

# SanMelix Laboratories, Inc.



## Annual Report – Form C-AR

525 Lago Matisse Street  
Poinciana, FL 34759

This Annual Report is dated March 1, 2023.

## BUSINESS

### Overview

SanMelix Laboratories, LLC was formed on August 29, 2016 in the State of Florida. SanMelix Laboratories, Inc. was incorporated on January 13, 2017 in the State of Delaware. On February 6, 2018 SanMelix Laboratories, LLC was merged into SanMelix Laboratories, Inc., with SanMelix Laboratories, Inc. (“SanMelix” or “SanMelix Laboratories” or “We”) being the surviving entity.

SanMelix Laboratories is a bioactive skin and wound care company focusing on the unique medicinal properties of buckwheat honey for tissue regeneration and moist wound healing. With IP protection on our BEECure® dressing and other patents, co-created by the renowned Harvard trained podiatric physician, Dr. Kenneth Sabacinski, SanMelix's advanced bioactive skin and wound care products can be used in a host of settings and situations. By combining the potency of natural Buckwheat Honey and other natural ingredients, SanMelix developed masstige and prestige formulated cosmetic solutions that repair, strengthen, and maintain a healthy skin barrier to meet key anti-aging, hydration, and brightening challenges. We have created over the counter (“OTC”) skin care products such as ointments and creams designed to help in the healing of minor burns, cuts, and scrapes, and to soothe skin damaged by radiation or laser therapy. Our products will also be used by physicians for advanced wound care healing in hospitals and rehabilitation centers pending U.S. Food & Drug Administration (“FDA”) clearance of our products in a clinical setting. The Company is a business whose planned principal operations are the research, formulation, and manufacturing of these advanced wound care and skin care honey-based products.

## Products

At SanMelix, we harness the power of nature and science in order to hydrate and strengthen the skin barrier as well as to revitalize skin integrity. Good skin integrity is vital to good health because the skin acts as a barrier to microbes and toxins as well as physical stressors such as sunlight and radiation. It is well known that the skin loses integrity as we age, and this makes adult skin susceptible to collagen loss, decreased elasticity, increased fine lines, wrinkles, and injury. In addition, diabetic foot ulcers, pressure ulcers and other types of wounds develop when the skin is breached due to either injury, surgery, or loss of skin integrity caused by aging and chronic diseases.

Our clinically proven buckwheat honey formulations and patented technologies help heal acute and chronic wounds, minor burns from radiation & laser therapy and sun burns, and improve hydration, brightness, and skin aging. Our products range from prestige and masstige products to medical devices and OTC/Rx offerings.

We chose buckwheat honey based on the following characteristics of this unique ingredient:

- (1) Studies have proven buckwheat honey has superior medicinal properties to Manuka honey and other natural remedies due to its higher anti-inflammatory, higher antioxidant, and superior tissue regeneration properties.
- (2) Buckwheat (*fagopyrum esculentum*) is a highly nutritious whole grain that many people consider to be a “superfood.” Buckwheat honey contains the polyphenols/flavonoids, amino acids, minerals, and the other potent natural healing ingredients of the buckwheat flower along with the hydrating properties of the honey to create a “superfood for the skin.”

Furthermore, our patented formulation has been fortified with a standardized amount of methylglyoxal to ensure consistency (1,000 + mg/kg) in preservative effectiveness by acting as a formulation stabilizer. The antioxidant properties inherent in Buckwheat honey also assist in wound closure and help to stimulate the wound healing process. The mix of Buckwheat honey and other natural ingredients with our patented formulation is anticipated to provide a stabilized moist wound environment to promote healing.

Accordingly, our products are being created to address the following health issues:

- (1) There are an estimated 26 million patients that develop diabetic foot ulcers globally which last on average 13 months and recur in up to 70% of patients resulting in 15% requiring amputations of which 47% of amputees ending in death. Case studies on our BEECure<sup>®</sup> advanced wound care dressings have illustrated healing and skin regeneration on severe limb threatening wounds and diabetic foot ulcers.
- (2) OTC products with synthetic drugs often have dangerous side effects. Our OTC products for minor burns, cuts, and scrapes and other skin condition will be natural and clean products with fewer side effects than synthetic drugs.
- (3) Of the 3 million patients receiving radiation, 85% experience moderate to severe skin reactions. Studies have shown honey reduces scarring and inflammation related to radiotherapy, laser therapy, and thermal burns. Our BEECure<sup>®</sup> Radiation and Laser Skin care formulation combines buckwheat honey with other natural ingredients (such as calendula, bisabol, willow bark extract, rosemary leaf extract,

shea butter, and jojoba seed oil), to hydrate and soothe damaged skin for patients undergoing radiation and laser therapy.

(4) There is a need for more potent and effective ingredients that are not drugs or FDA monographed ingredients to nourish, repair and strengthen our skin barrier. Skin is the largest organ in our bodies and is our primary defense against disease. When it is compromised, our defenses are weakened and we are more susceptible to different illnesses. Our BEECure<sup>®</sup> skin care products use the most potent buckwheat honey plant extracts, buckwheat honey and other natural ingredients to hydrate, soothe, and revive aging or damaged skin.

We have launched buckwheat honey-based cosmetic skin care products, including BEECure<sup>®</sup> R-Radiation & Laser skin care, that hydrate, soothe, and revive red, dry, itchy damaged skin related to radiation therapy, sunburns, and aging skin conditions.

## **Our Products in Use**

Our BEECure<sup>®</sup> products are categorized into two business segments with each being formulated with the common ingredient of buckwheat honey. The products can be used for a wide variety of advanced wound care (“AWC”) and skin irritations/skin conditions treatable by OTC or cosmetic-grade skin care products.

Because of the anticipated FDA claim in our AWC dressings, they will be instrumental in the treatment and healing of:

- ❖ Skin Ulcers, diabetic and otherwise (e.g. bed sores)
- ❖ Skin grafts
- ❖ Partial Thickness Burns
- ❖ Trauma and triage

In addition to our AWC products, SanMelix buckwheat honey-based OTC Skin Care creams and ointments can be used for the treatment of:

- ❖ Radiation and Laser Skin Care
- ❖ Minor burns
- ❖ Flaky and peeling skin
- ❖ Inflamed skin
- ❖ Rashes
- ❖ Rosacea
- ❖ Eczema
- ❖ Anti-aging
- ❖ Psoriasis

In January 2021, SanMelix launched its BEECure<sup>®</sup> R- Radiation and Laser Skin Care on Amazon.com. We have received an “Amazon Choice” designation which recommends highly rated and well-priced products. The advanced wound care products have been reviewed by the FDA, and the Company will need to perform additional testing and designation clarification for the FDA. Please see the Federal Food and Drug Administration section below for further discussion.

## **Manufacturing/Production Plan**

Our goal is to produce the highest quality dressings at the most cost-effective pricing for distributors and ultimately patients. Rather than building and operating our own manufacturing facilities, which require a significant capital investment, we are currently planning to utilize certified current Good Manufacturing Practices (“cGMP”) facilities as our contract manufacturers for our patented formulation wound care dressings.

The initial sample run for the patented technology was completed in February 2019 and was utilized for the 510(k) pre-market clearance testing. In addition, the Company must receive 510(k) pre-market clearance from the FDA prior to production and sale of its advanced wound care dressings. In 2020, SanMelix scheduled all FDA 510(k) testing based on the initial requirements provided by the FDA. Two 510(k) applications were submitted in July 2021. Both have been reviewed by the FDA and additional testing needs to be completed, along with product designation codes for the patented technology, have been provided to the company. Since the initial cGMP no longer manufactures our dressing, the Company has developed a strategic partnership with a South Korean manufacturer that operates in an FDA registered facility. See Federal Food and Drug Administration section below for further discussion.

Our initial BEECure® R- Radiation and Laser Skin Care was manufactured by a European International Organization for Standardization (“ISO”) Certified company. SanMelix launched this product on Amazon.com in January 2021. After the first two manufacturing runs in Europe, SanMelix plans to modify and improve its existing formulation and transfer manufacturing to a South Korean manufacturer. Due to modifications in our formulations during 2022, there were impairment losses related to the previously capitalized formulations and other intangible assets related to the formulations. The total amount of intangibles written off totaled \$300,000 of which \$130,000 was written off within R&D expense as this amount was previously paid for while the other \$170,000 reversed the accrued liability. The Company plans to launch its improved formulation in Q2 2023.

## **Sales Model**

Building from our existing retail relationships/distributions, we will grow our market share through strategic partnerships with Key Opinion Leaders (KOLs) across high growth OTC, medical, and cosmetic segments. Our customers may include the Veterans Affairs (“VA”) and Department of Defense (“DoD”), medical supply distributors, physician networks, hospitals, skilled nursing facilities (“SNFs”) as well as indirect sales channels for private label/white label for OTC opportunities. We are capitalizing on a market that has been desperately in need of a natural and safe products that promote healing of chronic and acute wounds and also repairs, strengthens, and maintains a healthy skin barrier to meet key anti-aging, hydration, brightening, burn and minor cut & scrape challenges.

Our initial sales focus will be two-fold for our AWC dressings. One focus will be for acute and hospital care for our patented, formulated wound dressing to assist hospitals to care for patients with diabetic foot ulcers. Upon receiving 510(k) clearance, our mission is to pursue a reimbursement code for our product by including our patented formulation in either a hydrogel/honey or a calcium alginate/honey dressing. Upon receiving a Healthcare Common Procedure Coding System (“HCPCS”) code, we anticipate approaching Part B Medicare distributors for use in physician networks and SNFs.

The Company will also focus on prestige retailers like QVC and Nordstrom. We have a strategic partnership with a K-Beauty innovator, P&J Medesthetics, US (“P&J”), who has successfully launched 350+ products with multiple brands on QVC/HSN generating over \$70 million. P&J has also developed

relationships with manufacturing companies, R&D teams and packaging companies in Seoul, South Korea (many with satellite offices in the USA). (See Manufacturing/Production Plan).

We will also leverage our relationship with P&J to offer supplier-enabled innovation by co-developing skin care formulations that can offer small batch and large batch manufacturing of age-defying formulas to align with customer brand and vision. We will provide a turnkey operation capability that can deliver resource and cost savings to the customer.

We launched our BEECure® R- Radiation and Laser skin care on Amazon.com and Walmart.com in January 2021. We plan to further sell to OTC consumers through digital marketing and social media. In addition, we are approaching distributors of skin care products who sell to dermatologists, oncologists, and cancer clinics. Lastly, we are pursuing drug store chains, QVC, and other retail outlets for distribution opportunities.

## **The Team**

The Company currently has two employees and works with multiple contractors in the areas of sales and marketing, research and development, reimbursement, regulatory, and advanced wound care. As we expand our operations, we anticipate our needs will change, at which time we intend to add additional contractors and employees in the areas of marketing, sales, manufacturing, and product development. In addition, we anticipate hiring additional employees to run the operations of the Company.

Dr. Kenneth Sabacinski, Chief Medical Officer (“CMO”), has worked in the advanced wound care space for over thirty years. He is a podiatric physician who started his training at Harvard Medical School and Beth Israel Deaconess Medical Center in Boston. His expertise is the treatment of limb and life-threatening wounds, including diabetic-related foot ulcers. He is the co-inventor of our patented formulations.

Diana Sabacinski, Chief Executive Officer (CEO) is a co-founder and dedicates herself full time to SanMelix. Diana has also been a successful entrepreneur with her prior company receiving the Inc. 500 award for the fastest-growing private companies in the U.S. She is a Certified Public Accountant (“CPA”) with over 25 years of financial consulting experience across a swath of fields including medical device manufacturing, as well as starting her career in a Big 4 CPA international accounting firm.

