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

FORM 10-K

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

For the fiscal year ended December 31, 2021
OR

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

For the transition period from _____ to _____

Commission File Number 001-39678

SANARA MEDTECH INC.
(Exact name of Registrant as specified in its charter)

Texas	59-2219994
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1200 Summit Ave, Suite 414, Fort Worth, Texas 76102
(Address of principal executive offices)

(817) 529-2300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SMTI	The Nasdaq Capital Market

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

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

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

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

Large accelerated filer	☐ Accelerated filer	☐
Non-accelerated filer	☒ Smaller reporting company	☒
	Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2021 based on the $36.95 closing price as of such date was approximately $113,199,429.

As of March 30, 2022, 7,813,738 shares of the Issuer's common stock, $0.001 par value per share were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Annual Report on Form 10-K, to the extent not set forth herein, is incorporated by reference to the registrant's Definitive Proxy Statement on Schedule 14A relating to the 2022 Annual Meeting of Shareholders which will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

SANARA MEDTECH INC.
Form 10-K
For the Year Ended December 31, 2021

Unless otherwise indicated, "Sanara," "we," "us," "our," and "the Company," refer to Sanara MedTech Inc. and its consolidated subsidiaries.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the federal securities laws. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "anticipates," "believes," "continue," "contemplates," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "target," "will" or "would" or the negative of these words, variations of these words or other similar terms or expressions that concern our expectations, strategy, plans, or intentions. Such forward-looking statements are subject to certain risks, uncertainties and assumptions relating to factors that could cause actual results to differ materially from those anticipated in such statements, including, without limitation, the following:

- the impact of the COVID-19 pandemic on our business, financial condition and results of operations;
- shortfalls in forecasted revenue growth;
- our ability to implement our comprehensive wound and skin care strategy through acquisitions and investments and our ability to realize the anticipated benefits of such acquisitions and investments;
- our ability to meet our future capital requirements;
- our ability to retain and recruit key personnel;
- the intense competition in the markets in which we operate and our ability to compete within our markets;
- the failure of our products to obtain market acceptance;
- the effect of security breaches and other disruptions;
- our ability to maintain effective internal controls over financial reporting;
- our ability to develop and commercialize new products and products under development, including the manufacturing, distribution, marketing and sale of such products;
- our ability to maintain and further grow clinical acceptance and adoption of our products;
- the impact of competitors inventing products that are superior to ours;
- disruptions of, or changes in, our distribution model, consumer base or the supply of our products;
- our ability to manage product inventory in an effective and efficient manner;
- the failure of third-party assessments to demonstrate desired outcomes in proposed endpoints;
- our ability to successfully expand into wound and skin care virtual consult and other services;
- our ability and the ability of our research and development partners to protect the proprietary rights to technologies used in certain of our products and the impact of any claim that we have infringed on intellectual property rights of others;
- our dependence on technologies and products that we license from third parties;
- the effects of current and future laws, rules, regulations and reimbursement policies relating the labeling, marketing and sale of our products and our planned expansion into wound and skin care virtual consult and other services and our ability to comply with the various laws, rules and regulations applicable to our business; and
- the effect of defects, failures or quality issues associated with our products.

All forward-looking statements speak only as of the date on which they are made. For a more detailed discussion of these and other factors that may affect our business, see the discussion in "Item 1A. Risk Factors" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report. We caution that the foregoing list of factors is not exclusive, and new factors may emerge, or changes to the foregoing factors may occur, that could impact our business. We do not undertake any obligation to update any forward-looking statement, whether written or oral, relating to the matters discussed in this report, except to the extent required by applicable securities laws.

PART I

Item 1. BUSINESS

Overview

We are a medical technology company focused on developing and commercializing transformative technologies to improve clinical outcomes and reduce healthcare expenditures in the surgical and chronic wound and skin care markets. Our portfolio of products, services and technologies is anticipated to allow us to deliver comprehensive wound and skin care solutions for patients in all care settings, including acute (hospitals and long-term acute care hospitals ("LTACHs")) and post-acute (wound care clinics, physician offices, skilled nursing facilities ("SNFs"), home health, hospice, and retail). Each of our products, services, and technologies contribute to our overall goal of achieving better clinical outcomes at a lower overall cost for patients regardless of where they receive care. We strive to be one of the most innovative and comprehensive providers of effective wound and skin care solutions and are continually seeking to expand our offerings for patients requiring wound and skin care treatments across the entire continuum of care in the United States.

