

SanMelix Laboratories, Inc.



ANNUAL REPORT

**1150 N 35th Ave
Suite 225
Hollywood, FL 33021**

This Annual Report is dated April 29, 2022.

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 wound care company focusing on the unique medicinal properties of buckwheat honey for tissue regeneration and accelerated healing. Our BEECure[®] M bioactive buckwheat honey formulations demonstrate intrinsic healing activity with anti-microbial additives to reduce microbial growth in the dressing while in use. With IP protection on our BEECure[®] M dressing and other patents, co-created by the renowned Harvard trained podiatric physician, Dr. Kenneth Sabacinski, SanMelix's advanced bioactive wound care products can be used in a host of settings and situations. We have created over the counter (“OTC”) skin care products such as ointments and creams designed to help in the healing of minor burns, scrapes, and radiodermatitis. 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 have developed products that combine nature with science to create wound care solutions. BEECure® products are made to support healing of chronic and non-healing wounds along with minor burns, cuts, and scrapes. Studies have proven that 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. In addition, our patented formulation has been fortified with a standardized amount of antimicrobial to ensure consistency in preservative effectiveness when applied to chronic wounds. The antioxidant properties inherent in Buckwheat honey assist in wound closure and help to stimulate the wound healing process. The mix of Buckwheat honey with our patented formulation is anticipated to reduce life-threatening microbial growth within the dressing while it is in use.

Our products are being developed and tested to address the following health issues: (1) the antimicrobial resistance (“AMR”) crisis; (2) diabetic foot ulcers; (3) radiation, chemical and thermal burns; and (4) moisturizers to help soothe, revive, and hydrate skin damaged from sunburn and other skin ailments (i.e., eczema).

- (1) The AMR crisis resulting from superinfections that are resistant to antibiotics is projected to kill 10 million people globally per year by 2050. Our patented formulation prevents antibiotic-resistant pathogens such as Methicillin-Resistant Staphylococcus Aureus (“MRSA”) from entering the wound while the dressing is in use. Our products could assist hospitals and clinics with their antibiotic stewardship programs.
- (2) 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 and 47% ending in death. Case studies on our BEECure® M advanced wound care dressings have illustrated healing and skin regeneration on severe limb threatening wounds and diabetic foot ulcers.
- (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. The studies also illustrate that honey dressings have a better outcome in terms of hypertrophic scars and postburn contractures, as compared to silver sulfadiazine dressings.
- (4) We launched seven buckwheat honey- based cosmetics in Q1 2022 that hydrate, soothe, and revive red, dry, itchy damaged skin related to sunburns, cracked heel skin, eczema, psoriasis, aging skin, and rosacea.

Our Products in Use

Our BEECure® 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 products.

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

- ❖ Ulcers, diabetic and otherwise
- ❖ Skin grafts
- ❖ Partial Thickness Burns
- ❖ Trauma and triage
- ❖ Surgical Site Infections

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

- ❖ Radiation and Laser Skin Care
- ❖ Minor burns
- ❖ Diabetic foot ulcer cream
- ❖ Acne
- ❖ Rosacea
- ❖ Eczema
- ❖ Anti-aging
- ❖ Psoriasis

In January 2021, SanMelix launched its BEECure®R- Radiation and Laser Skin Care on Amazon.com and Walmart.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 dressing 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 a certified current Good Manufacturing Practices (“cGMP”) facility as our contract manufacturer for our patented formulation wound care dressings.

The initial sample run for the patented technology was completed in February 2019 and will be 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 initial FDA requirements. 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. The Company is in search of a new manufacturer as the initial cGMP no longer manufactures our dressings. 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 and Walmart.com in January 2021. After the first two manufacturing runs in Europe, SanMelix plans to transfer its manufacturing rights to the U.S. In March 2021, the Company entered into an agreement with its European contract manufacturer to purchase the formulation and manufacturing rights and know-how for the BEECure®R- Radiation and Laser Skin Care product for \$300,000. The Company anticipates a cost savings upon moving its manufacturing to the U.S.

In Q1 2022, the Company launched seven additional skin care products for various skin conditions such as eczema and psoriasis. The Company has found multiple manufacturers in the U.S. for its skin care products.

Sales Model

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 channel 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 product that promotes healing and tissue growth that can assist with the AMR crisis. It has been recommended that each hospital implement an AMR Stewardship Program.