During the year ended December 31, 2019, Diana agreed to suspend her salary until the Company received funding in excess of \$750,000. The Company reached this goal in February 2021, and the CEO has agreed to re-invest her net compensation after taxes into the Company’s equity crowdfunding campaign until either the Company’s funding goal of \$1.07 million was reached or the equity crowdfunding campaign otherwise concluded. During 2021, StartEngine had several investment policy changes with the Company’s second crowdfunding campaign (Reg CF 2) which did not allow the CEO to make investments into the campaign. Based on that, the CEO agreed to forego her net salary once the policy changes took effect mid-year 2021. The net salary amount of \$138,791 is recorded as deferred compensation as of December 31, 2022.

John Kaufman is a co-founder and Board of Director member. Mr. Kaufman has been the founder, executive management, and innovator of multiple successful entities. He has 40+ years of management experience working with and for the U.S. Government, business startups, and large-scale manufacturing.

Steven Weinstein was elected to SanMelix’s Board of Directors in 2022. In addition to his Board duties, Steven acts Director & Lead of Partnership Development. Prior to joining SanMelix’s Board, Mr. Weinstein

was the Head of Supply Chain for Zarbee's Naturals (a Johnson & Johnson company), where he oversaw supply chain and operations for the fast-growing company (35+% YoY). Steven also had extensive knowledge and success in Demand and Supply Planning, Innovation and A&D activities within the skin care and supplement markets for J&J.

Hamid Khosrowshahi was elected to SanMelix's Board of Directors in 2019. In addition to his Board duties, Hamid acts as an AWC consultant to the Company. Hamid's experience includes President of FloSure Technologies, LLC, Founding Partner/President of Prospera Technologies, LLC, and President of BioCore Medical Technologies. Hamid possesses a wealth of knowledge in the medical device industry, including negative pressure wound care.

Samuel Hammer, CPA was elected to SanMelix's Board of Directors in 2020. In addition to his Board duties, Sam acts as a tax expert and financial consultant to the Company. Sam is the Managing Shareholder for Hammer Navarro and Associates, PA., a CPA firm with extensive experience and expertise in the healthcare industry.

In addition to our aforementioned directors, SanMelix's team includes consultants with expertise in sales and marketing, product development, manufacturing, and the regulatory and scientific fields along with reimbursement and government affairs.

## **Government Regulation**

Many governmental standards and regulations relating to safety, effectiveness and reimbursement are applicable to medical devices for sale in the United States, Europe, and elsewhere. In addition, manufacturing and other laboratory facilities in the United States, Europe, and elsewhere are subject to stringent standards regulating cGMP and Good Laboratory Practices ("GLP") and ISO. U.S. FDA approved manufacturers are also required to have Quality Control Management Systems ("QMS") that require the recall of products that have safety defects or noncompliance with respect to FDA standards; the cost of such recall campaigns could be substantial.

Our AWC products are medical devices or combination products that we expect to be cleared by the FDA through the 510(k) regulatory pathway in the United States and by CE Marking through Notified Bodies in Europe. Our cosmetic products are regulated under the Federal Food, Drug, and Cosmetic Act and the Code of Federal Regulations (CFR). The Company is required to comply with the CFRs related to medical devices and cosmetics as outlined in the Company's QMS.

## **Federal Food and Drug Administration**

In 2018, the company met with the FDA for a 510(k)-pre-submission meeting. The FDA considered our buckwheat honey-based products to be designated as Unclassified Product FRO (drug/device). During Q4 2020, the company contracted third-party GLPs to test the antimicrobial properties of our advanced wound care products and perform the 510(k)-testing recommended by the FDA. Our BEECure® patented buckwheat honey formulation demonstrated intrinsic healing activity and antimicrobial efficacy against six (6) superinfection bacteria (e.g., MRSA) using the AATCC 100 testing method modified for wound dressings. The results of the test exhibited a reduction in superinfection bacteria by 99.99% at 24 hours and at 72 hours intervals (estimated period of use).

During 2021 and 2022, the AWC MGO dressing 510(k) pre-market clearance application was reviewed by the FDA. After multiple discussions, the FDA changed its previous position from the initial pre-submission meeting on the preservative antimicrobial claim even though SanMelix passed all of the testing requested by the FDA (AATCC 100) in the pre-submission. The FDA's revised position stated that it will only consider an antimicrobial claim for the AWC MGO dressing if the Company considers MGO as a new "drug" and files a New Drug Application ("NDA"). If the Company chooses to continue on the 510(k) regulatory pathway, the Company will need to reapply for the 510(k) with the defining the role of MGO as a stabilizer instead of a preservative. The Company could mention the results of the AATCC 100 testing in its marketing but could not make the FDA antimicrobial preservative claim. The primary FDA claim in the new application for the patented formulation will be to provide a moist wound environment to promote healing, which is the claim that the FDA previously granted to the in-market predicate product.

In February 2023, the Company withdrew its 510(k) application on its patented formulation to prevent the product from receiving the NSE, not substantially equivalent, designation. In addition, our buckwheat honey dressing 510(k) application has received an NSE designation and the Company will be required to reapply. Per meetings with the FDA in 2022, additional testing and risk assessments will need to be performed. Upon completion of this new FDA-requested testing, the Company plans to resubmit two new 510(k) applications with additional information, The testing required for the new 510(k) application may result in significant expenditures requiring additional funding.

Additionally, we are exploring other OTC skin care products that would require compliance with the FDA Cosmetic Act as OTC monograph products. We will continue to test, research, and expand our products utilizing world renown physicians and scientists while complying with governmental standards and regulations relating to safety and effectiveness.

Based on initial 510(k) pre-market clearance testing, we believe that we will have a successful regulatory pathway; however, there can be no assurances that the products will pass all the required FDA standards for safety and effectiveness, which if not passed, would have a material adverse effect on the Company. In addition, the Company must obtain additional funding to perform additional testing and file revised 510(k) applications.

There are laws in which we may manufacture, market and/or sell our medical device products which could change and affect the acceptance of the products in the marketplace. There can be no assurance that our products will receive 510(k) pre-market clearance from the FDA or that the FDA will allow us to make certain claims. In addition, the FDA pre-market clearance process may take longer than anticipated.

## **Centers for Medicare & Medicaid Services**

The Centers for Medicare & Medicaid Services (CMS) is the government agency responsible for assigning Medicare Part B HCPCS codes for therapeutic dressings. At a minimum, the Company anticipates receiving a miscellaneous reimbursement code; however, the Company will also combine our patented formulation with hydrogel/collagen/calcium alginate and apply for various codes for surgical dressings. There can be no assurances that SanMelix will receive specific Medicare Part B HCPCS codes.

## **Market**

We are focusing on two major market segments for buckwheat honey formulations. Our first segment is for AWC dressings for burns and acute & chronic wounds, which require FDA pre-market clearance. The

second segment focuses on OTC ointments and creams for minor burns associated with skin irritations from radiation and laser therapy and cosmetic products to soothe, hydrate and revive dry and damaged skin. Our ability to convert medical-grade, patented formulations to prestige, masstige, and high-end cosmetic versions help companies, influencers and their brands source and commercialize innovations across a range of skin health and K-Beauty (Korean Beauty) focus areas. In addition, the skin and wound care market is expected to reach \$26 billion by 2025. The Company is focusing on the U.S. market which totals \$10 billion for the U.S. skin and wound care market. We are capitalizing on a market that has been desperately in search of natural, safe, and effective products to help heal acute and chronic wounds, minor burns from radiation & laser therapy and sun burns, and improve hydration, brightness, and skin aging. Our products range from high-end cosmetic skin care products, prestige and masstige products to medical devices and OTC/Rx offerings.

## Competition

The AWC dressing competitors are not only Integra, who purchased DermaScience Medihoney, and Medline, who distributes Therahoney, but also the larger market for antimicrobial wound dressings. The main players in the market include, but are not limited to, BSN Medical, Systagenix Wound Management Ltd., Mölnlycke Health Care, ConvaTec Inc., Paul Hartmann AG, Smith & Nephew, Covalon Technologies Inc, Organogenesis Inc, 3M Health Care, and Medtronic plc. Our over-the-counter (OTC) competitors include Difinsa53, J&J, Water Gel, Gold Bond, Neosporin and Miaderm.

Most of our current and potential competitors have significantly greater financial, technical, manufacturing, marketing, and other resources than we do and may be able to devote greater resources to the design, development, manufacturing, distribution, promotion, sale, and support of their products. Virtually all of our competitors have more extensive customer bases and broader customer and industry relationships than we do. In addition, almost all these companies have longer operating histories and greater name recognition than we do. Our competitors may be in a stronger position to respond quickly to new technologies and may be able to design, develop, market, and sell their products more effectively.

Our unique formulation technology is patented, supported by over 1,700 investors, and award winning, including the Amazon Choice Award, the prestigious Stevie Award, and the Mom's Choice Award. At SanMelix, we believe the difference is in the ingredients. Using our buckwheat honey products that combine our patented BEECure® formulations with other natural ingredients (such as calendula, bisabol, willow bark extract, rosemary leaf extract, shea butter, and jojoba seed oil), we harness the power of nature and science in order to hydrate and strengthen the skin barrier as well as to revitalize skin integrity.

Some of the Company's competitive advantages include:

1. **First mover advantage**--We are the only company to use raw buckwheat honey in our advanced wound care and over the counter skin care products.
2. **Superior clinical outcomes compared to Manuka honey products.**
  - a. Higher standardized and broader spectrum antimicrobial activity
  - b. Higher anti-inflammatory and antioxidant activity
  - c. Higher tissue repair and skin regeneration
3. **Supplier-enabled innovation**
  - a. Co-develop skin care formulations with a leading innovator in K-Beauty product formulations.
  - b. Offer small batch and large batch manufacturing of age defying formulas to align with customer brand and vision.



- c. Turnkey operation capability that can deliver resource and cost savings to the customer.

We expect competition in our industry to intensify in the future considering increased demand for AWC and OTC skin care products, continuing globalization, and consolidation in the worldwide AWC and OTC skin care markets. Factors affecting competition include product safety and effectiveness, quality and features, innovation and development time, pricing and reliability. Increased competition may lead to lower unit sales and increased inventory, which may result in price pressure and adversely affect our business, financial condition, operating results, and prospects. Our ability to successfully compete in our industry will be fundamental to our future success in existing and new markets and our market share. There can be no assurances that we will be able to compete successfully in our markets.

## Intellectual Property

On December 10, 2019, SanMelix was granted US Patent 10,500,235 B2 for Wound Healing Compositions Comprising Buckwheat Honey and Methylglyoxal and Methods of Use. On June 30, 2020, SanMelix was granted US Patent 10,695,382 B2 for Wound Healing Compositions and Methods of Use. During 2020, SanMelix was also granted Canadian Patent No. 3,009,754 for Wound Healing Compositions Comprising Buckwheat Honey and Methylglyoxal and Methods of Use. We have determined in 2021 that it is more than likely that we will not be granted the Buckwheat Honey/Povidone Iodine Continuation in Part No. 16/683784 and have written off the patent prosecution costs associated with this patent pending application. In Q1 2022, SanMelix was granted US Patent No. 11,213,564 B2 -- Buckwheat Honey/Bacitracin/MGO Continuation in Part. Dr. Sabacinski is the co-inventor of our patented technologies. The development of the Company's product and service offerings related to the patents are expected to take an extended amount of time and may be subject to government regulatory requirements.

The Company is currently conducting research and development and FDA testing activities to operationalize the patented technologies that the Company owns. As part of the Company's research and development strategy, we plan to conduct small evidence-based clinical trials with Key Opinion Leaders (KOLs) to support our claims. Dr. Kenneth Sabacinski will leverage his relationship with KOLs at Beth Israel Deaconess Hospital and Brigham and Women's hospital to test our products on patients with diabetic foot ulcers and cancer victims undergoing radiation therapy. Although we are in discussions with these KOLs, additional research and development may require additional funding, and there can be no assurance that we will be selected for clinical trial opportunities or receive additional funding.

We also have applied for trademarks for our BEECure<sup>®</sup> to continue to protect our intellectual property rights in two (2) categories: wound dressings and skin cream. In 2021, the USPTO granted our application and registered the trademark BEECure<sup>®</sup> under the above-referenced categories with SanMelix as the mark holder. We also received a European trademark.

