, premium cigarette papers, and tubes have long been subject to substantial federal, state, and local excise taxes. Such taxes have frequently been increased or proposed to be increased, in some cases significantly, to fund various legislative initiatives or further disincentivize tobacco usage. Since 1986, smokeless products have been subject to federal excise tax. Federally, smokeless products are taxed by weight (in pounds or fractional parts thereof) manufactured or imported. Any increases in tobacco- related taxes may materially adversely affect the demand for **the our Products-products**. The market for ENDS products is subject to a great deal of uncertainty and is still evolving. ENDS products, having recently been introduced to market over the past 10 to 15 years, are at a relatively early stage of development, and represent core components of a market that is evolving rapidly, highly regulated, and characterized by a number of market participants. Rapid growth in the use of, and interest in, ENDS products is recent, and may not continue on a lasting basis. The demand and market acceptance for these products is subject to a high level of uncertainty. Therefore, we are subject to all the business risks associated with a new enterprise in an evolving market. For example, ENDS products that are non- tobacco flavored continue to face the threat of prohibition at the local level, as many state and local authorities and attorneys general push for bans or request the FDA to deny a PMTA for flavored ENDS. To date, at least four states have banned the sale of flavored ENDS (e. g., New York, New Jersey, Rhode Island, and Massachusetts), with several more considering similar bans (e. g., Maryland, California, and Connecticut). As the September 9, 2021, PMTA review deadline has now passed, the FDA has implemented a de facto ban of **non- tobacco** flavored ENDS by denying over **93-99%** of pending applications, while issuing zero marketing authorizations **for non- tobacco flavored ENDS**. If flavors are ultimately prohibited to be sold by Bidi, **because of the FDA' s decision on the Section 10. 75 review regarding the inclusion of the Arctic BIDI @ Stick in the United States MDO, or otherwise**, the use of ENDS products may decline significantly, which may materially and adversely affect our business, financial condition, and results of operations. Continued evolution, uncertainty, and the resulting increased risk of failure of our new and existing product offerings in this market could have a material adverse effect on our ability to build and maintain market share and on our business, results of operations and financial condition. **For more information, see Item 1. Business-- FDA PMTA Determinations, 11th Circuit Decision and Impact on Our Business**. Some of our **Product-product** offerings through Bidi are subject to developing and unpredictable regulation. Our **Products-products** are sold through our distribution network and may be subject to uncertain and evolving federal, state, and local regulations,

including hemp, non- THC cannabidiol (CBD) and other non- tobacco consumable products. Enforcement initiatives by those authorities are therefore unpredictable and impossible to anticipate. We anticipate that all levels of government, which have not already done so, are likely to seek in some way to regulate these products, but the type, timing, and impact of such regulations remains uncertain. These regulations include or could include restrictions including prohibitions on certain form factors, such as smokable hemp products, or age restrictions. On January 26, 2023, **The** FDA announced that it would not initiate rulemaking to regulate CBD as a dietary food ingredient. Rather, after careful review, the FDA has concluded that a new regulatory pathway for CBD is needed that balances individuals' desire for access to CBD products with the regulatory oversight needed to manage risks. The FDA further indicated that it is prepared to work with Congress on this matter. Accordingly, we cannot give any assurance that such actions would not have a material adverse effect on this emerging business. Significant increases in state and local regulation of our **Products products** have been proposed or enacted and are likely to continue to be proposed or enacted in numerous jurisdictions. The **Prevent All Cigarette Trafficking (or PACT)** Act, which went into effect in June 2010, amended the Jenkins Act and initially only applied to the sales of cigarettes, roll- your- own tobacco, and smokeless tobacco. Specifically, the PACT Act regulates the sale, transfer, or shipment of these products for both business- to- business transactions as well as " delivery sales, " which are defined as any sale of cigarettes, roll- your- own tobacco, or smokeless tobacco where the consumer orders the product remotely and prohibits such deliveries through the U. S. Postal Service ("**or** USPS "), except in certain circumstances (e. g., business- to- business deliveries). Under the enactment of the Preventing Online Sales of E- Cigarettes to Children Act (part of the larger 2021 Consolidated Appropriations Act), effective March 27, 2021, the definition of " cigarettes " in the PACT Act was amended to include ENDS, which is defined as " any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device, " including " an e- cigarette; an e- hookah; an e- cigar; a vape pen; an advanced refillable personal vaporizer; an electronic pipe; and any component, liquid, part, or accessory of a device described above, without regard to whether the component, liquid, part, or accessory is sold separately from the device. " As such, delivery sales of the BIDI ® Stick are subject to the PACT Act. The PACT Act requires all sellers to register with the ATF, as well as the tobacco tax administrators of the states into which a shipment is made or in which an advertisement or offer is disseminated. Delivery sellers who ship cigarettes (including ENDS) or smokeless tobacco to consumers are further required to label packages as containing tobacco, verify the age, and identity of the customer at purchase, use a delivery method (other than through the USPS) that checks ID and obtains adult customer signature at delivery, and maintain records of delivery sales for a period of four years after the date of sale, among other things. Delivery sellers are also required to file a monthly report with the state tobacco tax administrator and any other local or tribal entity that taxes the sale of the products. Such reports must include the name and address of the persons delivering and receiving the shipment and the brand and quantity of the " cigarettes " that were shipped. These requirements apply to all sales, including sales to consumers and sales between businesses. In addition to the de facto FDA flavor ban that has resulted from the denial of nearly all PMTAs for flavored ENDS, ENDS products that are non- tobacco flavored continue to face the threat of prohibition at the local level, as many state and local authorities and attorneys general push for bans or request the FDA to deny PMTAs for flavored ENDS. To date, at least four states have banned the sale of flavored ENDS (e. g., New York, New Jersey, Rhode Island, and Massachusetts), with several more considering similar bans (e. g., Maryland, California, and Connecticut). Our supply to our wholesalers and retailers is dependent on the demands of their customers who are sensitive to increased sales taxes and economic conditions affecting their disposable income. Consumer purchases of tobacco products are historically affected by economic conditions, such as changes in employment, salary and wage levels, the availability of consumer credit, inflation, interest rates, fuel prices, sales taxes, and the level of consumer confidence in prevailing and future economic conditions. Discretionary consumer purchases, such as the BIDI ® Stick, may decline during recessionary periods or at other times when disposable income is lower, and taxes may be higher. We may be subject to increasing international control and regulation. The FCTC is the first international public health treaty that establishes a global agenda to reduce initiation of tobacco use and regulate tobacco to encourage tobacco cessation. Over 170 governments worldwide have ratified the FCTC. The FCTC has led to increased efforts to reduce the supply and demand of tobacco products and to encourage governments to further regulate the tobacco industry. The tobacco industry expects significant regulatory developments to take place over the next few years, driven principally by the FCTC. Regulatory initiatives that have been proposed, introduced or enacted include: ● the levying of substantial and increasing tax and duty charges; ● restrictions or bans on advertising, marketing and sponsorship; ● the display of larger health warnings, graphic health warnings and other labeling requirements; ● restrictions on packaging design, including the use of colors and generic packaging; ● restrictions or bans on the display of tobacco product packaging at the point of sale, and restrictions or bans on cigarette vending machines; ● requirements regarding testing, disclosure and performance standards for tar, nicotine, carbon monoxide and other smoke constituents levels; ● requirements regarding testing, disclosure and use of tobacco product ingredients; ● increased restrictions on smoking in public and workplaces and, in some instances, in private places and outdoors; ● elimination of duty- free allowances for travelers; and ● encouraging litigation against tobacco companies. Our business may be damaged by events outside of our own or Bidi' s control, such as the impact of epidemics (e. g., **political changes, or natural disasters. Our business could be adversely affected by the effects of epidemics, political changes, wars or natural disasters. World economies and capital markets have been adversely impacted by COVID- 19) and its variants , the Ukraine- Russia conflict, the recent eruption of hostilities in Israel and Gaza and political instability** changes, or natural disasters. COVID- 19 could adversely impact our business, including several key activities that are critical to our success. The global outbreak of COVID- 19 and variants of the virus continues to rapidly evolve. While business interruption due to COVID- 19 began to abate during 2022, global businesses have continued to be subject to intermittent closures and countries around the world have continued to sporadically limit travel. The extent to which COVID- 19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate impact of the disease on specific geographies, the duration of the outbreak, travel