We currently market several products across surgical and chronic wound care applications and have multiple products in our pipeline. We currently license our products from Applied Nutritionals, LLC ("AN") (through a sublicense with CGI Cellerate RX, LLC ("CGI Cellerate RX"), an affiliate of The Catalyst Group, Inc. ("Catalyst")) and Rochal Industries, LLC ("Rochal"), and have the right to exclusively distribute certain products manufactured by Cook Biotech Inc. ("Cook Biotech"). We are also developing additional products in our own product pipeline.

In June 2020, we formed a subsidiary, United Wound and Skin Solutions LLC ("UWSS", or "WounDerm"), to hold certain investments and operations in wound and skin care virtual consult services. We anticipate that these various service offerings will allow clinicians/physicians utilizing our technologies to collect and analyze large amounts of data on patient conditions and outcomes that will improve treatment protocols and ultimately lead to more evidence-based formulary to improve patient outcomes. Through a combination of our WounDerm services and our Sanara products, we believe we will be able to offer patient care solutions at every step in the continuum of wound and skin care, from diagnosis through healing.

Effective July 1, 2021, we acquired certain assets from Rochal, including, among others, intellectual property, four FDA 510(k) clearances, rights to license certain products and technologies currently under development, equipment and supplies. As a result of the asset purchase, our pipeline now contains product candidates for mitigation of opportunistic pathogens and biofilm, wound re-epithelialization and closure, necrotic tissue debridement and cell compatible substrates.

Market Scale

A study by a physician at the Department of Surgery for the Indiana University Health Comprehensive Wound Center found that approximately 8.2 million patients suffer from surgical and chronic wounds each year in the United States. Furthermore, according to an article published by the *American College of Surgeons and Surgical Infection Society*, in the United States, the annual treatment cost projections for all wounds is approximately $28 billion with the estimated annual cost of surgical site infections ranging from $3.5 billion to $10 billion. The U.S. teledermatology market alone is estimated to grow from $5 billion in 2019 to $45 billion by 2027 according to a research report by Fortune Business Insights. In addition to our surgical wound and chronic wound products, we are planning to fully launch virtual consult services through WounDerm for both virtual wound and virtual skin (dermatology) consultations.

Summary of our Product & Service Offerings and Development Programs

We are committed to developing and commercializing innovative products that address the challenges physicians face in diagnosing and treating wound and skin care ailments.

Our surgical wound care products, CellerateRX Surgical Activated Collagen (Powder and Gel) (collectively, "CellerateRX Surgical"), are used in a wide range of surgical specialties to help promote patient healing and reduce the risk of complications. The product is used in specialties including cardiothoracic, colorectal, general surgery, hand, head and neck, high-risk obstetrics and gynecology, Mohs surgery, neurosurgery, oncology, orthopedic (hip and knee, sports, spine, joint, foot and ankle, ortho trauma and ortho oncology), plastic/reconstructive, podiatric, urology, and vascular. Currently, substantially all of our revenue is derived from the sale of surgical wound care products. We anticipate that chronic wound care products and WounDerm technology-based services will become meaningful drivers of revenue in the future.

Our chronic wound care products, HYCOL Hydrolyzed Collagen (Powder and Gel) (collectively, "HYCOL"), BIAKŌS Skin and Wound Cleanser ("BIAKŌS AWC") and BIAKŌS Skin and Wound Gel, are used across the post-acute continuum of care, including home health, hospice, physician offices, podiatrists, retail, SNFs, and wound care centers. Our chronic wound care products can be used on stage I-IV pressure ulcers, diabetic foot ulcers ("DFUs"), venous stasis, arterial, post-surgical wounds, first- and second-degree burns and donor sites. BIAKŌS AWC is also available in an irrigation bottle (BIAKŌS Antimicrobial Skin and Wound Irrigation Solution) that can be used in conjunction with negative pressure wound therapy installation and dwell ("NPWTi-d") and other wound irrigation needs.