## Litigation

We are not involved in any litigation, and our management is not aware of any pending or threatened legal actions relating to our intellectual property, conduct of our business activities, or otherwise.

## Properties

We do not own any real estate or significant assets besides our intellectual property. SanMelix entered into a one-year lease in December 2020 for an office located at 160 S. University Drive, Suite F, Plantation, FL

33024. After the initial lease term, SanMelix extended the lease for four months with a lease termination date on March 31, 2022.

## Previous Offerings

On January 13, 2017, the Company issued 10,000,000 shares of common stock to its initial founders in exchange of assignment of patents to SanMelix and \$96,686 for patent prosecution contributed capital.

Between December 2017, and August 2018, we sold 836,000 shares of common stock in exchange for \$0.50 per share under Regulation 506(b). The Company recognized gross proceeds of \$418,000 and incurred offering costs of \$15,000, which reduced additional paid-in capital.

During the years ended December 31, 2020 and 2019, the Company sold 1,304,028 and 426,893 shares, respectively, of Class NV common stock through its Regulation Crowd Funding (“Reg CF”). The Company recognized gross proceeds of \$491,980 and \$212,666, respectively. In connection with this offering, the Company incurred offering costs of \$144,422, and \$73,460, respectively, which reduced additional paid-in capital. The proceeds of both offerings were used primarily to fund the testing, research, and development of the patented technology along with launching buckwheat honey-based skin care products.

In October 2020, the Company offered a convertible note financing (“Notes”) available exclusively to Accredited Investors as defined by Regulation D under the Securities Act of 1933. The amount of the financing was in total \$600,000 with a minimum placement of \$50,000. The Notes were issued with an original issue discount (“OID”) and, as such, the purchase price is net of interest from the date of the Note payments on the unpaid principal balance at a rate equal to nine percent (9%) over a 24- month period. During 2020, the Company issued \$125,000 in convertible notes for consideration of \$102,969, the difference between the proceeds from the notes and principal amounts consists of \$22,031 of OID. The note holder was also issued market-related warrants for 192,308 in shares of common stock.

In January and February of 2021, under the Company’s convertible note financing plan, the Company issued \$375,000 in convertible notes for consideration of \$307,500, the difference between the proceeds from the notes and principal amounts consists of \$67,500 of OID. The note holders were also issued market-related warrants for 576,923 in shares of common stock.

In September 2021, one note holder exercised 100% of his warrants and converted the warrants into 76,923 shares at an amended exercise price of \$0.85. The Company received \$65,385 in cash proceeds and recognized the capital stock at par value within common stock on the Balance Sheet as of December 31, 2021. The Company additionally recognized amortization of \$4,757 related to the exercised shares within interest expense as of December 31, 2021.

In November and December 2021, another one note holder exercised 13% and 15%, respectively, of his warrants and converted the warrants into 50,000 shares in total at an amended exercise price of \$0.85. The Company received \$42,500 in cash proceeds and recognized the capital stock at par value within common stock on the Balance Sheet as of December 31, 2021. The Company additionally recognized amortization of \$4,084 related to the exercised shares within interest expense as of December 31, 2021

During the year ended December 31, 2021, the Company sold 649,880 and 87,098 shares of Class NV common stock through its Reg CF and second Regulation Crowd Funding (“Reg CF 2”), respectively. The Company recognized gross proceeds of \$474,893 and had a subscription receivable of \$3,819 related to the sale of these shares as of December 31, 2021. In connection with these offerings, the Company incurred

offering costs of \$132,063, which reduced additional paid-in capital. The subscription receivable of \$3,819 was collected in the following fiscal year.

During the year ended December 31, 2022, the Company sold 9,318 shares of Class NV common stock through its Reg CF 2. The Company recognized gross proceeds of \$17,216 related to the sale of these shares as of December 31, 2022. In connection with this offering, the Company incurred offering costs of \$10,228, which reduced additional paid-in capital.

In August 2022, one note holder exercised 21% of his warrants and converted the warrants into 30,000 shares in total at an amended exercise price of \$0.85. The Company received \$25,500 in cash proceeds and recognized the capital stock at par value within common stock on the Balance Sheet as of December 31, 2022. The Company additionally recognized amortization of \$1,634 related to the exercised shares within interest expense as of December 31, 2022.

In October 2022, one debt holder converted his debt into shares of common stock on its maturity date. Per the conversion agreement, the debt holder received 192,308 shares of common stock in exchange for the conversion of debt. On conversion, the Company recorded a reduction to convertible debt of \$125,000 and increases to common stock and additional paid-in-capital.

Subsequent to December 31, 2022, the Company extended several note holders convertible debt. These extensions related to \$225,000 of convertible debt with maturity dates in January and February of 2024.

Subsequent to December 31, 2022, several note holders converted their notes on the maturity date to shares of common shares. These conversions amounted to \$150,000 of convertible debt which totaled 230,769 shares of common stock at \$0.65 per share.

## **Risk Factors**

The SEC requires the company to identify risks that are specific to its business and its financial condition. The company is still subject to all the same risks that all companies in its business, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events, and technological developments (such as hacking and the ability to prevent hacking). Additionally, early-stage companies are inherently more risky than more developed companies. You should consider general risks as well as specific risks when deciding whether to invest.

These are the risks that relate to the Company:

### *Uncertain Risk*

An investment in the Company (also referred to as "we", "us", "our", or "Company") involves a high degree of risk and should only be considered by those who can afford the loss of their entire investment. Furthermore, the purchase of any of the Common Stock NV should only be undertaken by persons whose financial resources are sufficient to enable them to indefinitely retain an illiquid investment. Each investor in the Company should consider all of the information provided to such potential investor regarding the Company as well as the following risk factors, in addition to the other information listed in the Company's Form C. The following risk factors are not intended, and shall not be deemed to be, a complete description of the commercial and other risks inherent in the investment in the Company.

*The Company's operations and revenue have been negatively impacted by the COVID-19 pandemic*

Any outbreak of contagious diseases, and other adverse public health developments, could have a material and adverse effect on our business operations. The recent outbreak of respiratory illness caused by a novel

coronavirus referred to as COVID-19 has had a material adverse effect on our business operations which remains ongoing. At this time, the extent of the effect is uncertain. The COVID-19-related governmental stay-at-home orders, prohibitions on public gatherings, delays or stoppages in non-COVID-19 medical testing and procedures, rise in unemployment, and related economic fallout have an ongoing negative effect on our business operations, the extent of which is currently unknown.

*We have not prepared audited financial statements for fiscal year 2022.*

Therefore, the investor does not have audited financial information regarding the Company's capitalization, assets, or liabilities to make investment decisions for fiscal year 2022.

*Our business projections are only projections.*

There can be no assurance that the Company will meet our projections. There can be no assurance that the Company will be able to find sufficient demand for our product, that people think it is a better option than a competing product, or that we will be able to provide the service at a level that allows the Company to make a profit and still attract business.

*Any valuation at this stage is difficult to assess.*

The valuations for the offerings were established by the Company. Unlike listed companies that are valued publicly through market-driven stock prices, the valuation of private companies, especially startups, is difficult to assess and you may risk overpaying for your investment.

*The transferability of the Securities purchased is limited.*

Any Common Stock NV purchased through these crowdfunding campaigns is subject to SEC limitations of transfer. This means that the stock/note that you purchase cannot be resold for a period of one year. The exception to this rule is if you are transferring the stock back to the Company, to an "accredited investor", as part of an offering registered with the Commission, to a member of your family, trust created for the benefit of your family, or in connection with your death or divorce.

*Equity investment could be illiquid for a long time.*

You should be prepared to hold this investment for several years or longer. For the 12 months following your investment, there will be restrictions on how you can resell the securities you receive. More importantly, there is no established market for these securities and there may never be one. As a result, if you decide to sell these securities in the future, you may not be able to find a buyer. The Company may be acquired by an existing player in the advanced wound care and skin care industries. However, that may never happen or it may happen at a price that results in you losing money on this investment.

*If the Company cannot raise sufficient funds, it will not succeed.*

Even if the maximum amounts of the prior offerings were raised, the Company still requires additional funds in the future in order to grow, and if it cannot raise those funds for whatever reason, including reasons relating to the Company itself or the broader economy, it may not survive.

*We may not have enough capital as needed and may be required to raise more capital.*

We anticipate needing access to credit in order to support our working capital requirements as we grow. In the current economy, it is a difficult environment for obtaining credit on favorable terms. If we cannot obtain credit when we need it, we could be forced to raise additional equity capital, modify our growth plans, or take some other action. Issuing more equity may require bringing on additional investors. Securing these additional investors could require pricing our equity below its current price. If so, your investment

could lose value as a result of this additional dilution. In addition, even if the equity is not priced lower, your ownership percentage would be decreased with the addition of more investors. If we are unable to find additional investors willing to provide capital, then it is possible that we will choose to cease our sales activity. In that case, the only asset remaining to generate a return on your investment could be our intellectual property. Even if we are not forced to cease our sales activity, the unavailability of credit could result in the Company performing below expectations, which could adversely impact the value of your investment.

*Terms of subsequent financings may adversely impact equity holders' investments.*

We will likely need to engage in common equity, debt, or preferred stock financings in the future, which may reduce the value of your investment in the Common Stock. Interest on debt securities could increase costs and negatively impact operating results. Preferred stock could be issued in series from time to time with such designation, rights, preferences, and limitations as needed to raise capital. The terms of preferred stock could be more advantageous to those investors than to the holders of Common Stock. In addition, if we need to raise more equity capital from the sale of Common Stock, institutional or other investors may negotiate terms that are likely to be more favorable than the terms of your investment, and possibly a lower purchase price per share.

*Some of our products are still in prototype phase and might never be operational products.*

It is possible that some of our products in the pipeline may never be operational products or that the products may never be used to engage in transactions. It is possible that the failure to release the product is the result of a change in business model upon the Company's making a determination that the business model, or some other factor, will not be in the best interest of the Company and its stockholders.

*Developing new products and technologies entails significant risks and uncertainties.*

We are currently in the research and development stage for the majority of our products and have only manufactured a prototype for our advanced wound care dressing. Delays or cost overruns in the development of our advanced wound care dressing and failure of the product to meet our performance estimates may be caused by, among other things, unanticipated technological and cost hurdles, difficulties in the supply chain, changes to design and regulatory hurdles. Any of these events could materially and adversely affect our operating performance and results of operations.

*Minority Holder; Securities with No Voting Rights*

The Non-Voting Common Stock that an investor is buying has no voting rights attached to them. This means that the investor will have no rights in dictating on how the Company will be run. The investor is trusting in management discretion in making good business decisions that will grow the equity investments. Furthermore, in the event of a liquidation of our company, the Non-Voting Common stockholders will only be paid out if there is any cash remaining after all of the creditors of our company have been paid out.

*The Company faces significant market competition.*

We will compete with larger, established companies who currently have products on the market and/or various respective product development programs. They may have much better financial means and marketing/sales and human resources than us. They may succeed in developing and marketing competing equivalent products earlier than us, or superior products than those developed by us. There can be no assurance that competitors will render our technology or products obsolete or that the products developed by us will be preferred to any existing or newly developed technologies. It should further be assumed that competition will intensify.

*Our trademarks, copyrights and other intellectual property could be unenforceable or ineffective.*

Intellectual property is a complex field of law in which few things are certain. It is possible that competitors will be able to design around our intellectual property, find prior art to invalidate it, or render our patents unenforceable through some other mechanism. If competitors are able to bypass our trademark and copyright protection without obtaining a sublicense, it is likely that the Company's value will be materially and adversely impacted. This could also impair the Company's ability to compete in the marketplace.