restrictions and social distancing in the United States and elsewhere. The lasting impacts of other countries, business closures or business disruptions and the these matters on effectiveness of actions taken in the United States and broader other countries to contain and treat the disease. The spread of COVID-19 throughout the world has also created global economic economy uncertainty, including which may cause partners, suppliers, and potential customers to closely monitor their costs and reduce their spending budget. Either of the foregoing could materially adversely affect our research and development activities, clinical trials, supply chain disruption, may have a significant continuing negative effect on our company and may continue to materially impact our company, our ability to conduct business, our financial condition and results of cash flows. If the COVID-19 outbreak continues to spread, we may need to limit operations or implement other limitations on our activities. There is a risk that other countries or regions may be less effective at containing COVID-19, in which case the risks described herein could be elevated significantly. Reliance on information technology means a significant disruption could affect our communications and operations. We increasingly rely on information technology systems for our internal communications, controls, reporting and relations with customers and suppliers, and information technology is becoming a significantly important tool for our sales staff. In addition, our reliance on information technology exposes us to cyber- security risks, which could have a material adverse effect on our ability to compete. Security and privacy breaches may expose us to liability and cause us to lose customers or may disrupt our relationships and ongoing transactions with other entities with whom we contract throughout our network. The failure of our information systems to function as intended, or the penetration by outside parties' intent on disrupting business processes, could result in significant costs, loss of revenue, assets or personal or other sensitive data and reputational harm. Security and privacy breaches may expose us to liability and cause us to lose customers. Federal and state laws require us to safeguard our wholesalers', retailers', and consumers' financial information, including credit information. Although we have established security procedures to protect against identity theft and the theft of our customers' financial information, our security and testing measures may not prevent security breaches. We cannot guarantee that a future breach will not result in material liability or otherwise harm to our business. In the event of any such breach, we may be required to notify governmental authorities or consumers under breach disclosure laws, indemnify consumers, or other third parties for losses resulting from the breach, and expend resources investigating and remediating any vulnerabilities that contributed to the occurrence of the breach. We rely on third- party technology to safeguard the security of sensitive information in our possession. Advances in computer capabilities, new discoveries in the field of cryptography, inadequate facility security or other developments may result in a compromise or breach of the technology used by us to protect customer data. Any compromise of our security, even a security breach that does not result in a material liability could harm our reputation and, therefore, our business and financial condition. In addition, a party who can circumvent our security measures or exploit inadequacies in our security measures, could, among other effects, misappropriate proprietary information, cause interruptions in our operations or expose customers and other entities with which we interact to computer viruses or other disruptions. Actual or perceived vulnerabilities may lead to claims against us. Any insurance coverage that we obtain to cover such risks may be insufficient to cover all claims or losses. To the extent the measures we have taken prove to be insufficient or inadequate, we may become subject to litigation or administrative sanctions, which could result in significant fines, penalties or damages and harm to our reputation. We may fail to manage our growth. We have grown significantly in a short amount of time and intend to continue to grow in the future. However, any future growth will place additional demands on our resources, and we cannot be sure we will be able to manage our growth effectively. If we are unable to manage our growth while expanding the distribution of our Products-products and increasing profit margins, or if new systems that we implement to assist in managing our growth do not produce the expected benefits, our business, financial position, results of operations and cash flows could be adversely affected. We may not be able to support, financially or otherwise, future growth, or hire, train, motivate and manage the required personnel. Our failure to manage growth effectively could also limit our ability to achieve our goals as they relate to streamlined sales, marketing and distribution operations and the ability to achieve certain financial metrics. We are subject to fluctuations in our results that make it difficult to track trends and develop strategies in the short