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 with their AMR stewardship programs. Our mission is to pursue a specific and unique reimbursement code for our product due to its specific anti-microbial claim. 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 the military, DoD, and the VA systems. We are pursuing military grant opportunities for severe burns and wound healing with Trauma Insight as our contract research organization (“CRO”) that was founded by retired military personnel. If we obtain a government grant for clinical trial testing, we anticipate pursuing government purchasing opportunities. However, there can be no assurances that we will receive military funding or that the government will want to purchase our wound dressings.

We launched our BEECure®R- Radiation and Laser skin care on Amazon.com and Walmart.com in January 2021, and seven additional skin care products in February 2022. 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 and oncologists. 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.

SanMelix is proud to have some of the most experienced and widely renowned minds behind our products. 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.

In addition to co-founder Dr. Sabacinski, our medical team of experts includes Dr. Jason Green, D.O. Board Certified Dermatologist and COL (ret) George E. Peoples, MD, FACS. Dr. Green is our Advisory Board Director and has performed product testing of our initial CE Marked skin care product for radiodermatitis. Dr. George Peoples is the founder of our CRO, Trauma Insight. Through his military career as a staff surgeon at a level I trauma center and multiple combat deployments, Dr. Peoples has extensive trauma experience and has developed close relationships with some of the most prominent military and civilian

trauma and critical care physicians in the country. We expect to engage Trauma Insight to manage our clinical trials, if needed.

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 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 \$69,969 is recorded as deferred compensation as of December 31, 2021.

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.

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 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. He is the Managing Shareholder for Hammer Navarro and Associates, PA. Sam is a CPA and Certified Chartered Global Management Accountant (“CGMA”) with more than 30 years of healthcare experience serving as a C-Suite Operating Executive, Board of Director and Advisor to physicians, employers, payors, hospitals, physician groups, law firms, manufacturers, and government. He provides advice on mergers and acquisitions, strategy, physician integration, taxes, and litigation support.

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 requires recall

of products that have safety defects or noncompliance with respect to FDA standards; the cost of such recall campaigns could be substantial.

Our 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 patented formulation may have a different regulatory pathway as a Class II De Novo product.

Federal Food and Drug Administration

In 2018, the company met with the FDA for a 510(k) pre-submission meeting. The FDA considers 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 advance wound care products and perform the 510(k) testing recommended by the FDA.

The AWC MGO dressing 510(k) pre-market clearance has been reviewed by the FDA. Since the formulation is unique and patented, the FDA has not been able to determine if the device is substantially equivalent to manuka honey predicate devices and has declared the product to be NSE, not substantially equivalent. The FDA states that they have never approved a product that contains MGO, they have not approved our predicate based on MGO (even though the predicate device promotes MGO in their advertising); and therefore, they have nothing with which to compare BEECure® MGO wound dressing. That decision has been appealed. We plan to pursue a Class II De Novo application or a Class III Premarket Approval (PMA), which may result in significant expenditures requiring additional funding, if not received would have a material adverse effect on the Company. In addition, our buckwheat honey dressing 510(k) application has been withdrawn until additional testing and risk assessments are performed as requested by the FDA. Upon completion of the new FDA testing, the Company plans to resubmit a new 510(k) application with additional information.

Additionally, we are exploring other OTC skin care products that would require compliance with the FDA Cosmetic Act as OTC monograph products. In addition, the products will need to comply with CE Marking requirements in Europe. 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 file either the Class II De Nova application or Class II Premarket approval.

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 be applying for a unique and specific code for our dressings, but there can be no assurances that SanMelix will receive a unique and specific Medicare Part B HCPCS code.

Market

We are focusing on two major market segments for buckwheat honey formulations. Our first segment is for AWC dressings for burns, acute and chronic wounds, which require FDA pre-market clearance. The second segment focuses on ointments and creams for minor burns associated with skin irritations from radiation and laser therapy and moisturizers to soothe, hydrate and revive dry and damaged skin. These products are considered moisturizers under the FDA Cosmetic Act. We plan on also developing OTC monograph products such as burn creams and acne medication.

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 U.S. skin and wound care market. We are capitalizing on a market that has been desperately in search of a natural, safe, and effective product to promote healing through moist wound healing while providing antimicrobial properties to prevent infection. For the OTC skin care market, we are focusing on skin care for skin conditions such as radiodermatitis, eczema, psoriasis, minor burns, rashes, anti-aging, and acne.

Competition

The AWC dressing competitors are not only Integra who purchased DermaScience Medihoney products and Medline who distributes Therahoney, but 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 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 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.

At SanMelix, we believe the difference is in the ingredients. Although manuka honey is the most commonly used honey-based wound dressing on the market, studies have shown that buckwheat honey has superior inherent healing properties when compared to manuka honey due to its higher anti-inflammatory and higher antioxidant activities.