*The cost of enforcing our trademarks and copyrights could prevent us from enforcing them.*

Trademark and copyright litigation has become extremely expensive. Even if we believe that a competitor is infringing on one or more of our trademarks or copyrights, we might choose not to file suit because we lack the cash to successfully prosecute a multi-year litigation with an uncertain outcome; or because we believe that the cost of enforcing our trademark(s) or copyright(s) outweighs the value of winning the suit in light of the risks and consequences of losing it; or for some other reason. Choosing not to enforce our trademark(s) or copyright(s) could have adverse consequences for the Company, including undermining the credibility of our intellectual property, reducing our ability to enter into sublicenses, and weakening our attempts to prevent competitors from entering the market. As a result, if we are unable to enforce our trademark(s) or copyright(s) because of the cost of enforcement, investment in the Company could be significantly and adversely affected.

*The loss of one or more of our key personnel, or our failure to attract and retain other highly qualified personnel in the future, could harm our business.*

To be successful, the Company requires capable people to run its day-to-day operations. As the Company grows, it will need to attract and hire additional employees in sales, marketing, design, development, operations, finance, legal, human resources and other areas. Depending on the economic environment and the Company's performance, we may not be able to locate or attract qualified individuals for such positions when we need them. We may also make hiring mistakes, which can be costly in terms of resources spent in recruiting, hiring and investing in the incorrect individual and in the time delay in locating the right employee fit. If we are unable to attract, hire and retain the right talent or make too many hiring mistakes, it is likely our business will suffer from not having the right employees in the right positions at the right time. This would likely adversely impact the value of equity investment.

*Our ability to sell our product or service is dependent on outside government regulation which can be subject to change at any time.*

Our ability to sell product is dependent on the outside government regulation such as the FDA (Food and Drug Administration), FTC (Federal Trade Commission) and other relevant government laws and regulations. The laws and regulations concerning the selling of product may be subject to change and if they do then the selling of product may no longer be in the best interest of the Company. At such point the Company may no longer want to sell product and therefore your investment in the Company may be affected.

*FDA 510(k) Market Clearance*

The FDA may not provide 510(k) market clearance to our advanced wound care dressings. If clearance is not obtained SanMelix cannot sell those products in the U.S.

## **Regulatory Information**

The Company has not previously failed to comply with the requirements of Regulation Crowdfunding.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

## Operating Results – 2022 Compared to 2021

The Company launched its initial product BEECure<sup>®</sup> R- Radiation and Laser Skin Care product in January 2021 resulting in \$52,695 in revenues in 2021. In 2022, the Company generated \$50,233 net revenues. In order to increase the revenues, the Company is currently in negotiations with major retailers like QVC, along with major cancer treatment centers like Brigham and Women's Hospital (oncology) at Harvard Medical School. We do not expect to generate revenues for our AWC dressings until after obtaining 510(k) pre-market clearance from the FDA.

Cost of sales in 2022 and 2021 related to our product sales and includes the Cost of Manufacturing Goods along with the landed costs (i.e., freight-in). The gross margin of \$11,194 and \$39,069 in 2022 and 2021, respectively, represents a 74% and 22% gross margin percentage. Note that there was a \$28,455 inventory allowance for expiring inventory included in 2022. Excluding the allowance, 2022 had a \$39,649 gross margin which represents a 79% gross margin percentage.

General and administrative expenses decreased from \$455,342 to \$434,845 for the years ending December 31, 2021 and 2022, respectively. General and administrative expenses decreased primarily due the decrease in professional fees related to audit fees. The Company is foregoing an audit in the current year in order to use funds towards product development and potential partnership opportunities.

Research and development expenses immaterially increased to \$157,149 from \$155,871 for the years ending December 31, 2022 and 2021, respectively. The expenses remain consistent as the Company is working towards FDA approval as well as product development in both years.

Sales and marketing expenses decreased to \$73,296 from \$105,282 for the years ending December 31, 2022 and 2021, respectively due to a decreased monthly retainer paid to a previous sales and marketing consulting company.

Interest expense decreased to \$114,858 from \$137,553 primarily due to no additional convertible debt issuance costs in the current year as opposed to significant expense related to the issuances in 2021.

Other Income decreased to \$0 from \$18,590 due to the one-time income related to the forgiveness of the COVID 19 Paycheck Protection Program Loan and miscellaneous referral fees in 2021.

As a result, the Company's net loss decreased from \$796,389 to \$768,955 for the years ended December 31, 2021, and 2022, respectively.

## Liquidity and Capital Resources

We have an accumulated deficit of \$2,502,987 as of December 31, 2022. On December 31, 2022, the Company had cash and restricted cash of \$128,710. The Company intends to continue to raise additional funds through an equity financing.

*Cash Flow*

The following table summarizes, for the periods indicated, selected items in our Statements of Cash Flows:

	<b>2022</b>	<b>2021</b>
<i>Net cash (used in) provided by:</i>	<i>(Unaudited)</i>	<i>(Audited)</i>
Operating activities	\$ (238,194)	\$ (541,752)
Investing activities	(5,414)	(141,174)
Financing activities	32,488	758,288

Operating Activities:

Cash used in operating activities decreased to \$238,194 from \$541,752 for the years ended December 31, 2022 and 2021, respectively. The decrease in cash used in operating activities was primarily due to a lower net loss and no inventory purchases in 2022 as opposed to 2021 as the Company implemented cost savings synergies in order to maximum funds received for business and product development.

Investing Activities:

Cash used in investing activities decreased to \$5,414 from \$141,174 for the years ended December 31, 2022 and 2021, respectively. The decrease in cash used in investing activities was primarily due to no additional costs being necessary in the current year, while in 2021, we had purchased \$130,000 of the BEECure<sup>®</sup>-R formulation and related intangible assets that have since been written off. See Footnote 6—Intangible Assets.

Financing Activities:

Cash provided by financing activities decreased to \$32,488 from \$758,288 for the years ended December 31, 2022 and 2021, respectively. The decrease in cash provided by financing activities was primarily due to: (1) the closing of the Company's Reg CF 2 in the first quarter of 2022 and (2) no additional proceeds were received from Convertible Debt offering in 2022.

*Off-Balance Sheet Arrangements*

We have no off-balance sheet arrangements, including arrangements that would affect the liquidity, capital resources, market risk support and credit risk support or other benefits.

*Current maturities of long-term debt:*

In January and February of 2021, under the Company's convertible note financing plan, the Company issued \$375,000 in convertible notes for consideration of \$307,500, the difference between the proceeds from the notes and principal amounts consists of \$67,500 of OID. The note holders were also issued market-related warrants for 576,923 in shares of common stock. These convertible notes mature in the first quarter of 2023; and thus, classified within the current maturities of long-term debt as of December 31, 2022. See Footnote 13 of instrument conversions and extensions subsequent to December 31, 2022.

*Long term debt:*

As of December 31, 2022, the Company does not have any long-term debt; however, see Footnote 13 for subsequent events that either extended the maturity date of convertible debt or converted the debt into shares of common stock.

The interest expense related to the Convertible Notes as of December 31, 2022 totaled \$114,858.



## **DIRECTORS, EXECUTIVE OFFICERS, AND SIGNIFICANT EMPLOYEES**

Our directors and executive officers as of the date hereof, are as follows:

- ❖ Dr. Kenneth Sabacinski, age 65, has been Chief Medical Officer, Director, Secretary, and Treasurer since 2016. Dr. Sabacinski's current primary role is with Kenneth Sabacinski DPM d/b/a Harvard Podiatry d/b/a Harvard Foot and Ankle since 1990.
- ❖ Diana Sabacinski, age 62, has been Director, President, and CEO since 2016. Diana is a CPA, CFE, and prior to her role with SanMelix, she was the Director of Advisory Services for Hammer Navarro & Associates.
- ❖ John Kaufman, age 75, has been Director since 2016. Prior to his role as Director of SanMelix, Mr. Kaufman was the Chairman/Director of Be Power Tech, Inc, and Managing Director of InteSec Group, LLC.
- ❖ Hamid Khosrowshahi, age 71, has been Director since 2019. Mr. Khosrowshahi is the President of FloSure Technologies, LLC.
- ❖ Samuel Hammer, age 62, has been Director since 2020. Mr. Hammer is the Managing Principal of Hammer Navarro and Associates, PA.
- ❖ Steven Weinstein, age 55, has been Director since 2022. Prior to his role as Director of SanMelix, Mr. Weinstein was the Head of Supply Chain & Operations at Zarbee's Inc., a leading Health & Wellness company that is part of Johnson & Johnson Consumer Companies.

## PRINCIPAL SECURITY HOLDERS

Set forth below is information regarding the beneficial ownership of our Common Stock, our only outstanding class of voting capital stock, as of December 31, 2022, by (i) each person whom we know owned, beneficially, more than 5% of the outstanding shares of our Common Stock, and (ii) all of the current officers and directors as a group. We believe that, except as noted below, each named beneficial owner has sole voting and investment power with respect to the shares listed. Unless otherwise indicated herein, beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to shares beneficially owned.

Name of beneficial owner	Amount of beneficial ownership <sup>(1)</sup>	Percent of class <sup>(2)</sup>
Dr. Kenneth A. Sabacinski	3,980,000	31.49%
Diana L. Sabacinski	3,980,000	31.49%
John L. Kaufman	2,040,000	16.14%
Hamid Khosrowshahi	0 <sup>(3)</sup>	*
Samuel Hammer	0 <sup>(3)</sup>	*
Steven Weinstein	0 <sup>(3)</sup>	*
Current Officers and Directors as a group	10,000,000	79.12%

\* Less than 1%

<sup>(1)</sup> Designated person or group has sole voting and investment power.

<sup>(2)</sup> Pursuant to SEC Rule 13d-3, amounts shown include common shares that may be acquired by a person within 60 days of December 31, 2022. Therefore, the column titled “Percent of class” has been computed based on (a) 11,235,231 common shares actually outstanding as of December 31, 2022; and (b) solely with respect to the person whose Rule 13d-3 Percentage Ownership of common shares is being computed, common shares that may be acquired within 60 days of December 31, 2022 upon exercise of options, warrants and/or convertible debt held only by such person.

<sup>(3)</sup> Persons listed below have the right to acquire the listed number of shares upon exercise of stock options:

Name	Right to acquire
Hamid Khosrowshahi	235,917
Samuel Hammer	50,000
Steven Weinstein	200,000

## RELATED PARTY TRANSACTIONS

In 2021, the Company received funding in excess of \$750,000 through its equity crowdfunding and Convertible Debt offerings. The CEO agreed to re-invest her net compensation after taxes into the Company’s equity crowdfunding campaign until either the Company’s funding goal of \$1.07 million has been reached or the equity crowdfunding campaign otherwise concludes. During 2021, StartEngine had several investment policy changes with the Company’s second crowdfunding campaign (“Reg CF 2”) which did not allow the CEO to make investments into the campaign. Based on that, the CEO agreed to forego her net salary in 2021 as well as the first 90 days of 2022. As of February 15, 2022, the CEO started to accrue the gross salary amount. The deferred salary amount of \$138,791 is recorded as deferred

compensation on the Balance Sheet as of December 31, 2022. See Note 8 for further information on Reg CF 2.

On September 1, 2019, the Company entered into a consulting agreement ('Agreement') with a Board of Director member. The Agreement provisions included consulting time-based compensation and granted stock options to purchase up to 925,000 shares at \$0.60 per share based on time-based and milestone-based criteria expiring on September 30, 2022. On September 30, 2022, the Company granted a non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 60,000 of its common shares at the current fair market value of \$0.85 per share. As of December 31, 2022, and 2021, the Company accrued compensation payable of \$36,775 and \$33,775 and 235,917 and 207,583 shares of common stock were vested under the option agreements, respectively.

On July 15, 2020, the Company granted a director a non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 50,00 of its common shares at the current fair market value of \$0.60 per share. The option will expire on September 1, 2027, and the shares shall vest with respect to 5,000 shares at the end of each calendar quarter that the director remains a director of the Company, starting with the quarter ending November 30, 2020. This option was terminated on September 30, 2022 and the Company granted a new non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 60,000 of its common shares at the current fair market value of \$0.85 per share. As of December 31, 2022 and 2021, 50,000 and 25,000 shares of common stock, respectively, were vested under the director's option agreements.