term. In response to competitor actions and pricing pressures, we have engaged in significant use of promotional and sales incentives. We regularly review the results of our promotional spending activities and adjust our promotional spending programs to maintain our competitive position as well as to confirm compliance with our adult- focused marketing policies. Accordingly, unit sales volume and sales promotion costs in any period are not necessarily indicative of sales and costs that may be realized in subsequent periods. Additionally, promotional activity significantly increases net sales in the month in which it is initiated, and net sales are adversely impacted in the month after a promotion. Accordingly, based upon the timing of our marketing and promotional initiatives, we have and may continue to experience significant variability in our results, which could affect our ability to formulate strategies that allow us to maintain our market presence across volatile periods. If our fluctuations obscure our ability to track important trends in our key markets, it may have a material adverse effect on our business, results of operations and financial condition. Adverse U. S. and global economic conditions could negatively impact our business, prospects, results of operations, financial condition or cash flows. Our business and operations are sensitive to global economic conditions. These conditions include interest rates, energy costs, inflation, recession, fluctuations in debt and equity capital markets, and the general condition of the United States and world economies, including as a result of the effect of the COVID- 19 pandemic. A material decline in the economic conditions affecting consumers, which cause a reduction in disposable income for the average consumer, may change consumption patterns, and may result in a reduction in spending on our Product-product offerings or a switch to cheaper products or products obtained through illicit channels. As such, demand for our Products-products may be particularly sensitive to economic conditions such as inflation, recession, high energy costs, unemployment, changes in interest rates and money supply, changes in the political environment, the ultimate effect on the economy of the COVID- 19 pandemic and other factors beyond our control, any combination of which could result in a material adverse effect on our business, results of operations, and financial condition. The departure of key management personnel and the failure to attract and retain talent could adversely affect our

operations. Our success depends upon the continued contributions of our senior management, especially our **Executive Chairman and Interim Chief Executive Officer and President, Barry Hopkins, our Chief Financial Officer, Treasurer and Secretary, Thomas Metzler, our Chief Operating Officer, Stephen Sheriff** ~~Eric Messer~~, and our Chief Science & Regulatory Officer, Nirajkumar Patel. If one or more of our executive officers are unable or unwilling to continue in their present positions, we may not be able to replace them readily, if at all. Additionally, we may incur additional expenses to recruit and retain new executive officers. If any of our executive officers join a competitor or forms a competing company, we may lose some or all of our customers. Finally, we do not maintain “key person” life insurance on any of our executive officers. Because of these factors, the loss of the services of any of these key persons could adversely affect our business, financial condition, and results of operations. Our insurance may be insufficient to cover losses that may occur as a result of our operations. We currently maintain directors’ and officers’ liability insurance and property and general liability insurance. This insurance or other insurance we may elect to obtain may not be or remain available to us or be obtainable by us at commercially reasonable rates, and the amount of our coverage may not be adequate to cover any liability we incur. Future increases in insurance costs, coupled with the increase in deductibles, will result in higher operating costs and increased risk. If we were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if we were to incur such liability at a time when we were not able to obtain liability insurance, our business, results of operations and financial condition could be materially adversely affected.

Risks Related to our Securities Our Restated Certificate of Incorporation, as amended (our “Certificate of Incorporation”), and our Bylaws (our “Bylaws”), as well as the DGCL and certain regulations, could discourage or prohibit acquisition bids or merger proposals, which may adversely affect the market price of our Common Stock. Provisions of our Certificate of Incorporation and Bylaws and the DGCL may discourage, delay or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares of our Common Stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In addition, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, which generally refers to a person which together with its affiliates owns, or within the last three years has owned, 15 percent or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of Common Stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that our stockholders could receive a premium for their Common Stock in an acquisition.