In addition, SanMelix's AWC products have been fortified with natural antimicrobial found in honey to ensure a higher standardized and broader spectrum antibacterial activity. We believe our patented formulation utilized in our AWC dressings permits SanMelix to launch the first bioactive honey-based dressing to make an antimicrobial device claim in the U.S. With our anticipated FDA antimicrobial device claim, we believe our AWC dressings may be used to prevent pathogens from entering the wound as well as promote healing, without contributing to the growing AMR crisis. Although we are anticipating an

antimicrobial device claim, there can be no assurances the FDA will allow SanMelix to market our products with an antimicrobial device claim. The FDA has reviewed our patented formulation and has determined that it is not substantially equivalent (NSE) requiring either a Class II De Novo application with the device anticipated claim or a Class III PMA application (See FDA section above). Accordingly, the regulatory pathway for our patented formulation has not yet been finalized.

Along with debriding action, there will be antimicrobial properties and improved skin and tissue regeneration with our AWC dressings. This prevents the necessity for excess skin grafts or skins substitutes, which run the added risk of infection or rejection.

We believe we have developed the only AWC dressings that contain the three main characteristics of an ideal wound dressing (1) debridement, (2) antimicrobial claim and (3) skin regeneration properties. The dressing will prevent biofilms from forming, control wound odor, reduce pain and treatment time while being cost-effective and more environmentally sound.

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 two additional formulation patent pending applications. We continued to prosecute Buckwheat Honey/Bacitracin/MGO Continuation in Part No. 16/686799 during 2022. Based on recent office actions with the US Patent & Trademark Office (“USPTO”), 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 to support our claims. Since the World Health Organization (“WHO”) considers AMR an increasingly serious threat to global public health, the Company will be exploring government grant opportunities to assist with the funding of our research and development activities and evidence-based clinical trials that address the AMR crisis, wounds,

and burns. Although we anticipate applying for government grants to fund additional research and development, including clinical trials, there can be no assurance that we will be selected for government grant opportunities.

We also have applied for trademarks for our BEECure® 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® 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 Crowdfunding (“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 are being 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 subsequent to December 31, 2021.

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 – 2021 Compared to 2020

We did not generate any revenues in 2020; however, the Company launched its initial product BEECure®R- Radiation and Laser Skin Care product in January 2021 resulting in \$52,695 in revenues in 2021. We also launched an additional seven skin care products in February 2022. 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 2021 related to our initial product sales and includes the Cost of Manufacturing Goods along with the landed costs (i.e., freight-in). The gross margin of \$39,069 represents a 74% gross margin percentage.

General and administrative expenses increased to \$455,342 from \$260,546 for the years ending December 31, 2021 and 2020, respectively. General and administrative expenses increased primarily due the increase in compensation expense for the CEO which was primarily deferred and/or invested into the Reg CF campaigns (See related party transactions in footnote disclosures below).

Research and development expenses increased to \$155,871 from \$106,370 for the years ending December 31, 2021 and 2020, respectively due to increased FDA product testing.

Sales and marketing expenses increased to \$105,282 from \$29,755 for the years ending December 31, 2021 and 2020, respectively due to increased expenses for branding, packaging, website design and marketing materials for the BEECure®R product launch in January 2021 and the seven skin care product launches in Q1 2022.

Interest expense increased to \$137,553 from \$11,091 primarily due to the convertible debt issuance costs and related warrant modifications that took place during the current year.

Other Income increased to \$18,590 from \$3,583 due to the forgiveness of the COVID 19 Paycheck Protection Program Loan and miscellaneous referral fees.

As a result, the Company’s net loss increased to \$796,389 from \$404,179 for the years ended December 31, 2021, and 2020, respectively.

Liquidity and Capital Resources

We have an accumulated deficit of \$1,734,032 as of December 31, 2021. On December 31, 2021, the Company had cash and restricted cash of \$339,829. 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:

	2021	2020
<i>Net cash (used in) provided by:</i>		
Operating activities	\$ (541,752)	\$ (235,068)
Investing activities	(141,174)	(15,810)
Financing activities	758,288	464,027

Operating Activities:

Cash used in operating activities increased to \$541,752 from \$235,068 for the years ended December 31, 2021 and 2020, respectively. The increase in cash used in operating activities was primarily due to a higher net loss and inventory purchases for new products.