On July 28, 2022, the Company granted a director a non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 1,000,000 of its common shares at the current fair market value of \$0.85 per share based on milestone-based criteria. As of December 31, 2022, 200,000 shares of common stock were vested under the director's option agreement.

## OUR SECURITIES

During the year ended December 31, 2021, the Company's Articles of Incorporation were amended to increase the number of Common Shares authorized from 25,000,000 to 28,000,000 and provide that 6,000,000 of such shares be a non-voting-class called "Class NV", each share having a par value of \$0.0001. The Company has authorized the issuance of 5,000,000 shares of our Preferred Stock with par value of \$0.0001 of which 0 shares are issued and outstanding.

During 2022 and 2021, the Company issued 30,000 and 126,923 shares, respectively, related to exercised warrants - refer to Note 7 for further discussion. As of December 31, 2022, and 2021, the Company has issued and outstanding 11,235,231 and 11,012,923 shares, respectively, of our voting class of common stock.

The following is a summary of the rights of our capital stock and preferred stock as provided in our certificate of incorporation and bylaws:

### *Voting Rights:*

The holders of the common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, except for common stock Class NV, which does not have any voting rights.

*Preferred Stock:*

The Board of Directors is expressly authorized at any time and from time to time to provide for the issuance of shares of Preferred Stock in one or more series, with such voting powers, full or limited, or without voting powers, and with such designations, preferences and relative participating, option or other rights, qualifications, limitations or restrictions, as shall be fixed and determined in the resolution or resolutions providing for the issuance thereof adopted by the Board of Directors, and as are not stated and expressed in the Articles of Incorporation.

*Dividends:*

Subject to preferences that may be granted to any then outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor as well as any distributions to the stockholders. The payment of dividends on the common stock will be a business decision to be made by our board of directors from time to time based upon the results of our operations and our financial condition and any other factors that our board of directors considers relevant. Payment of dividends on the common stock may be restricted by law and by loan agreements, indentures and other transactions entered into by us from time to time.

*Liquidation Rights:*

In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in all of our assets remaining after payment of liabilities and the liquidation preference of any then outstanding preferred stock.

*Absence of Other Rights or Assessments*

Holders of common stock have no preferential, preemptive, conversion or exchange rights. There is no redemption or sinking fund provisions applicable to the common stock. When issued in accordance with our certificate of incorporation and Delaware General Corporation Law, shares of our common stock will be fully paid and not liable to further calls or assessments by us.

*2017 Stock Incentive Plan:*

In addition to the foregoing, the Company reserved 1,500,000 shares of Common Shares for stock options under its 2017 Stock Incentive Plan (the “Plan”) to issue shares to employees, directors, and consultants (“Service Providers”), especially in the first few years of its operations, when, to preserve capital, it may be paying employees and consultants less than their market rate. As of December 31, 2022, the Company has increased its reserve from 1,500,000 shares up to 3,000,000 shares of Common Shares for stock options under the Plan and 737,500 stock options have vested.

## **WHAT IT MEANS TO BE A MINORITY HOLDER**

As a minority holder, you will have limited ability, if at all, to influence our policies or any other corporate matter, including the election of directors, changes to our company’s governance documents, additional issuances of securities, company repurchases of securities, a sale of the company or of assets of the company or transactions with related parties.

### **Dilution**

Investors should understand the potential for dilution. The investor’s stake in a company could be diluted due to the company issuing additional shares. In other words, when the company issues more shares, the

percentage of the company that you own will decrease, even though the value of the company may increase. You will own a smaller piece of a larger company. This increase in number of shares outstanding could result from a stock offering (such as an initial public offering, another crowdfunding round, a venture capital round, or angel investment), employees exercising stock options, or by conversion of certain instruments (e.g., convertible notes, preferred shares, or warrants) into stock. If we decide to issue more shares, an investor could experience value dilution, with each share being worth less than before, and control dilution, with the total percentage an investor owns being less than before. There may also be earnings dilution, with a reduction in the amount earned per share (though this typically occurs only if we offer dividends, and most early-stage companies are unlikely to offer dividends, preferring to invest any earnings into the company).

The type of dilution that hurts early-stage investors most occurs when the company sells more shares in a “down round,” meaning at a lower valuation than in earlier offerings.

If you are making an investment expecting to own a certain percentage of the company or expecting each share to hold a certain amount of value, it is important to realize how the value of those shares can decrease by actions taken by the company. Dilution can make drastic changes to the value of each share, ownership percentage, voting control, and earnings per share.

## **RESTRICTIONS ON TRANSFER**

The common stock sold in the Regulation CF offering, may not be transferred by any purchaser, for a period of one year beginning when the securities were issued, unless such securities are transferred:

- (1) to the Company;
- (2) to an accredited investor;
- (3) as part of an offering registered with the SEC; or
- (4) to a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance.

## SIGNATURES

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100-503), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C and has duly caused this Form to be signed on its behalf by the duly authorized undersigned, on March 1, 2023. The issuer also certifies that the attached financial statements are true and complete in all material respects.

### **SanMelix Laboratories, Inc.**

DocuSigned by:  
*Diana Sabacinski*  
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Diana Sabacinski  
Chief Executive Officer

# **SANMELIX LABORATORIES, INC.**

## **FINANCIAL STATEMENTS YEAR ENDED DECEMBER 31, 2022 (UNAUDITED) AND 2021 (AUDITED)**

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Management  
of SanMelix Laboratories, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of SanMelix Laboratories, Inc. (the “Company”) as of December 31, 2021 and 2020, the related statements of operations, stockholders’ equity, and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### **Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 12 to the financial statements, the Company has suffered recurring losses from operations and has not generated sufficient revenues from its intended operations, which raises substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 12. 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 audits 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.

*dbbmckennon*  
San Diego, California  
April 29, 2022

## CHIEF EXECUTIVE OFFICER'S FINANCIAL STATEMENT CERTIFICATION

I, Diana Sabacinski, the Chief Executive Officer of SanMelix Laboratories, Inc., hereby certify that the financial statements of SanMelix Laboratories, Inc., and notes thereto for the period ending December 31, 2022 included in this Form C offering statement are true and complete in all material respects. SanMelix Laboratories, Inc. has not yet filed its federal tax return for 2022.

IN WITNESS THEREOF, this Chief Executive Officer's Financial Statement Certification has been executed as of March 1, 2023.

DocuSigned by:  
*Diana Sabacinski*  
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Diana Sabacinski

CEO

## SANMELIX LABORATORIES, INC.

### BALANCE SHEETS

As of December 31,	2022	2021
<b>ASSETS</b>	<i>(Unaudited)</i>	<i>(Audited)</i>
Cash, cash equivalents, and restricted cash	\$ 128,710	\$ 339,829
Accounts receivable	839	1,590
Inventories	16,690	57,037
Other current assets	21,960	2,521
<i>Total current assets</i>	<i>168,199</i>	<i>400,977</i>
Property and equipment, net	1,291	3,871
Intangible assets, net	154,184	460,315
<i>Total noncurrent assets</i>	<i>155,475</i>	<i>464,186</i>
<b>Total assets</b>	<b>\$ 323,674</b>	<b>\$ 865,163</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable	\$ 1,742	\$ 24,100
Other current liabilities	37,032	203,907
Put option liability	67,550	67,550
Current maturities of long-term debt	369,667	116,563
<i>Total current liabilities</i>	<i>475,991</i>	<i>412,120</i>
Convertible note, net	-	266,547
Deferred compensation	208,760	69,969
<i>Total noncurrent liabilities</i>	<i>208,760</i>	<i>336,516</i>
<b>Total liabilities</b>	<b>684,751</b>	<b>748,636</b>
<b>STOCKHOLDERS' EQUITY</b>		
Common stock	1,124	1,101
Common stock - NV	205	204
Additional paid-in capital	2,162,301	1,853,073
Subscription receivable	-	(3,819)
Accumulated deficit	(2,524,707)	(1,734,032)
<b>Total stockholders' equity</b>	<b>(361,077)</b>	<b>116,527</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 323,674</b>	<b>\$ 865,163</b>

*See accompanying notes to financial statements*

## SANMELIX LABORATORIES, INC.

### STATEMENTS OF OPERATIONS

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For Fiscal Year Ended December 31,	2022	2021
	<i>(Unaudited)</i>	<i>(Audited)</i>
Net revenues	\$ 50,233	\$ 52,695
Cost of sales	39,039	13,626
Gross Profit	11,194	39,069
Operating expenses		
General and administrative	456,565	455,342
Research and development	157,149	155,871
Sales and marketing	73,296	105,282
Total operating expenses	687,011	716,495
<i>Operating income/(loss)</i>	<i>(675,817)</i>	<i>(677,426)</i>
Interest expense	(114,858)	(137,553)
Other income/(loss)	-	18,590
<i>Income/(Loss) before provision for income taxes</i>	<i>(790,675)</i>	<i>(796,389)</i>
Provision/(Benefit) for income taxes	-	-
<b>Net income/(loss)</b>	<b>\$ (790,675)</b>	<b>\$ (796,389)</b>
<i>See accompanying notes to financial statements.</i>		

## SANMELIX LABORATORIES, INC.

### STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Common Stock NV		Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance—December 31, 2020</b>	<b>10,886,000</b>	<b>\$ 1,089</b>	<b>1,304,028</b>	<b>\$ 130</b>	<b>\$ 1,283,969</b>	<b>\$ (13,400)</b>	<b>\$ (937,643)</b>	<b>\$ 334,145</b>
<i>(Audited)</i>								
Net income/(loss)							(796,389)	(796,389)
Common stock issued for cash			733,711	73	474,893			474,966
Common stock subscribed			5,009	1	(9,581)	9,581		1
Stock compensation expense					71,815			71,815
Put option liability reclassified out of stock compensation expense					(17,731)			(17,731)
Offering costs					(132,063)			132,063
Fair value of issued warrants					107,077			107,077
Exercised warrants for common stock	126,923	12			122,340			122,352
Removal of beneficial conversion feature					(48,321)			(48,321)
Fair value of services provided					675			675
<b>Balance—December 31, 2021</b>	<b>11,012,923</b>	<b>\$ 1,101</b>	<b>2,042,748</b>	<b>\$ 204</b>	<b>\$ 1,853,073</b>	<b>\$ (3,819)</b>	<b>\$ (1,734,032)</b>	<b>\$ 116,527</b>
<i>(Unaudited)</i>								
Net income/(loss)							(790,675)	(768,955)
Common stock issued for cash			9,318	1	17,216			17,217
Stock compensation expense					152,280			130,560
Offering costs					(10,288)			(10,288)
Exercised warrants for common stock	30,000	3			28,797			28,800
Removal of subscription receivable					(3,819)	3,819		-
Conversion of debt	192,308	20			124,981			125,001
<b>Balance—December 31, 2022</b>	<b>11,235,231</b>	<b>\$ 1,124</b>	<b>2,052,066</b>	<b>\$ 205</b>	<b>\$ 2,162,301</b>	<b>\$ -</b>	<b>\$ (2,524,707)</b>	<b>\$ (361,077)</b>