In addition, we expect to fully commercialize three products with Cook Biotech in 2022. The first two, FORTIFY TRG Tissue Repair Graft and FORTIFY FLOWABLE Extracellular Matrix, are currently 510(k) cleared for use in the surgical wound care segment, and VIM Amnion Matrix is categorized by the U.S. Food and Drug Administration ("FDA") as an HCT/P, subject to regulation under Section 361 of the Public Health Service Act ("PHSA") (for which no premarket approval or clearance is required).

In addition, we have a robust pipeline of products under development for the chronic wound care, surgical wound care, and virtual consult markets. We believe our pipeline efforts will deepen our comprehensive portfolio of offerings as well as allow us to address additional clinical applications. Wound care products in our pipeline include an antimicrobial skin protectant, a debrider product that leverages the body's own enzymes and moisture, next generation CellerateRX and HYCOL, and a sterile BIAKŌS product for use in surgical settings.

The WounDerm technology-based services include an electronic medical record ("EMR") software platform for both wound and skin conditions, skin and wound virtual consult services (through Direct Dermatology Inc. ("DirectDerm") and MGroup Integrated Physician Services, P.A. ("MGroup")), and diagnostic products and services for chronic wounds (through Precision Healing Inc. ("Precision Healing")). Once WounDerm's service offerings are fully integrated, we expect to be able to provide wound treatment solutions for patients across the entire acute and post-acute continuum of care.

Strategy

- ***Drive additional market penetration as well as geographic expansion for our products.*** We intend to leverage our comprehensive product and technology-based services portfolio and relationships with key constituents to deepen our presence in the surgical and chronic wound and skin care markets. We believe the breadth and flexibility of the products we offer allow us to address a wide variety of wound types and sizes and offer significant new opportunities for sales growth. In addition, we believe that as we continue to offer new products and technology-based services, our salesforce's ability to reach additional customers in new and existing geographic regions while penetrating further in existing customer accounts will be enhanced.

- ***Expand into new markets for our products and services.*** In 2020 and 2021, we made significant investments in virtual consult technologies and services. The COVID-19 pandemic has dramatically increased demand for these services with expanded reimbursements and patients being more comfortable seeing their care provider virtually. We believe that the virtual consult technologies and services that we will offer, when combined with our innovative and highly efficacious products, will offer a differentiated comprehensive wound and skin care solution for patients and care givers.

- ***Launch new innovative products.*** We are internally developing, and actively working with third-party research and development partners to develop additional proprietary products for the surgical and chronic wound and skin care markets. We expect these products and services to deepen our portfolio of technologies to treat chronic wounds as well as improve surgical site outcomes. We are focused on offering additional products and services that are more efficacious than competing products and services and provide a stronger value proposition (lower total cost to heal and less time to heal, leading to reduced costs to the healthcare system).

- ***Capture patients throughout the entire continuum of care.*** We intend to continue expanding our platform to aid in treating wound and skin care patients as they progress through the healing process in all care settings. As discussed above, in June 2020, we formed a subsidiary, UWSS, to hold certain investments in technologies and operations in wound and skin care virtual consult services. We believe our service offerings will allow us to collect and analyze large amounts of data on patient conditions and outcomes that will improve treatment protocols and ultimately lead to more evidence-based healing formularies to improve outcomes in the future. We anticipate that this data will also enable us to participate in the creation of new standards of care that promote patient compliance and enable direct dialogue between patients, clinicians and payors, resulting in greater satisfaction for patients, their caregivers, clinicians and payors.

- ***Seek and establish partnerships and product, technology, and/or services acquisitions.*** We plan to continue to seek and establish partnerships in the United States and internationally to provide innovative products, services, and technologies. We believe that partnerships will be a key driver of our growth in the future. We also intend to selectively pursue acquisitions of businesses and technologies that complement our existing strategy and footprint.

Competitive Strengths

- ***Comprehensive solution for improved wound care outcomes.*** We are dedicated to offering a comprehensive portfolio of products and services to improve wound care treatment outcomes. We are currently developing the capability to provide telehealth services for the diagnosis and treatment of wound and skin care patients. During the fourth quarter of 2021, we conducted a pilot program with a large home health agency. The pilot program realized positive results and will expand to include the service offering to six more agencies in the first quarter of 2022. Our product offerings are able to disinfect wounds and accelerate the body's healing process for acute and chronic wounds and allow clinicians to provide a consistent plan of care for a patient from diagnosis through treatment.