Investing Activities:

Cash used in investing activities increased to \$141,174 from \$15,810 for the years ended December 31, 2021 and 2020, respectively. The increase in cash used in investing activities was primarily due to the purchase of the BEECure®R formulation and related intangible assets. See Footnote 6—Intangible Assets.

Financing Activities:

Cash provided by financing activities increased to \$758,288 from \$464,027 for the years ended December 31, 2021 and 2020, respectively. The increase in cash provided by financing activities was primarily due to: (1) proceeds received from Convertible Debt offering (2) the issuance of non-voting common stock for cash through the Company's Regulation Crowdfunding offerings, and (3) proceeds from exercised warrants.

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.

Debt and Related Party Transactions

SBA PPP Loan:

As of December 2020, the Company received a loan from a Bank in the amount of \$13,500 related to the Paycheck Protection Program established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The Company received formal approval of loan forgiveness in the full amount of \$13,500 plus accrued interest on February 4, 2021. The loan forgiven amount of \$13,500 was recorded as other income as of December 31, 2021.

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:

On October 15, 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. This convertible note matures on October 15, 2022; and, thus, is classified within the current maturities of long-term debt as of December 31, 2021.

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. See Footnote 7—Notes Payable.

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 warrant modification within the statement of operations as of December 31, 2021.

In November and December 2021, another 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 warrant modifications within the statement of operations as of December 31, 2021.

The interest expense related to the Convertible Notes as of December 31, 2021 totaled \$119,090.

DIRECTORS, EXECUTIVE OFFICERS, AND SIGNIFICANT EMPLOYEES

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

- ❖ Dr. Kenneth Sabacinski, age 64, 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 61, 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 74, 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 70, has been director since 2019. Hamid is the President of FloSure Technologies, LLC.
- ❖ Samuel Hammer, age 61, has been Director since 2020. Mr. Hammer is the Managing Principal of Hammer Navarro and Associates, PA

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, 2021, 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 ⁽¹⁾	Percent of class ⁽²⁾
Dr. Kenneth A. Sabacinski	3,980,000	32.95%
Diana L. Sabacinski	3,980,000	32.95%
John L. Kaufman	2,040,000	16.89%
Hamid Khosrowshahi	0 ⁽³⁾	*
Samuel Hammer	0 ⁽³⁾	*
Current Officers and Directors as a group	10,000,000	82.78%

* Less than 1%

⁽¹⁾ Designated person or group has sole voting and investment power.

⁽²⁾ Pursuant to SEC Rule 13d-3, amounts shown include common shares that may be acquired by a person within 60 days of December 31, 2021. Therefore, the column titled "Percent of class" has been computed based on (a) 11,012,923 common shares actually outstanding as of December 31, 2021; 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, 2021 upon exercise of options, warrants and/or convertible debt held only by such person.

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

Name	Right to acquire
Hamid Khosrowshahi	207,583
Samuel Hammer	25,000

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. The net salary amount of \$69,969 is recorded as deferred compensation on the Balance Sheet as of December 31, 2021. 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. As of December 31, 2021, and 2020, the Company accrued compensation payable of \$33,775 and \$21,575 and 207,583 and 96,917 shares of common stock were vested under the consultant option agreement, 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. The option will terminate with respect to any shares covered by the option not vested at the time that director ceases to be a director of the Company. As of December 31, 2021 and 2020, 25,000 and 5,000 shares of common stock, respectively, 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 2021, the Company issued 126,923 shares related to exercised warrants- refer to Note 7 for further discussion. As of December 31, 2021, and 2020, the Company has issued and outstanding 11,012,923 and 10,886,000 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, 2021, the Company has granted up to 1,560,000 stock options under the Plan and 334,166 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 April 29, 2022.

SanMelix Laboratories, Inc.

X DocuSigned by:
Diana Sabacinski
03CE84E089EA435

Diana Sabacinski
Chief Executive Officer

SANMELIX LABORATORIES, INC.

FINANCIAL STATEMENTS YEARS ENDED DECEMBER 31, 2021 AND 2020

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*Certified Public Accountants
Registered Firm - Public Company Accounting Oversight Board*