*See accompanying notes to financial statements*

## SANMELIX LABORATORIES, INC.

### STATEMENTS OF CASH FLOWS

For Fiscal Year Ended December 31,	2022	2021
	<i>(Unaudited)</i>	<i>(Audited)</i>
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (790,675)	\$ (796,389)
<i>Adjustments to reconcile net income to net cash provided/(used) by operating activities:</i>		
Depreciation of property	2,581	4,833
Amortization of intangibles	11,547	9,975
Fair value of services provided	-	675
Stock based compensation expense	152,280	71,815
Amortization of debt discount	111,558	104,623
Loss on modification of warrants	3,300	14,467
Allowance for expiring inventory	28,455	-
Write-off of abandoned intangible assets	130,000	-
PPP forgiveness other income - tax exempt	-	(13,500)
Deferred compensation	138,791	69,969
<i>Changes in operating assets and liabilities:</i>		
Accounts receivable	751	(1,590)
Inventory	11,891	(30,898)
Other current assets	(19,440)	-
Accounts payable and accrued expenses	(22,358)	(6,526)
Other current liabilities	3,125	30,794
<b>Net cash used by operating activities</b>	<b>(238,194)</b>	<b>(541,752)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>		
Purchases of intangible assets	(5,414)	(141,174)
<b>Net cash used in investing activities</b>	<b>(5,414)</b>	<b>(141,174)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>		
Common stock issued for cash	17,216	474,966
Offering costs	(10,228)	(132,063)
Proceeds from exercised warrants	25,500	107,885
Proceeds received from convertible debt, net OID	-	307,500
<b>Net cash provided by financing activities</b>	<b>32,488</b>	<b>758,288</b>
Change in cash, cash equivalents, and restricted cash	(211,119)	75,362
Cash, cash equivalents, and restricted cash—beginning of year	339,829	264,467
Cash, cash equivalents, and restricted cash—end of year	<b>\$ 128,710</b>	<b>\$ 339,829</b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>		
Cash paid during the year for interest	\$ -	\$ -
Cash paid during the year for income taxes	-	-

**OTHER NONCASH INVESTING AND FINANCING ACTIVITIES AND  
SUPPLEMENTAL DISCLOSURES**

Purchase of intangible in accounts payable	-	170,000
Subscription receivable	-	3,819
Warrants allocated as a discount to convertible debt	-	107,077
Removal of beneficial conversion feature	-	48,321
Put option liability	-	17,731
Conversion of debt to common stock	124,981	-

*See accompanying notes to financial statements.*

**SANMELIX LABORATORIES, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**FOR THE YEARS ENDED DECEMBER 31, 2022 (UNAUDITED) AND**  
**DECEMBER 31, 2021 (AUDITED)**

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**1. SUMMARY**

SanMelix Laboratories, LLC was formed on August 29, 2016, in the State of Florida. SanMelix Inc. was incorporated on January 13, 2017, in the State of Delaware. SanMelix Laboratories, LLC was merged into SanMelix Laboratories, Inc. on February 6, 2017, with SanMelix Laboratories, Inc. being the surviving entity. The Company is headquartered in Hollywood, Florida through March 2022 and now operates in Orlando, Florida. The financial statements of SanMelix Laboratories, Inc. (which may be referred to as the “Company,” “we,” “us”, or “our”) are prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Note that the only operation for SanMelix Laboratories, LLC related to previous capitalized patent prosecution costs, which was contributed to SanMelix Laboratories, Inc at the date of the merger.

SanMelix Laboratories, Inc. is a bioactive wound and skin care product company focusing on the unique medicinal properties of buckwheat honey for tissue regeneration and accelerated healing. Our BEECure<sup>®</sup> bioactive buckwheat honey formulations demonstrate intrinsic healing activity. The Company is a business whose planned principal operations are the design, formulation, and manufacturing of these advanced wound care and skin care honey-based products.

**2. SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, and the reported amount of expenses during the reporting periods. Actual results could materially differ from these estimates. It is reasonably possible that changes in estimates will occur in the near term.

**Fair Value of Financial Instruments**

Fair value is defined 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 market participants as of the measurement date. Applicable accounting guidance provides an established hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company’s assumptions about the factors that market participants would use in valuing the asset or liability. There are three levels of inputs that may be used to measure fair value:

**Level 1** - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

**Level 2** - Include other inputs that are directly or indirectly observable in the marketplace.

**Level 3** - Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.



Fair value estimates discussed herein are based upon certain market assumptions and pertinent information available to management as of December 31, 2022 and 2021. These financial instruments include cash, accounts payable, put option liability, and accrued liabilities. Fair values for these items were assumed to approximate carrying values because of their short term in nature or they are payable on demand.

### **Risks and Uncertainties**

The Company has a limited operating history and has not yet generated significant or material revenues from its intended operations. The Company is currently conducting research and development activities to operationalize certain patent pending technologies that the Company owns. The development of the Company's product and service offerings are expected to take an extended amount of time to develop and may be subject to government regulatory requirements. The Company's business operations are sensitive to general business and economic conditions in the U.S. and worldwide along with policy decisions. A host of factors beyond the Company's control could cause fluctuations in these conditions. Adverse developments may also include but are not limited to the Coronavirus Disease 2019 ("COVID-19") postponing laboratory testing, not obtaining clearance from the FDA, changes in medical device technology, government policy decisions and law changes, changes in consumer tastes and trends, and acceptance of its products in the marketplace.

The Company also is in the process of raising additional equity capital to support the completion of its development activities to obtain FDA 510(k) approval of the advanced wound care dressings and the manufacturing and inventory build for the commercialization of its skin care products. Like any new business, the Company faces challenges that come from early-stage branding and financing.

Other significant risks and uncertainties include failing to secure additional funding to operationalize the Company's current technology before another company develops similar technology and products. These adverse conditions could affect the Company's financial condition and the results of its operations. See Note 13 for discussion of going concern and management's plans.

### **Cash, Cash Equivalents, and Restricted Cash**

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. Amounts included in restricted cash represent those funds required to be set aside by a contractual agreement with the escrow agent for our Crowdfunding offering for the benefit of Subscribers until the Offering is closed for six months.

<b>As of Year Ended December 31,</b>	<b>2022</b>	<b>2021</b>
Cash and cash equivalents	\$ 128,710	\$ 320,900
Restricted cash	-	18,929
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 128,710</b>	<b>\$ 339,829</b>

### **Accounts Receivable—Net**

Accounts receivable are reported at net realizable value and consist primarily of amounts due from customers for the sale of our BEECure® R skin care product. The Company is not exposed to a significant concentration of credit risk. The Company has not recorded an allowance on trade accounts receivable as the Company has no estimated credit losses expected based on its history of collections. As of December 31, 2022 and 2021, the Company recorded \$839 and \$1,590, respectively, as accounts receivable, net, in the accompanying consolidated balance sheets. See revenue recognition section below for further discussion.

**Inventories**

The Company accounts for inventories using the weighted average cost method and are stated at the lower of cost or net realizable value. Inventories consist primarily of products for resale. Obsolete or excess inventories are recorded at their estimated realizable value.

**Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed primarily using the straight-line method over the estimated useful lives of the assets, which is three (3) years for the existing assets as of December 31, 2022 and 2021. Expenditures for repairs and maintenance are charged to expense as incurred.

**Intangible Assets**

The Company capitalizes its patent filing fees and legal patent prosecution fees in connection with internally developed pending patents. When pending patents are issued, patents will be amortized over the expected period to be benefitted, not to exceed the patent lives, which may be as long as 17 years.

**Impairment of Long-Lived Assets**

The long-lived assets held and used by the Company are reviewed for impairment no less frequently than annually or whenever event or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In the event that facts and circumstances indicate that the cost of any long-lived assets may be impaired, an evaluation of recoverability is performed. Due to modifications in our formulations during 2022, there was impairment losses related to the previously capitalized formulations and other intangible assets related to the formulations. The total amount of intangibles written off totaled \$300,000 of which \$130,000 was written off within R&D expense as this amount was previously paid for while the other \$170,000 reversed the accrued liability.

**Concentration of Credit Risk**

The Company maintains its cash with a major financial institution located in the United States of America which it believes to be creditworthy. Balances are insured by the Federal Deposit Insurance Corporation up to \$250,000. At times, the Company may maintain balances in excess of the federally insured limits.

**Equity Offering Costs**

The Company accounts for offering costs in accordance with Accounting Standards Codification (“ASC”) 340, Other Assets and Deferred Costs. Prior to the completion of an offering, offering costs will be capitalized as deferred offering costs on the Balance Sheet. The deferred offering costs will be charged to stockholders’ equity upon the completion of an offering or to expense if the offering is not completed. Offering costs charged to stockholders’ equity totaled \$10,228 and \$132,063 for the year ended December 31, 2022 and 2021, respectively.

**Revenue Recognition**

The Company records revenue in accordance with Accounting Standards Codification (“ASC”), Topic 606, Revenue from Contracts with Customers, which is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contracts with customers; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies the performance obligations. ASC 606 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising

from customer contracts. Revenue is recorded net of sales-related taxes collected from customers and remitted or payable to government taxing authorities.

The Company started generating revenues in 2021; and therefore, the Company does not have any transitional disclosures as ASC 606 was effective prior to the Company generating revenue. As of December 31, 2022, the Company sells its skin care products at a point in time and records revenues when the customer order is placed (i.e., no deferred revenue/ performance obligations). The \$839 receivable balance as of December 31, 2022, related to the Company's third-party distributor and is a timing difference of when the order is placed and payment received by the distributor.

### **Research and Development Costs**

The Company incurs research and development costs during the process of developing and designing its advanced wound care and skin care products. Research and development costs consist primarily of outside services. The Company expenses these costs as incurred until the resulting products have been completed, tested, and made ready for commercial use.

### **Stock Based Compensation**

The Company accounts for stock options issued to employees under ASC 718 Share-Based Payment. Under ASC 718, share-based compensation cost to employees is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite vesting period. The fair value of each stock option or warrant award is estimated on the date of grant using the Black-Scholes option valuation model.

The Company has implemented ASU 2018-07—Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. Accordingly, the Company has recorded nonemployee share-based payments and stock option costs measured at the date of grant based on the fair value of the award during the year ended December 31, 2022 and 2021.

### **Income Taxes**

The Company applies ASC 740 Income Taxes ("ASC 740"). Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial statement reported amounts at each period end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax expense for the period, if any and the change during the period in deferred tax assets and liabilities.

ASC 740 also provides criteria for the recognition, measurement, presentation, and disclosure of uncertain tax positions. A tax benefit from an uncertain position is recognized only if it is "more likely than not" that the position is sustainable upon examination by the relevant taxing authority based on its technical merit. The Company is subject to tax in the United States ("U.S.") and files tax returns in the U.S. Federal jurisdiction and state jurisdiction. The Company is subject to U.S. Federal, state, and local income tax examinations by tax authorities for all periods. The Company currently is not under examination by any tax authority.

### **Recently Issued and Adopted Accounting Pronouncements**

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial

statements. Among other changes, the new guidance removes from GAAP separation models for convertible debt that require the convertible debt to be separated into a debt and equity component, unless the conversion feature is required to be bifurcated and accounted for as a derivative or the debt is issued at a substantial premium. As a result, after adopting the guidance, entities will no longer separately present such embedded conversion features in equity and will instead account for the convertible debt wholly as debt. The new guidance also requires use of the “if-converted” method when calculating the dilutive impact of convertible debt on earnings per share, which is consistent with the Company’s current accounting treatment under the current guidance. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, but only at the beginning of the fiscal year. The Company did early adoption of the new guidance on January 1, 2021. As of December 31, 2021, the impact of adoption resulted in a reduction to additional paid in capital of \$48,321 related to amounts attributable to beneficial conversion feature that had previously been recorded in equity. Additionally, the Company recorded an increase to its convertible notes, net balance by \$44,151 and credited interest expense for the prior year amortization of \$4,169 as a result of reversal of the separation of the convertible debt between debt and equity.

In May 2021, FASB issued ASU No. 2021-04, to clarify and reduce diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this Update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The Company recorded our warrant modifications in accordance with this standard for both fiscal years 2022 and 2021. As these modifications related to equity raises, the Company recorded these within additional-paid-in-capital and interest expense. See Footnote 8 for further discussion of the exercised warrants.