For so long as any shares of Series B Preferred Stock remain outstanding, the majority holders of the Series B Preferred Stock are entitled to designate one individual to be nominated to serve as a director on our board of directors. For so long as any shares of Series B Preferred Stock remain outstanding, the majority holders of the Series B Preferred Stock (or the Majority Holders) will be entitled to designate one (1) individual to be nominated to serve as a director (who we refer to as the Series B Preferred Director) on our board of directors (or the Board). At each annual meeting of the stockholders of our company, or at any special meeting called for the purpose of electing directors, the Board shall nominate such designee for election. Unless the Board shall have received from the Majority Holders a written designation by March 1 of each calendar year of an individual other than the then-sitting Series B Preferred Director, the Board shall nominate the then-sitting Series B Preferred Director for re-election to the Board. The Series B Preferred Director is subject to any board of directors-related provisions that may be contained in our Certificate of Incorporation or Bylaws. The Majority Holders, voting as a single class at a meeting called for such purpose (or by written consent signed by the Majority Holders in lieu of such a meeting), have the sole right to remove the Series B Preferred Director from the Board. Any vacancy created by the removal, resignation or death of a Series B Preferred Director may solely be filled by the Majority Holders, voting as a single class, at a meeting called for such purpose (or by written consent signed by the Majority Holders in lieu of such a meeting). The Series B Preferred Director shall be entitled to receive similar compensation, benefits, reimbursement (including of reasonable travel expenses), indemnification and insurance coverage for his or her service as a director of our company as the other non-employee directors of on the Board. The initial Series B Preferred Director is Mr. James P. Cassidy. As of the date of this Report, the seat on our Board designated for the Series B Preferred Director is vacant due to Mr. Cassidy’s resignation from the Board on January 25, 2024. As a result of their Board appointment right, the Majority Holders could have a disproportionate impact on our governance and operations, which could have an adverse effect on our company. The Series B Preferred Stock ranks senior to our Common Stock. The Series B Preferred Stock ranks, with respect to dividend rights, rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of our company, and redemption rights, senior to the Common Stock and each other class or series of securities now existing or hereafter authorized classified or reclassified, the terms of which do not expressly provide that such class or series ranks on a parity basis with or senior to the Series B Preferred Stock as to dividend rights, rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of our company, and redemption rights. Future offerings of debt or equity securities may rank senior to our Common Stock. We may have a present need for additional capital, and we will likely continue to seek to raise new funding from time to time through the issuance of debt or equity securities. Our Board of Directors has the ability, without further approval of our stockholders, to issue debt or equity securities in the future, **in addition to the Series B Preferred Stock**, ranking senior to our Common Stock or otherwise incur additional indebtedness, it is possible that these securities or indebtedness will be governed by an indenture or other instrument containing covenants restricting our operating flexibility and limiting our ability to pay dividends to stockholders. Additionally, any convertible or exchangeable securities that we issue in the future may have rights, preferences, and privileges, including with respect to dividends, more favorable than those of our Common Stock and may result

in dilution (perhaps significant) to our stockholders. Because our decision to issue debt or equity securities in any future offering or otherwise incur indebtedness will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, or nature of our future offerings or financings, any of which could reduce the market price of our Common Stock and dilute its value. ~~Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies, if any, or Products. We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interests will be diluted, and the terms of such financings may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our Products or grant licenses on terms that are not favorable to us.