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

SANMELIX LABORATORIES, INC.
BALANCE SHEETS

As of December 31,	2021	2020
ASSETS		
Cash, cash equivalents, and restricted cash	\$ 339,829	\$ 264,467
Accounts receivable	1,590	-
Inventories	57,037	26,139
Other current assets	2,521	2,521
<i>Total current assets</i>	<i>400,977</i>	<i>293,127</i>
Property and equipment, net	3,871	8,704
Intangible assets, net	460,315	159,116
<i>Total noncurrent assets</i>	<i>464,186</i>	<i>167,820</i>
Total assets	\$ 865,163	\$ 460,947
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 24,100	\$ 30,536
Other current liabilities	203,907	21,576
Put option liability	67,550	-
Current maturities of long-term debt	116,563	-
<i>Total current liabilities</i>	<i>412,120</i>	<i>52,112</i>
SBA PPP loan	-	13,590
Convertible note, net	266,547	29,744
Deferred compensation	69,969	-
Put option liability	-	31,356
<i>Total noncurrent liabilities</i>	<i>336,516</i>	<i>74,690</i>
Total liabilities	748,636	126,802
STOCKHOLDERS' EQUITY		
Common stock	1,101	1,089
Common stock - NV	204	130
Additional paid-in capital	1,853,073	1,283,969
Subscription receivable	(3,819)	(13,400)
Accumulated deficit	(1,734,032)	(937,643)
Total stockholders' equity	116,527	334,145
Total liabilities and stockholders' equity	\$ 865,163	\$ 460,947

See accompanying notes to financial statements

SANMELIX LABORATORIES, INC.
STATEMENTS OF OPERATIONS

For Fiscal Year Ended December 31,	2021	2020
Net revenues	\$ 52,695	\$ -
Cost of sales	13,626	-
Gross Profit	39,069	-
Operating expenses		
General and administrative	455,342	260,546
Research and development	155,871	106,370
Sales and marketing	105,282	29,755
Total operating expenses	716,495	396,671
Operating income/(loss)	(677,426)	(396,671)
Interest expense	(137,553)	(11,091)
Other income/(loss)	18,590	3,583
Income/(Loss) before provision for income taxes	(796,389)	(404,179)
Provision/(Benefit) for income taxes	-	-
Net income/(loss)	\$ (796,389)	\$ (404,179)

See accompanying notes to financial statements.

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				
Balance—December 31, 2019	10,886,000	\$ 1,089	426,893	\$ 43	\$ 747,792	\$ (14,903)	\$ (533,464)	\$ 200,557
Net income/(loss)	-	-	-	-	-	-	(404,179)	(404,179)
Common stock issued for cash	-	-	848,748	85	491,895	-	-	491,980
Common stock subscribed	-	-	28,387	2	(1,503)	1,503	-	2
Stock compensation expense reclassified out of stock compensation expense	-	-	-	-	109,740	-	-	109,740
Put option liability					(12,099)			(12,099)
Offering costs	-	-	-	-	(144,422)	-	-	(144,422)
Fair value of warrants	-	-	-	-	35,905	-	-	35,905
Fair value of beneficial conversion feature	-	-	-	-	48,321	-	-	48,321
Fair value of services provided	-	-	-	-	8,340	-	-	8,340
Balance—December 31, 2020	10,886,000	\$ 1,089	1,304,028	\$ 130	\$ 1,283,969	\$ (13,400)	\$ (937,643)	\$ 334,145
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
Balance—December 31, 2021	11,012,923	\$ 1,101	2,042,748	\$ 204	\$ 1,853,073	\$ (3,819)	\$ (1,734,032)	\$ 116,527

See accompanying notes to financial statements

SANMELIX LABORATORIES, INC.

STATEMENTS OF CASH FLOWS

For Fiscal Year Ended December 31,	2021	2020
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	\$ (796,389)	\$ (404,179)
<i>Adjustments to reconcile net income to net cash provided/(used) by operating activities:</i>		
Depreciation of property	\$ 4,833	\$4,491
Amortization of intangibles	9,975	10,361
Fair value of services provided	675	8,340
Stock based compensation expense	71,815	109,740
Amortization of debt discount	104,623	11,001
Loss on modification of warrants	14,467	-
Write-off of abandoned intangible assets	-	18,886
PPP forgiveness other income - tax exempt	(13,500)	-
Deferred compensation	69,969	-
<i>Changes in operating assets and liabilities:</i>		
Accounts receivable	(1,590)	-
Inventory	(30,898)	(26,139)
Other current assets	-	(2,521)
Accounts payable and accrued expenses	(6,526)	26,626
Other current liabilities	30,794	8,326
Net cash used by operating activities	(541,752)	(235,068)
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of property and equipment	-	(10,351)
Purchases of intangible assets	(141,174)	(5,459)
Net cash used in investing activities	(141,174)	(15,810)
CASH FLOW FROM FINANCING ACTIVITIES		
Common stock issued for cash	474,966	491,980
Offering costs	(132,063)	(144,422)
Proceeds from exercised warrants	107,885	-
Proceeds received from SBA PPP loan	-	13,500
Proceeds received from convertible debt, net OID	307,500	102,969
Net cash provided by financing activities	758,288	464,027
Change in cash, cash equivalents, and restricted cash	75,362	213,149
Cash, cash equivalents, and restricted cash—beginning of year	264,467	51,318
Cash, cash equivalents, and restricted cash—end of year	\$ 339,829	\$ 264,467
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid during the year for interest	\$ -	\$ -
Cash paid during the year for income taxes	-	-