In October 2021, FASB issued ASU No. 2021-07, Compensation—Stock Compensation (Topic 718): Determining the Current Price of an Underlying Share for Equity-Classified Share-Based Awards (a consensus of the Private Company Council). The amendments in ASU 2021-07 offer nonpublic entities a practical expedient to use when determining the “current price input” of an equity-classified share-based payment award issued to employees and nonemployees. The current price input is used when calculating the award’s fair value. The practical expedient in ASU 2021-07 allows a nonpublic entity to determine the current price input of a share option using the “reasonable application of a reasonable valuation method,” which is determined as of the award’s measurement date, taking into consideration the following factors: (1) The value of the nonpublic entity’s tangible and intangible assets, (2) The present value of the entity’s anticipated future cash flows, (3) The market value of stock or equity interests in similar entities engaged in substantially similar trades or businesses, (4) Recent arm’s-length transactions involving the sale or transfer of the entity’s stock or equity interests, (5) Other relevant factors, such as control premiums or discounts for lack of marketability, (6) The entity’s consistent use of a particular valuation method to determine the value of stock or assets for other purposes. The practical expedient may be applied prospectively for all equity-classified awards granted or modified during fiscal years beginning after December 15, 2021 and during interim periods within fiscal years beginning after December 15, 2022. The Company estimates the fair value of each option on the grant date using a Black-Scholes option-pricing model. As such, the Company is in line with this standard. Refer to Footnote 8 for further discussion.

The FASB issues ASUs to amend the authoritative literature in ASC. There have been a number of ASUs to date, including those above, that amend the original text of ASC. Management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, (iii) are not applicable to us, or (iv) are not expected to have a significant impact on our financial statements.

### 3. INVENTORIES

As of December 31, 2022, and 2021, inventories consist of:

<b>As of Year Ended December 31,</b>	<b>2022</b>	<b>2021</b>
OTC RMelix products	\$ 31,599	\$ 55,571
AWC raw materials	1,466	1,466
Raw materials - honey	12,080	
Inventory allowance- OTC	(28,455)	
<b>Total</b>	<b>\$ 16,690</b>	<b>\$ 57,037</b>

### 4. OTHER CURRENT ASSETS

As of December 31, 2022, and 2021, other current assets consist of:

<b>As of Year Ended December 31,</b>	<b>2022</b>	<b>2021</b>
Security deposit	\$ -	\$ 2,521
Down Payments – Purchase Orders	\$ 21,960	\$ -
<b>Total</b>	<b>\$ 21,960</b>	<b>\$ 2,521</b>

The Company entered into a month-to-month lease office lease on November 15, 2020. As of March 31, 2022, the Company terminated this lease and no longer occupied the office and therefore the remaining security deposit of \$2,521 was applied to rent expense for the last month's rent per the rent agreement. The Company additionally made several down payments to our new manufacturer for product development purposes, we expect the products to be formulated during 2023.

### 5. PROPERTY AND EQUIPMENT

As of December 31, 2022, and 2021, property and equipment consist of:

<b>As of Year Ended December 31,</b>	<b>2022</b>	<b>2021</b>
Furniture and equipment	\$ 16,039	\$ 16,039
Less: accumulated depreciation	(14,748)	(12,167)
<b>Property and equipment, net</b>	<b>\$ 1,291</b>	<b>\$ 3,871</b>

Depreciation expense for property and equipment for the years ended December 31, 2022 and 2021 was approximately \$2,581 and \$4,833, respectively.

### 6. INTANGIBLE ASSETS

The components of intangible assets, net as of December 31, 2022 and 2021, consisted of the following:

<b>As of Year Ended December 31,</b>	<b>2022</b>	<b>2021</b>
Patents	\$ 173,481	\$ 173,147
Trademarks	13,392	8,311
Formulations	-	200,000
Non-compete covenant	-	62,500
Option to offset/purchase	-	37,500

Less: accumulated amortization	(32,689)	(21,143)
<b>Intangible assets, net</b>	<b>\$ 154,184</b>	<b>\$ 460,315</b>

Amortization expense was approximately \$11,547 and \$9,975 for the years ended December 31, 2022 and 2021, respectively.

On March 12, 2021, the Company executed a declaration of intent with a manufacturing company for the Company to do the following: (1) to purchase the technical knowledge and the know-how required to manufacture the Company's BEECure<sup>®</sup>R product in the United States, and (2) the perpetual right to manufacture the product in the United States and sell it throughout the world.

The manufacturer agreed to these terms based on the Company paying the manufacturer \$300,000 based on an agreed upon milestone schedule. The \$300,000 is included in several intangible assets as of December 31, 2021 noted in the table above: (1) Formulations, (2) Non-compete covenant, and (3) Option to offset/purchase.

As of December 31, 2022, the Company terminated this agreement due to a formulation adjustment that required a different manufacturer. As such, the Company wrote off the aforementioned assets of which \$130,000 was expensed to R&D (this amount was previously paid for in 2021) and the remaining amount of \$170,000 was reversed from accrued liabilities.

The following is a roll forward of the Company's intangible assets and amortization for the year ended December 31, 2022;

	<b>Assets</b>	<b>Accumulated Amortization</b>
Balance at December 31, 2021	\$ 481,485	\$ (21,143)
Addition of new assets	5,414	-
Write-offs	(300,000)	-
Amortization		(11,547)
<b>Balance at December 31, 2022</b>	<b>\$ 186,872</b>	<b>\$ (32,689)</b>

The following table outlines future amortization expense as of December 31, 2022:

<b>Period</b>	<b>Amortization Expense</b>
2023	\$ 11,565
2024	11,565
2025	11,565
2026	11,565
2027	11,565
Thereafter	96,359
<b>Total</b>	<b>\$ 154,184</b>

## 7. NOTES PAYABLE

Notes payable consist of the following:

<b>Short term</b>	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Convertible note, net	\$ 369,667	\$ 116,563

<b>Long term</b>	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Convertible notes, net	\$ -	\$ 266,547
<b>Total long term debt, net</b>	<b>\$ 369,667</b>	<b>\$ 266,547</b>

Details of notes payable as of December 31, 2022, are as follows;

	<b>Principal Amount</b>	<b>Carrying Value</b>	<b>Interest Rate</b>	<b>Conversion Price</b>	<b>Maturity Date</b>
<b>Short term</b>					
Convertible notes, net	\$ 375,000	\$ 369,667	9%	\$0.65	1/23/2023

### **Convertible Notes**

In October 2020, the Company offered a convertible note financing (“Notes”) available exclusively to accredited investors as defined by Regulation D under the Securities Act of 1933. The amount of the financing was in total \$600,000 with a minimum placement of \$50,000. The Notes were issued with an original issue discount (“OID”) and, as such, the purchase price is net of interest from the date of the Note payments on the unpaid principal balance at a rate equal to nine percent (9%) over a 24-month period. The Note’s outstanding principal and interest will convert into the Company’s common shares at a conversion price of \$0.65 per share any time after issuance thereby having an embedded beneficial conversion feature.

In addition, each investor who purchases Notes will receive 100% warrant coverage. Each warrant has a five-year term and an exercise price equal to \$1.40 or 50% premium over the price received by the Company in next offering. The beneficial conversion feature, if any, and the warrants were recorded to additional paid-in-capital. The Company allocated the proceeds received to the notes, the beneficial conversion feature, and the warrants on a relative fair value basis at the time of issuance. The total debt discount is amortized over the life of the notes to interest expense using the straight-line method.

#### *Current maturities of long-term debt:*

In January and February of 2021, under the Company’s convertible note financing plan, the Company issued \$375,000 in convertible notes for consideration of \$307,500, the difference between the proceeds from the notes and principal amounts consists of \$67,500 of OID. The note holders were also issued market-related warrants for 576,923 in shares of common stock. These convertible notes mature in the first quarter of 2023; and thus, classified within the current maturities of long-term debt as of December 31, 2022. See Footnote 13 of instrument conversions and extensions subsequent to December 31, 2022.

Note that one note holder’s instrument matured on October 15, 2022, on which date the note holder converted his note to shares of common stock. Per the conversion agreement, the Company reclassified the \$125,000 previously issued note from the convertible debt into 192,308 shares of common stock at \$0.65 per share. The remaining \$124,981 was recorded as additional-paid-in-capital as of December 31, 2022.

#### *Long term debt:*

As of December 31, 2022, the Company does not have any long-term debt; however, see Footnote 13 for subsequent events that either extended the maturity date of convertible debt or converted the debt into shares of common stock.

#### *Exercised Warrants:*

In August 2022, one note holder exercised 21% of his remaining warrants and converted the warrants into 30,000 shares at an amended exercise price of \$0.85. The Company received \$25,500 in cash proceeds. The

Company additionally recognized \$3,300 of interest expense related to the warrant modification as of December 31, 2022.

The interest expense related to the Convertible Notes for the year ended December 31, 2022 was recognized as follows;

<b>For Year Ended December 31, 2022</b>		
Interest expense - OID	\$	42,188
Interest expense - Warrants		69,370
<b>Total</b>	<b>\$</b>	<b>111,558</b>

The remaining original issuance discount balance as of December 31, 2022 totaled \$2,063 and the expected annual amortization per year is as follows;

<b>Period</b>	<b>Amortization Expense</b>	
2023		2,063
<b>Total</b>	<b>\$</b>	<b>2,063</b>

The remaining warrants discount balance as of December 31, 2022 totaled \$3,270 and the expected annual amortization per year is as follows;

<b>Period</b>	<b>Amortization Expense</b>	
2023	\$	3,270
<b>Total</b>	<b>\$</b>	<b>3,270</b>

## **8. CAPITALIZATION AND EQUITY TRANSACTIONS**

### **Common Stock**

During the year ended December 31, 2021, the Company's Articles of Incorporation were amended to increase the number of Common Shares authorized from 25,000,000 to 28,000,000 and provide that 6,000,000 of such shares be a non-voting-class called "Class NV", each share having a par value of \$0.0001.

During 2022 and 2021, the Company issued 30,000 and 126,923 shares, respectively, related to exercised warrants- refer to Note 7 for further discussion.

As of December 31, 2022, and 2021, the Company has issued 11,235,231 and 11,012,923 shares, respectively, of our voting class of common stock.

### **Common Stock: Class NV**

In 2019, as part of the Regulation Crowd Funding ("Reg CF"), the Board of Directors adopted a resolution that the Company is authorized to issue and sell up to 2,500,000 Shares of its Common Stock: Class NV for a price of \$0.60 per share. The Class NV shares will be offered in the Reg CF funding and the par value, dividend and liquidation and other rights of the Class NV shares shall be the same as the other shares of Common Stock except that Class NV shares shall not be entitled to a vote on any matters whatsoever and shall not be considered in calculating a quorum. This Reg CF concluded in April 2021. The Company sold 649,880 shares of Class NV common stock through this Reg CF.



In 2021, the Board of Directors adopted a resolution that the Company is authorized to issue and sell up to 2,666,667 Shares of its Common Stock: Class NV for a price of \$1.50 per share as part of another Regulation Crowd Funding (“Reg CF 2”). The Class NV shares will be offered in the Reg CF 2 funding and the par value, dividend and liquidation and other rights of the Class NV shares shall be the same as the other shares of Common Stock except that Class NV shares shall not be entitled to a vote on any matters whatsoever and shall not be considered in calculating a quorum.

During the year ended December 31, 2021, the Company sold 649,880 and 87,098 shares of Class NV common stock through its Reg CF and Reg CF 2, respectively. The Company recognized gross proceeds of \$474,893 and had a subscription receivable of \$3,819 related to the sale of these shares as of December 31, 2021. In connection with these offerings, the Company incurred offering costs of \$132,063, which reduced additional paid-in capital. The subscription receivable of \$3,819 was collected subsequent to December 31, 2021. Also, as of December 31, 2021, the Company included 1,742 shares within common stock subscribed due to a placement agent in connection with the Reg CF 2.

During the year ended December 31, 2022, the Company sold 9,318 shares of Class NV common stock through its Reg CF 2. The Company recognized gross proceeds of \$17,216 as of December 31, 2021. The Company did not have a subscription receivable as of December 31, 2022 as the campaign closed in the first quarter of 2022. In connection with this offering, the Company incurred offering costs of \$10,228, which reduced additional paid-in capital. Also, as of December 31, 2022, the Company included 183 shares within Class NV common stock due to a placement agent in connection with the Reg CF 2.