- ***Wound care products for all care settings.*** Our wound care product portfolio allows clinicians to personalize solutions to meet the needs of individual wound care patients in all care settings including acute (hospitals and LTACHs) and post-acute (wound care clinics, physician offices, SNFs, home health, hospice, and retail).

- ***Innovative pipeline and proven clinical performance.*** We have a robust pipeline of surgical and chronic wound and skin care products that we expect to market in the near term. We believe the efficacy of our offerings, will be proven via statistically significant collected and analyzed clinical and health economic outcomes data, resulting in expanded adoption of our products at a lower overall cost to payors.

- ***Attractive markets for acute and chronic wound care.*** We believe the acute and chronic wound care markets will continue to see accelerated growth given favorable global tailwinds that include an aging population, increasing costs of health care, recognition of difficult-to-treat infection threats such as biofilms, and the increasing prevalence of diabetes and obesity. We believe there will be growing adoption of our products due to their clinical efficacy and cost effectiveness for all key constituents compared to traditional wound care products.

- ***Proven executive leadership team with a long-term track record of value creation.*** We are led by a dedicated and seasoned management team with significant industry experience who have successfully executed our strategic implementation to date by launching new products and technologies through investment in new areas of growth. We believe our management has the vision and experience to implement our future growth strategy.

Market Opportunities for our Products and Technology-Based Services

In October 2019, Centers for Medicare & Medicaid Services' ("CMS") reimbursement methodology for home health agencies and SNFs (Patient Driven Group Model and Patient Driven Payment Model, respectively) created unique opportunities to provide efficacious wound healing inside of those sites of care in unprecedented fashion. With those payment models now focused on a patient's characteristics (including number of wounds and skin conditions) rather than the volume of services provided, greater remuneration is provided to home health agencies and SNFs for the treatment of wound care patients. As a result, the incentive to transfer patients with both acute and chronic wounds to more burdensome and costly care settings, such as inpatient or outpatient wound-care centers, has been discouraged or, in some cases, eliminated. This shift in vertical economics provides us with a unique opportunity, in adjunctive fashion with home health agencies and SNFs, to deliver highly technical and comprehensive wound care where this most vulnerable patient population resides thus achieving CMS's desired results: better patient outcomes at a lower total cost of care.

Chronic and Other Hard-to-Heal Wounds

According to a study published by the *Value in Health* journal, roughly 15% of the Medicare beneficiary population has chronic nonhealing wounds. Chronic wounds do not advance through the phases of healing in a normal progression and do not show significant progress toward healing in 30 days. Factors contributing to the chronicity of the wound may include pressure / friction, trauma; insufficient blood flow and oxygenation in locations such as the lower extremities; increased bacterial load; excessive proteases; degraded growth factors; matrix metalloproteinases ("MMPs"); senescent / aberrant cells; or inappropriate treatment. Examples of chronic wounds include DFUs, venous leg ulcers ("VLUs"), arterial ulcers, pressure ulcers and hard-to-heal surgical/traumatic wounds. In each of the various wound types, the presence of biofilms is a frequent cause for chronification of wounds and the removal of biofilms is a crucial step to commence healing. Biofilms need to be eradicated to prevent further deterioration of the wound that may result in additional negative patient outcomes. If not effectively treated, these wounds can lead to potentially severe complications, including further infection, osteomyelitis, fasciitis, amputation and increased mortality. Chronic wounds are primarily seen in the elderly population. For example, a 2019 study published in *Advances in Wound Care* reported that in the United States, 3% of the population over the age of 65 had open wounds. According to the same study, in 2020, the U.S. government estimated that the elderly population totaled 55 million people, suggesting that chronic wounds will continue to be an increasingly persistent problem in this population. Four common chronic and other hard-to-heal wounds are:

- *Diabetic Foot Ulcers.* Diabetes can lead to a reduction in blood flow, which can cause patients to lose sensation in their feet and may prevent them from noticing injuries, sometimes leading to the development of DFUs, which are open sores or ulcers on the feet that may take several weeks to heal, if ever. According to the 2020 National Diabetes Statistics Report by the Center for Disease Control and Prevention, in the United States alone, over 34 million people, or approximately 10% of the population, suffer from diabetes, a chronic, life-threatening disease.