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

Unearned deferred compensation	\$	-	\$	675
Purchase of intangible in accounts payable		170,000		-
Subscription receivable		3,819		13,400
Warrants allocated as a discount to convertible debt		107,077		-
Removal of beneficial conversion feature		48,321		-
Put option liability		17,731		31,356

See accompanying notes to financial statements.

SANMELIX LABORATORIES, INC.

NOTES TO FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020

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 care and skin care product company focusing on the unique medicinal properties of buckwheat honey for tissue regeneration and accelerated healing. Our BEECure® bioactive buckwheat honey formulations demonstrate intrinsic healing activity with anti-microbial additives to prevent infection. 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, 2021 and 2020. 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, the USPTO not granting the Company's pending patents, 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 market clearance and of manufacturing and commercialization of its initial skin product. 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.

As of Year Ended December 31,	2021	2020
Cash and cash equivalents	\$ 320,900	\$ 229,008
Restricted cash	18,929	35,459
Total cash, cash equivalents and restricted cash	\$ 339,829	\$ 264,467

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, 2021 and 2020, the Company recorded \$1,590 and \$0, 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, 2021 and 2020. 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. There were no impairment losses during 2021 and 2020. There can be no assurance, however, that the patents will be issued, the market conditions will not change or demand for the Company's products and services will continue, which could result in impairment of long-lived assets in the future.

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 \$132,063 and \$144,422 for the year ended December 31, 2021 and 2020, 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, 2021, 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 \$1,590 receivable balance as of December 31, 2021, 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, 2021 and 2020.

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 is currently evaluating the impact of this new standard on its financial statements and related disclosures.

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 is currently evaluating the offer of this new standard and assess the relevance on its financial statements and related disclosures for the future.

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, 2021, and 2020, inventories consist of:

As of Year Ended December 31,	2021	2020
OTC RMelix products	\$ 55,571	\$ 26,139
AWC raw materials	1,466	-
Total	\$ 57,037	\$ 26,139

4. OTHER CURRENT ASSETS

As of December 31, 2021, and 2020, other current assets consist of:

As of Year Ended December 31,	2021	2020
Security deposit	\$ 2,521	\$ 2,521

The Company entered into a month-to-month lease office lease on November 15, 2020. As of December 31, 2021, the Company occupied the office and therefore the remaining security deposit totaled \$2,521. Note that the Company terminated this lease as of March 31, 2022.

5. PROPERTY AND EQUIPMENT

As of December 31, 2021, and 2020, property and equipment consist of:

As of Year Ended December 31,	2021	2020
Furniture and equipment	\$ 16,038	\$ 16,038
Less: accumulated depreciation	(12,167)	(7,334)
Property and equipment, net	\$ 3,871	\$ 8,704

Depreciation expense for property and equipment for the years ended December 31, 2021 and 2020 was approximately \$4,833 and \$4,491, respectively.

6. INTANGIBLE ASSETS

The components of intangible assets, net as of December 31, 2021 and 2020, consisted of the following;

As of Year Ended December 31,	2021	2020
Patents	\$ 173,147	\$ 168,380
Trademarks	8,311	1,904
Formulations	200,000	-
Non-compete covenant	62,500	-
Option to offset/purchase	37,500	-
Less: accumulated amortization	(21,143)	(11,168)
Intangible assets, net	\$ 460,315	\$ 159,116

Amortization expense was approximately \$9,975 and \$10,361 for the years ended December 31, 2021 and 2020, 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®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 noted in the table above: (1) Formulations, (2) Non-compete covenant, and (3) Option to offset/purchase.

As of December 31, 2021, the Company has paid \$130,000 based on the milestones reached which is included within the Formulations intangible asset class. The remaining amount of \$170,000 was accrued as of December 31, 2021 and recorded within the other current liabilities as the Company deems it reasonable that the remaining milestones may be achieved within the next year. As of December 31, 2021, the Company is still determining the final amortization period for the \$300,000 intangible assets as the manufacturing process of the Company's products has not yet been finalized.