As of December 31, 2022, and 2021, the Company has 2,052,066 and 2,042,748 shares, respectively, of Class NV common stock issued and outstanding.

### **Preferred Stock**

We have authorized the issuance of 5,000,000 shares of our preferred stock with par value of \$0.0001. As of December 31, 2022, the Company has issued 0 shares of our preferred stock. The Board of Directors is expressly authorized at any time and from time to time to provide for the issuance of shares of Preferred Stock in one or more series, with such voting powers, full or limited, or without voting powers, and with such designations, preferences and relative participating, option or other rights, qualifications, limitations or restrictions, as shall be fixed and determined in the resolution or resolutions providing for the issuance thereof adopted by the Board of Directors, and as are not stated and expressed in the Articles of Incorporation.

### **Stock Based Compensation**

The Company authorized 50,000 shares of its common stock as stock-based compensation for consulting services of an individual in 2019. The fair value of the services provided which included such shares will vest at the rate of 1,390 shares at the end of each calendar month which started January 31, 2018 and continuing until December 31, 2020, with the final 1,350 shares which vested on January 31, 2021. The stock-based compensation was recognized over the service period and was recorded within research and development expense within the statement of operations which totaled \$0 and \$675 for the years ended December 31, 2022 and 2021, respectively.

During the year ended December 31, 2021, \$675 of the Unearned-Deferred Compensation was recognized as consulting expense. The Unearned-Deferred Compensation totaled \$0 as of December 31, 2022 and 2021. Additionally, 50,000 shares of common stock were vested as of December 31, 2021.

### **2017 Stock Incentive Plan**

The Company has entered into several stock option agreements as of December 31, 2022. As of December 31, 2022, the Company had a plan amendment to increase its reserve from 1,500,000 shares up to 3,000,000

shares of Common Shares for stock options under the Plan and 737,500 stock options have vested. A summary of our stock option activity for the year ended December 31, 2022, is as follows:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life (years)
Outstanding at December 31, 2021	1,560,000	\$ 0.60	5.40
Granted	1,440,000	\$ 0.72	-
Exercised	-	-	-
Forfeited or expired	-	-	-
Outstanding at December 31, 2021	3,000,000	\$ 0.66	5.33
Exercisable at December 31, 2021	737,500	\$ 0.65	5.52

We estimated the fair value of each option on the grant date using a Black-Scholes option-pricing model with the following assumptions:

As of Year Ended December 31,	2022	2021
Expected term	3- 8 years	5.5 years
Volatility	95%	95%
Risk free rate	2.93% - 4.28%	0.07%
Market price	\$ 0.85	\$ 0.60
Exercise price	\$ 0.72	\$ 0.60

The risk-free interest rate assumption for options granted is based upon observed interest rates on the United States government securities appropriate for the expected term of the Company's employee stock options. The expected term of employee stock options is calculated using the simplified method which takes into consideration the contractual life and vesting terms of the options. The Company determined the expected volatility assumption for options granted using the historical volatility of comparable public companies' common stock. The Company will continue to monitor peer companies and other relevant factors used to measure expected volatility for future stock option grants, until such time that the Company's common stock has enough market history to use historical volatility. The dividend yield assumption for options granted is based on the Company's history and expectation of dividend payouts. The Company has never declared or paid any cash dividends on its common stock, and the Company does not anticipate paying any cash dividends in the foreseeable future. Management based the fair value of common stock through recent sales at the time of grant. Forfeitures are recorded as they occur.

As part of one of the stock option agreements, the stock option holder was issued put options to sell shares back to the Company. The holder has the exercise right to require the Company to repurchase after the Company raises a specific amount of capital. The value of the shares at the time of exercise of the option is defined within the agreements. The Company records the estimated fair market value of the put option at each reporting period based upon the agreement terms. During 2021, the Company was able to surpass the specific amount of capital within the agreement; and, therefore, the Company recorded the change in fair value of \$18,463 within the statement of operations. The current liability associated with the put option was \$67,550 and \$67,550 as of December 31, 2022 and 2021, respectively.

The Company recognized stock option compensation costs in the amount of \$152,280 and \$71,815 for the year ended December 31, 2022 and 2021, respectively. Note that these shares are authorized with common stock voting rights; however, none of these shares are outstanding or issued as of December 31, 2022.

The remaining stock compensation balance to be expensed in future years as of December 31, 2022 totaled \$857,360 and the expected annual expense per year is as follows:

Period	Stock Compensation Expense
2023	\$ 164,912
2024	128,179
2025	118,477
2026	106,326
2027	105,028
2028	90,750
2029	90,750
2030	52,938
<b>Total</b>	<b>\$ 857,360</b>

## 9. INCOME TAXES

The provision for income taxes for the year ended December 31, 2022 and 2021 consists of the following:

As of Year Ended December 31,	2022	2021
<b>Current tax provision:</b>		
Federal	\$ -	\$ -
State	-	-
<b>Total</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Deferred tax provision:</b>		
Federal	\$ 142,908	\$ 142,638
State	33,278	32,929
<b>Total</b>	<b>\$ 176,186</b>	<b>\$ 175,567</b>
Valuation allowance	(176,186)	(175,567)
<b>Total provision for income taxes</b>	<b>\$ -</b>	<b>\$ -</b>

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2022, and December 31, 2021 are as follows:

As of Year Ended December 31,	2022	2021
Stock options expense	\$ 101,024	\$ 61,979
Organizational costs	4,507	4,507
Charitable contribution	177	177
Net operating loss carryforwards	472,085	334,944
Valuation allowance	(577,793)	(401,607)
<b>Net deferred tax asset (liability)</b>	<b>\$ -</b>	<b>\$ -</b>

Reconciliation between statutory income tax rate and the Company's effective income tax provision (benefit) rate for the years ended December 31, 2022 and 2021 as follows:

<b>As of Year Ended December 31,</b>	<b>2022</b>	<b>%</b>	<b>2021</b>	<b>%</b>
Income tax at federal statutory rate	\$ (166,042)	21%	\$ (167,242)	21%
State taxes, net of federal benefit	(28,990)	4%	(28,931)	4%
Nondeductible stock options expense	39,045	-4%	18,384	-2%
Nondeductible organizational costs	-	0%	-	0%
Nondeductible charitable contribution	-	0%	-	0%
Permanent differences	18,846	-3%	20,606	-3%
NOL carryforward	137,141	-18%	157,183	-20%
<b>Income tax provision (benefit)</b>	<b>\$ -</b>	<b>0%</b>	<b>\$ -</b>	<b>0%</b>

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. On the basis of this evaluation, the Company has determined that it is more likely than not that the Company will not recognize the benefits of the federal and state net deferred tax assets, and, as a result, full valuation allowance has been set against its net deferred tax assets as of December 31, 2022 and 2021. The amount of the deferred tax asset to be realized could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased.

Based on federal tax returns filed, or to be filed, through December 31, 2022, we had available approximately \$1,948,086 in U.S. tax net operating loss carryforwards, pursuant to the Tax Act, which assesses the utilization of a Company's net operating loss carryforwards resulting from retaining continuity of its business operations and changes within its ownership structure.

The Company recognizes the impact of a tax position in the financial statements if that position is more likely than not of being sustained on a tax return upon examination by the relevant taxing authority, based on the technical merits of the position. As of December 31, 2022 and 2021, the Company had no unrecognized tax benefits.

The Company recognizes interest and penalties related to income tax matters in income tax expense. As of December 31, 2022 and 2021, the Company had no accrued interest and penalties related to uncertain tax positions.

The Company is subject to examination for its US federal jurisdictions for each year in which a tax return was filed.

## **10. COMMITMENTS AND CONTINGENCIES**

### **Contingencies**

The Company's operations are subject to a variety of local and state regulation. Failure to comply with one or more of those regulations could result in fines, restrictions on its operations, or losses of permits that could result in the Company ceasing operations. As of December 31, 2022 and 2021, there were no contingencies that could reasonably be expected to have a material effect on the results of the Company's operations.

### **Litigation and Claims**

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of December 31, 2022 and 2021, there were no pending or threatened

lawsuits that could reasonably be expected to have a material effect on the results of the Company's operations.

## **11. RELATED PARTY TRANSACTIONS**

In 2021, the Company received funding in excess of \$750,000 through its equity crowdfunding and Convertible Debt offerings. The CEO agreed to re-invest her net compensation after taxes into the Company's equity crowdfunding campaign until either the Company's funding goal of \$1.07 million has been reached or the equity crowdfunding campaign otherwise concludes. During 2021, StartEngine had several investment policy changes with the Company's second crowdfunding campaign ("Reg CF 2") which did not allow the CEO to make investments into the campaign. Based on that, the CEO agreed to forego her net salary in 2021 as well as the first 90 days of 2022. As of February 15, 2022, the CEO started to accrue the gross salary amount. The deferred salary amount of \$138,791 is recorded as deferred compensation on the Balance Sheet as of December 31, 2022. See Note 8 for further information on Reg CF 2.

On September 1, 2019, the Company entered into a consulting agreement ('Agreement') with a Board of Director member. The Agreement provisions included consulting time-based compensation and granted stock options to purchase up to 925,000 shares at \$0.60 per share based on time-based and milestone-based criteria expiring on September 30, 2022. On September 30, 2022, the Company granted a non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 60,000 of its common shares at the current fair market value of \$0.85 per share. As of December 31, 2022, and 2021, the Company accrued compensation payable of \$36,775 and \$33,775 and 235,917 and 207,583 shares of common stock were vested under the option agreements, respectively.

On July 15, 2020, the Company granted a director a non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 50,00 of its common shares at the current fair market value of \$0.60 per share. The option will expire on September 1, 2027, and the shares shall vest with respect to 5,000 shares at the end of each calendar quarter that the director remains a director of the Company, starting with the quarter ending November 30, 2020. This option was terminated on September 30, 2022 and the Company granted a new non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 60,000 of its common shares at the current fair market value of \$0.85 per share. As of December 31, 2022 and 2021, 50,000 and 25,000 shares of common stock, respectively, were vested under the director's option agreements.

On July 28, 2022, the Company granted a director a non-statutory stock option pursuant to the 2017 Stock Incentive Plan to purchase up to 1,000,000 of its common shares at the current fair market value of \$0.85 per share based on milestone-based criteria. As of December 31, 2022, 200,000 shares of common stock were vested under the director's option agreement.

See Note 8 for related party consulting agreement and non-statutory stock options.

## **12. GOING CONCERN**

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company commenced revenue generating activities starting in 2021 for one of many products, incurred losses from operations, and had an accumulated deficit of \$2,502,987 and \$1,734,032 as of December 31, 2022 and 2021, respectively. Losses are expected to continue until such time that Company can design, produce, and sell all its product offerings as well as obtain clearance from the FDA on the Company's advanced wound care products. These matters raise substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern in the next twelve months following the date the financial statements were available to be issued is dependent upon its ability to produce revenues and/or obtain financing sufficient to meet current and future obligations and deploy such to produce profitable operating results.

Management has evaluated these conditions and plans to generate revenues and raise capital as needed to satisfy its capital needs. During the next twelve months, the Company intends to fund its operations through debt and/or equity financing and revenues from product launches.

There are no assurances that management will be able to raise capital on terms acceptable to the Company. If it is unable to obtain sufficient amounts of additional capital, it may be required to reduce the scope of its planned development, which could harm its business, financial condition, and operating results. The accompanying financial statements do not include any adjustments that might result from these uncertainties.

### **13. SUBSEQUENT EVENTS**

Subsequent to December 31, 2022, the Company extended several note holders convertible debt. These extensions related to \$225,000 of convertible debt with maturity dates in January and February of 2024.

Subsequent to December 31, 2022, several note holders converted their notes on the maturity date to shares of common shares. These conversions amounted to \$150,000 of convertible debt which totaled 230,769 shares of common stock at \$0.65 per share.

The Company has evaluated subsequent events that occurred after December 31, 2021 through March 1, 2023, the issuance date of these financial statements. There have been no other events or transactions during this time which would have a material effect on these financial statements.