- *Venous Leg Ulcers.* VLUs develop as a result of vascular insufficiency, or the inability for the vasculature of the leg to return blood back toward the heart properly and, according to a 2013 report published by the *International Journal of Tissue Repair and Regeneration*, VLUs affect approximately 600,000 people per year in the United States alone. These ulcers usually form on the sides of the lower leg, above the ankle and below the calf, and are slow to heal and often recur if preventative steps are not taken. The risk of venous ulcers can be increased as a result of a blood clot forming in the deep veins of the legs, obesity, smoking, lack of physical activity or work that requires many hours of standing.

- *Pressure Ulcers.* Pressure ulcers, also known as decubitus ulcers or bed sores, are injuries to skin and underlying tissue resulting from prolonged pressure, or pressure in combination with shear or friction. Constant pressure on an area of skin reduces blood supply to the area and over time can cause the skin to break down and form an open ulcer. These often occur in patients who are hospitalized or confined to a chair or bed and most often form on the skin over bony areas, where there is little cushion between the bone and the skin, such as heels, ankles, hips and the tailbone. Annually, 2.5 million pressure ulcers are treated in the United States in acute care facilities alone, according to a 2006 study published in the *Journal of the American Medical Association*.

- *Surgical/traumatic wounds.* Surgical wounds form as a result of various types of surgical procedures such as investigative or corrective, minor or major, open (traditional) or minimal access surgery, elective or emergency, and incisions (simple cuts) or excision (removal of tissue), among others. Traumatic wounds form as a result of cuts, lacerations or puncture wounds, which have caused damage to the skin and underlying tissue. Severe traumatic wounds may require surgical intervention to close the wound and stabilize the patient. Surgical/traumatic hard-to-heal wounds develop for various reasons, such as local surgical complications, suboptimal closure techniques, presence of foreign materials, exposed bones or tendons and infection. In the United States, millions of people receive post-surgical wound care annually, and the typical operative patient has comorbidities that create challenges with post-operative wound healing.

Sanara Products

We market, develop and distribute wound and skin care products and services to physicians, hospitals, clinics, and post-acute care settings. Our products are primarily sold in the U.S. surgical tissue repair and advanced wound care markets. We are actively seeking to expand within our six focus areas of wound and skin care for the surgical, acute, and post-acute markets: (1) debridement, (2) biofilm removal, (3) hydrolyzed collagen, (4) advanced biologics, (5) negative pressure wound therapy products and (6) the oxygen delivery system segment of the wound and skin care market.

CellerateRX Surgical is a medical hydrolysate of Type I bovine collagen indicated for the management of surgical, traumatic, and partial- and full-thickness wounds as well as first- and second-degree burns. It is manufactured in what we believe to be a trade secret process and the powder is further processed for use in a sterile, surgical environment. The gel is typically applied post-operatively. CellerateRX Surgical products are primarily purchased by hospitals and ambulatory surgical centers for use by surgeons on surgical wounds. The predominance of CellerateRX Surgical is used in foot and ankle, neuro/spinal, orthopedic/hip and knee replacement, ortho trauma, and ortho oncology surgeries. Additional specialties benefiting from the use of CellerateRX Surgical include cardiothoracic, colorectal, general, general trauma, gynecologic oncology, hand, head and neck, Mohs, obstetrics and gynecology (including caesarean deliveries), plastic/reconstructive, urologic, and vascular.

CellerateRX Surgical is used in operative cases where patients might have trouble healing normally due to underlying health complications. There is always a risk of complication with surgical incisions. This is especially true in patients with certain comorbidities, including obesity, diabetes and hypertension. These complications can include surgical site infections, dehiscence (where an incision opens after primary closure) and necrosis. Surgeons use CellerateRX Surgical to complement the body's normal healing process. By helping the body heal normally without complications, improved patient outcomes are achieved, thereby reducing downstream costs related to complications (such as re-operation, longer hospitalization, re-admittance, extended rehabilitative care and other additional treatments). Wound infections have become increasingly problematic due to the high rates of surgical patient comorbidities and the financial strain on insurance carriers as well as hospitals who suffer exorbitant costs for readmission of these patients within 30 days of surgery.

In a prospective study published by SciMedCentral in 2017, of 102 consecutive neurosurgery cases in which a mixture of 5 grams of CellerateRX Surgical powder and 1 gram Vancomycin powder was applied at closure, there were no cases of wound dehiscence, infection, complication or allergic reaction to the product. This compares to neurosurgery infection rates ranging from as high as 24% for cranioplasty surgery to 6.3% for spine surgery patients. Two similar retrospective studies are underway using CellerateRX powder in ortho/spine surgeries and general/colorectal surgeries.