~~ We may issue **additional classes or series of** preferred stock whose terms could adversely affect the voting power or value of our ~~Common~~ **Common Stock**. Our Certificate of Incorporation authorizes 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 may determine. The terms of one or more **additional** 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 some 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 dividend or liquidation preferences we might assign to holders of preferred stock could affect the residual value of our Common Stock. The market ~~prices~~ **price** for our Common Stock ~~are is~~ **and has** and will fluctuate. The market price for shares of our Common Stock may be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond our control, including the following: (i) **action by the FDA with respect to Bidi's PMTAs or regulatory action by FDA generally against Bidi, our company or our industry,** (ii) actual or anticipated fluctuations in our quarterly financial results; (iii) recommendations by securities research analysts; (iv) changes in the economic performance or market valuations of other issuers that investors deem comparable to ours; (v) addition or departure of our executive officers or members of our Board and other key personnel; (vi) release or expiration of lock-up or other transfer restrictions on outstanding shares of Common Stock; (vii) sales or perceived sales of additional shares ~~of our Common Stock;~~ (viii) **the liquidity of our Common Stock or lack thereof;** (ix) significant acquisitions or business combinations, strategic partnerships, joint ventures, or capital commitments by or involving us or our competitors; and (x) news reports relating to trends, concerns, technological or competitive developments, regulatory changes, and other related issues in our industry or target markets. Financial markets often experience significant price and volume fluctuations that affect the market prices of equity securities of public entities and that are, in many cases, unrelated to the operating performance, underlying asset values or prospects of such entities. Accordingly, the market price of our shares of Common Stock may decline even if our operating results, underlying asset values or prospects have not changed. Our Common Stock is listed on the Nasdaq ~~Capital Market ("Nasdaq")~~ but there can be no assurance that we will be able to comply with the continued listing standards of Nasdaq in the future, **particularly since we are presently experiencing a Nasdaq continuing listing deficiency.** ~~We~~ **Although our Common Stock is listed on Nasdaq, we** cannot assure you that we will be able to comply with the standards that we are required to meet in order to maintain a listing of our Common Stock on Nasdaq in the future. Nasdaq listing rules require us to maintain certain closing bid price, stockholders' equity, and other financial metric criteria, as well as certain corporate governance requirements, for our Common Stock to continue trading on Nasdaq. If we fail to comply with the continued listing standards, our Common Stock could be delisted. We have been subject to Nasdaq listing deficiency issues in the past ~~on~~. **On** January 26, 2022, Nasdaq notified ~~us the Company~~ **that it was we were** not in compliance with the requirement to maintain a minimum closing bid price of \$ 1.00 per share, as set forth in Nasdaq Listing Rule 5550 (a) (2) **(the "Bid Price Rule")**, because the closing bid price of ~~our the Company's common stock (the "Common Stock")~~ was below \$ 1.00 per share for 30 consecutive business days. While this listing deficiency was cured ~~during~~, **on January 30, 2022-2023**, **Nasdaq again notified us that we were not in compliance with** ~~may become subject to potential delisting if the Bid price Price of Rule given that our Common Stock again falls had traded at~~ below \$ 1.00, ~~or for 30 consecutive business days.~~ **While we regard compliance with other -- the reasons Bid Price Rule as of February 8, 2024 as a result of our January 2024 reverse stock split, we remain subject to the risk that our Common Stock price could again fall below \$ 1.00 and we may again become subject to delisting for failure to comply with the Bid Price Rule. Moreover, on November 7, 2023, we received written notice from Nasdaq stating that we failed to hold an annual meeting of shareholders within twelve (12) months after our fiscal year ended on October 31, 2022, as required by Nasdaq Listing Rule 5620 (a) (or the Annual Meeting Listing Rule). We submitted a plan of compliance to Nasdaq and have been granted until April 29, 2024 to hold our annual meeting. There can be no assurances given that we will be able to cure any listing deficiencies related to our company.** A failure to maintain listing on Nasdaq could have a material adverse effect on the liquidity and price of ~~the our~~ Common Stock. Future sales of shares of our Common Stock by our controlling shareholder ~~H~~ or by our officers and directors may negatively impact the market price for our Common Stock. Subject to compliance with applicable securities laws, our controlling shareholder ~~KH~~ **Kaival Holdings** as well as our directors and officers and their affiliates may sell some or all of their