The following is a rollforward of the Company's intangible assets and amortization for the year ended December 31, 2021;

	Assets	Accumulated Amortization
Balance at December 31, 2020	\$ 170,284	\$ (11,168)
Addition of new assets	311,174	-
Write-offs	-	-
Amortization	-	(9,975)
Balance at December 31, 2021	\$ 481,458	\$ (21,143)

The following table outlines future amortization expense as of December 31, 2021:

Period	Amortization Expense
2022	\$ 11,543
2023	11,543
2024	11,543
2025	11,543
2026	11,543
Thereafter	102,600
Total	\$ 160,315

As noted above, the amortization expense table does not include the \$300,000 intangible assets related to the manufacturing agreement as the final amortization period is still being determined as of December 31, 2021.

7. NOTES PAYABLE

Notes payable consist of the following;

Short term	December 31, 2021	December 31, 2020
Convertible note, net	\$ 116,563	\$ -

Long term	December 31, 2021	December 31, 2020
SBA PPP loan	\$ -	\$ 13,590
Convertible notes, net	266,547	29,744
Total long term debt, net	\$ 266,547	\$ 43,334

Details of notes payable as of December 31, 2021, are as follows;

	Principal Amount	Carrying Value	Interest Rate	Conversion Price	Maturity Date
Short term					
Convertible notes, net	\$ 125,000	\$ 116,563	9%	\$0.65	10/15/2022
Long term					
Convertible notes, net	\$ 375,000	\$ 266,547	9%	\$0.65	1/31/2023

SBA PPP Loan

As of December 2020, the Company received a loan from a Bank in the amount of \$13,500 plus \$90 of accrued interest under the Paycheck Protection Program established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The Company received formal approval of loan forgiveness in the full amount of \$13,500, plus accrued interest on February 4, 2021. The loan forgiven amount of \$13,500 was recorded as other income as of December 31, 2021.

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:

On October 15, 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. This convertible note matures on October 15, 2022; and, thus, is classified within the current maturities of long-term debt as of December 31, 2021.

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.

We estimated the fair value of the warrants on the issue date using a Black-Scholes pricing model with the following assumptions:

Warrants	
Expected term	5 years
Volatility	95%
Risk free rate	0.10% to 0.06%
Market price	\$ 0.60
Exercise price	\$ 1.40

The proceeds of the Notes issued in 2021 were allocated to the components as follows:

Proceeds allocated at issue date	
Convertible notes - debt	\$ 200,423
Convertible notes - warrants	107,077
Total	\$ 307,500

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. The Company additionally recognized \$8,692 of interest expense related to the warrant modification as of December 31, 2021.

In November and December 2021, another 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. The Company additionally recognized \$5,775 of interest expense related to the warrant modifications as of December 31, 2021.

The interest expense related to the Convertible Notes for the year ended December 31, 2021 was recognized as follows:

For Year Ended December 31, 2021		
Interest expense - OID	\$	42,938
Interest expense - BCF		(4,169)
Interest expense - Warrants		65,854
Total	\$	104,623

Note the Company eliminated the beneficial conversion feature from the 2021 financials in accordance with the early adoption of ASU 2020-06—see Note 2 for further details of the applicable ASU.

The remaining original issuance discount balance as of December 31, 2021 totaled \$44,250 and the expected annual amortization per year is as follows:

Period	Amortization Expense
2022	\$ 42,187
2023	2,063
Total	\$ 44,250

The remaining warrants discount balance as of December 31, 2021 totaled \$72,640 and the expected annual amortization per year is as follows;

Period	Amortization Expense
2022	\$ 69,370
2023	3,270
Total	\$ 72,640

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 2021, the Company issued 126,923 shares related to exercised warrants- refer to Note 7 for further discussion. As of December 31, 2021, and 2020, the Company has issued 11,012,923 and 10,886,000 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, 2020, the Company sold 877,135 shares of Class NV common stock through its Reg CF. The Company recognized gross proceeds of \$491,895 and had a subscription receivable of \$13,400 related to the sale of these shares as of December 31, 2020. In connection with this offering, the Company incurred offering costs of \$144,422, which reduced additional paid-in capital. The subscription receivable of \$13,400 was collected subsequent to December 31, 2020.

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.

As of December 31, 2021, and 2020, the Company has 2,042,748 and 1,304,028 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, 2021, 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. Note that fair value was determined based on the most recent common stock offering of \$0.50 per share. Therefore, the stock-based compensation was recognized over the service period at \$0.50 per share and was recorded within research and development expense within the statement of operations which totaled \$675 and \$8,340 for the years ended December 31, 2021 and 2020, respectively.