shares of our Common Stock in the future. No prediction can be made as to the effect, if any, such future sales of shares of our Common Stock may have on the market price of the shares of our Common Stock prevailing from time to time. However, the future sale of a substantial number of shares of our Common Stock by our directors and officers and their affiliates, or the perception that such sales could occur, could adversely affect prevailing market prices for our shares of our Common Stock. The concentration of ownership ~~among by Kaival Holdings and~~ our officers ~~;~~ and directors ~~;~~ **may result in conflicts of interest** and ~~principal stockholders~~ may prevent other stockholders from influencing significant corporate decisions and depress our stock price. Based on the number of shares outstanding as of ~~January 27~~ **as of the date of this Report**, 2023 **Kaival Holdings, our affiliated majority stockholder, together with** our officers ~~;~~ and directors, and stockholders who hold at least 5% of our stock ~~beneficially own a combined total of approximately 77.1~~ **68.64** percent of our outstanding Common Stock, including shares of our Common Stock subject to stock options that are currently exercisable or are exercisable and that vest within 60 days ~~after January 27, 2023~~ **as of the date of this prospectus**. If **our controlling stockholder, together with** these officers ~~;~~ and directors ~~;~~ and principal stockholders or a group of our principal stockholders act together, they will be able to exert a significant degree of influence over our management and affairs and control matters requiring stockholder approval, including the election of directors and approval of mergers, business combinations, or other significant transactions. **The In particular, the** interests of ~~one Kaival Holdings (which is controlled by Nirajkumar Patel, or our~~ **more of these stockholders Chief Science and Regulatory Officer and director)** may not always coincide with our interests or the interests of other stockholders **, which could cause Mr. Patel to become subject to conflicts of interests which may not be resolved in favor of our minority stockholders. Mr. Patel also controls Bidi, our principal commercial partner, as well as the entity that is the landlord of our principal officer and warehouse, all of which creates the potential for conflicts of interest for Mr. Patel.** For ~~instance~~ **example**, **Kaival Holdings, together with our** officers ~~;~~ and directors ~~;~~ and principal stockholders, acting together ~~,~~ could cause us to enter into transactions or agreements that we would not otherwise consider **or might not be in the best interests of our minority stockholders**. Similarly, this concentration of ownership may have the effect of delaying or preventing a change in control of our company otherwise favored by our other stockholders. This, in turn, could have a negative effect on the market price of our Common Stock. It could also prevent our stockholders from realizing a premium over the market price for their shares of our Common Stock. The concentration of ownership also may contribute to the low trading volume and volatility of our Common Stock. **Moreover, any such conflicts of interests may not be easy to resolve and could impair our ability to operate our business.** Our Common Stock may become the target of a “short squeeze.” Beginning in 2021, the securities of several companies have increasingly experienced significant and extreme volatility in stock price due to short sellers of shares of ~~common~~ **Common stock Stock** and buy- and- hold decisions of longer investors, resulting in what is sometimes described as a “short squeeze.” Short squeezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies trading at a significantly inflated rate that is disconnected from the underlying value of the company. Sharp rises in a company’s stock price may force traders in a short position to buy ~~the~~ stock to avoid even greater losses. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks has abated. We may be a target of a short squeeze, and investors may lose a significant portion or all their investment if they purchase our shares at a rate that is significantly disconnected from our underlying value. If securities or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline. The trading market for our Common Stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our Common Stock, or if our results of operations do not meet their expectations, our stock price could decline. We do not currently pay dividends on our shares of ~~our~~ Common Stock and have no intention of paying dividends on shares of our Common Stock for the foreseeable future. No dividends on the shares of our Common Stock have been paid by us to date. We do not intend to declare or pay any cash dividends in the foreseeable future. Payment of any future dividends will be at the discretion of our Board, after considering a multitude of factors appropriate in the circumstances, including our operating results, financial condition, and current and anticipated cash needs. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends unless certain consents are obtained, and certain conditions are met. There is no assurance that future dividends will be paid, and, if dividends are paid, there is no assurance with respect to the amount of any such dividend. Unless our Board decides to pay dividends, our stockholders will be required to look at appreciation of our Common Stock to realize a gain on their investment. There can be no assurance that this appreciation will occur. For as long as we are an “emerging growth company” we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our Common Stock being less attractive to investors and could make it more difficult for us to raise capital as and when we need it. We are an “emerging growth company,” as defined in the JOBS Act, and we have taken advantage, and intend to continue to take advantage, of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (“Sarbanes- Oxley”), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non- binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors may find our Common Stock less attractive because we rely on these exemptions, which could contribute to a less active trading market for our Common Stock or volatility in our share price. In addition, we may be less attractive to investors, and it may be difficult for us to raise additional

capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We have identified material weaknesses in our system of internal controls over financial reporting and, if we cannot remediate these material weaknesses, we may not be able to accurately report our financial condition, results of operations, or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our Common Stock. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of Sarbanes- Oxley also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our system of internal controls over financial reporting. However, if we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement. Our management has identified, and we have disclosed, certain material weaknesses in our system of internal controls over financial reporting as of our fiscal year ended October 31, 2022 2023. Specifically, our management has found that our internal control system over financial reporting was ineffective as of October 31, 2022-2023, based on a determination that there was a lack of sufficient resources to provide adequate segregation of duties consistent with control objectives, the lack of sufficient and consistent real time remote communications, and the lack of a fully developed formal review process that includes multiple levels of review over financial disclosure and reporting processes. To address these material weaknesses, and subject to the receipt of additional financing or cash flows, we have undertaken, and intend to continue to undertake, remediation measures to address such material weaknesses, including implementing prevent and detect internal control procedures pursuant to which we can ensure segregation of duties and hire additional resources to ensure appropriate review and oversight. Our compliance with Section 404 of Sarbanes- Oxley will require that we incur substantial accounting expenses and spend significant management efforts. We may not be able to complete our evaluation, testing, and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our system of internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. This may expose us, including individual executives, to potential liability which could significantly affect our business. We cannot assure you that we will, in the future, identify areas requiring improvement in our system of internal controls over financial reporting. We cannot assure you that the measures we will take to remediate any areas in need of improvement will be successful or that we will implement and maintain adequate controls over our financial reporting process and reporting in the future as we continue to grow. If we are unable to establish appropriate internal financial reporting controls and procedures, if we are unable to conclude that our system of internal controls over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our system of internal controls over financial reporting once that firm begins its audits of our systems of internal controls over financial reporting, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, cause investors to lose confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our system of internal controls over financial reporting, or to implement or maintain other effective internal control systems required of public companies, could also restrict our future access to the capital markets. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. As of October 31, 2022-2023, our President and Chief Operating Executive Officer and our Interim Chief Financial Officer concluded that the disclosure controls and procedures were not effective as of such date due to material weaknesses in internal controls identified above. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our internal controls system, misstatements, or insufficient disclosures due to error or fraud may occur and not be detected. We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management has been required, and will continue to be required, to devote substantial time to new compliance initiatives. As a public company, we have incurred and are continuing to incur significant legal, accounting, and other expenses and these expenses may increase even more after we are no longer an “ emerging growth company ” and “ smaller reporting company. ” We are subject to the reporting requirements of the Exchange Act and the rules adopted, and to be adopted, by the SEC. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time- consuming and costly. The increased costs can result in our reporting a net loss. These rules and regulations may make it more difficult and more expensive for us to maintain sufficient directors’ and officers’ liability insurance coverage. We cannot predict or estimate the amount or timing of additional costs we may continue to incur to respond to these requirements. The ongoing impact of these requirements could also make it more

difficult for us to attract and retain qualified people to serve on our Board, our Board committees, or as executive officers.