During the year ended December 31, 2020, \$8,340 of the Unearned-Deferred Compensation was recognized as consulting expense. The remaining Unearned-Deferred Compensation included in the additional paid-in-capital balance totaled \$675 as of December 31, 2020. Additionally, 48,650 shares of common stock were vested as of December 31, 2020.

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, 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, 2021. A summary of our stock option activity for the year ended December 31, 2021, is as follows:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life (years)
Outstanding at December 31, 2020	1,325,000	\$ 0.60	6.00
Granted	235,000	\$ 0.60	-
Exercised	-	-	-
Forfeited or expired	-	-	-
Outstanding at December 31, 2021	1,560,000	\$ 0.60	5.40
Exercisable at December 31, 2021	334,166	\$ 0.59	6.01

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,	2021	2020
Expected term	5.5 years	4.5 years
Volatility	95%	95%
Risk free rate	0.07%	0.15%
Market price	\$ 0.60	\$ 0.60
Exercise price	\$ 0.60	\$ 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 \$0.60 per share, as defined within the agreement. 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 \$31,356 as of December 31, 2021 and 2020, respectively.

The Company recognized stock option- stock compensation costs in the amount of \$71,815 and \$109,740 for the year ended December 31, 2021 and 2020, 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, 2021.

The remaining stock compensation balance to be expensed in future years as of December 31, 2021 totaled \$27,520 and the expected annual expense per year is as follows;

Period	Stock Compensation Expense
2022	\$ 23,040
2023	2,240
2024	2,240
Total	\$ 27,520

9. INCOME TAXES

The provision for income taxes for the year ended December 31, 2021 and 2020 consists of the following:

As of Year Ended December 31,	2021	2020
Current tax provision:		
Federal	\$ -	\$ -
State	-	-
Total	\$ -	\$ -
Deferred tax provision:		
Federal	\$ 142,638	\$ 80,421
State	32,929	19,272
Total	\$ 175,567	\$ 99,693
Valuation allowance	(175,567)	(99,693)
Total provision for income taxes	\$ -	\$ -

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2021, and December 31, 2020 are as follows:

As of Year Ended December 31,	2021	2020
Stock options expense	\$ 61,979	\$ 43,595
Organizational costs	4,507	4,507
Charitable contribution	177	177
Net operating loss carryforwards	334,944	177,761
Valuation allowance	(401,607)	(226,040)
Net deferred tax asset (liability)	\$ -	\$ -

Reconciliation between statutory income tax rate and the Company's effective income tax provision (benefit) rate for the years ended December 31, 2021 and 2020 as follows:

As of Year Ended December 31,	2021	%	2020	%
Income tax at federal statutory rate	\$ (167,242)	21%	\$ (84,878)	21%
State taxes, net of federal benefit	(28,931)	4%	(15,309)	4%
Nondeductible stock options expense	18,384	-2%	28,302	-7%
Nondeductible organizational costs	-	0%	4,507	-1%
Nondeductible charitable contribution	-	0%	-	0%
Permanent differences	20,606	-3%	494	0%
NOL carryforward	157,183	-20%	66,884	-17%
Income tax provision (benefit)	\$ -	0%	\$ -	0%

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, 2021 and 2020. 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, 2021, we had available approximately \$1,383,158 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, 2021 and 2020, 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, 2021 and 2020, 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, 2021 and 2020, 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, 2021 and 2020, 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 reached cumulative 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 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. The net salary amount of \$69,469 is recorded as deferred compensation on the Balance Sheet as of December 31, 2021. See Note 8 for further information on Reg CF 2.

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 \$1,734,032 and \$937,643 as of December 31, 2021 and 2020, 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, 2021, the Company extended another consulting agreement resulting in continuance of the consulting services of the related board member. Based on this extension amendment, the related put option will be converted to stock options and the agreement removed such put option for future vesting milestones.

Subsequent to December 31, 2021, the Company continued to sell 4,324 shares of Class NV common stock through its Reg CF 2. The Reg CF 2 ended in January 2022. The Company recognized gross proceeds of \$5,994 and \$596 was held in escrow related to the sale of these shares as January 31, 2022. No additional offering costs in connection with this offering were incurred subsequent to December 31, 2021.

Subsequent to December 31, 2021, the Company terminated one of its consulting agreements resulting in a resignation of the related board member.

The Company has evaluated subsequent events that occurred after December 31, 2021 through April 29, 2022, 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.