In a retrospective study published by SciMed Central in November 2021, a retrospective review was conducted of 154 patients who underwent spinal surgery using CellerateRX® Surgical powder. A total of three (representing 1.9%) high-risk patients developed postoperative wound complications (SSI or dehiscence). All complications resolved with local wound care and oral antibiotics; no hospital readmissions were required. This low incidence of surgical complications further supports the use of type 1 hydrolyzed collagen as an effective wound therapy agent in spinal surgery.

HYCOL Hydrolyzed Collagen products are a medical hydrolysate of Type I bovine collagen intended for the management of full and partial thickness wounds including pressure ulcers, venous and arterial leg ulcers and DFUs. HYCOL is primarily used in SNFs, wound care centers and physician offices and is currently approved for reimbursement under Medicare Part B. HYCOL provides the benefit of hydrolyzed collagen fragments directly in the wound bed. Therefore, unlike with the body's own native collagen or native collagen products, the body does not have to break HYCOL down before use, which is extremely beneficial when treating elderly and otherwise compromised patients with comorbidities such as diabetes and cardiovascular disease.

We believe our CellerateRX and HYCOL products are unique in composition, superior to other products in clinical performance, demonstrate the ability to reduce costs associated with the standards of care for their intended uses and have been safely used on over seventy-five thousand patients.

BIAKŌS AWC is an FDA 510(k) cleared, patented product that laboratory tests show effectively disrupts extracellular polymeric substances to eradicate mature biofilm microbes. BIAKŌS AWC is indicated for the mechanical removal of debris, dirt, foreign materials, and microorganisms from wounds including stage I-IV pressure ulcers, DFUs, post-surgical wounds, first and second-degree burns as well as grafted and donor sites. BIAKŌS AWC is effective in killing free-floating microbes, immature, and mature bacterial biofilms and fungal biofilms within the product. In addition, safety studies demonstrated that BIAKŌS AWC is biocompatible and supports the wound healing process. Initial sales of BIAKŌS AWC occurred in July 2019.

BIAKŌS AWC is also available in an irrigation bottle (BIAKŌS Antimicrobial Skin and Wound Irrigation Solution) that can be used in conjunction with NPWTi-d and other wound irrigation needs.

BIAKŌS Antimicrobial Wound Gel is an antimicrobial hydrogel wound dressing that can be used alone or in combination with BIAKŌS AWC. In February 2020, we received notification of FDA 510(k) clearance for BIAKŌS Antimicrobial Wound Gel and launched the product in November 2020 to complement BIAKŌS AWC.

BIAKŌS AWC and BIAKŌS Antimicrobial Wound Gel are effective against planktonic microbes as well as immature and mature biofilms within the product. When used together, the cleanser can be used initially to clean a wound and disrupt biofilms (removing 99% in 10 minutes). The gel can then be applied and remains in the wound for up to 72 hours helping to continue disrupting biofilm microbes. In a study conducted in 2020, BIAKŌS Antimicrobial Wound Gel, in combination with BIAKŌS AWC, was compared to a number of wound cleansers to treat chronic wounds such as pressure, diabetic, and venous ulcers in the inflammatory phase of wound healing. The BIAKŌS system reduced the biofilm burden by 7.5 logs (>99.99% reduction) by the 24-hour time point and eradicated it by the 48-hour time point while the remaining commercial controls reduced the Methicillin-resistant Staphylococcus aureus (“MRSA”) biofilms by less than 1 log.

FORTIFY TRG Tissue Repair Graft is a freeze-dried, multi-layer small intestinal submucosa (SIS) extracellular matrix (ECM) sheet. The graft is used for implantation to reinforce soft tissue, has a thin profile, is available in multiple sizes, and can be cut to size to accommodate the patient’s anatomy. FORTIFY TRG Tissue Repair Graft is provided sterile and can be hydrated with autologous blood fluid. It is an FDA 510(k) cleared product and terminally sterilized. First sales of this product occurred in the fourth quarter of 2021.

FORTIFY FLOWABLE Extracellular Matrix is an advanced wound care device that presents the SIS ECM technology in a way that can fill irregular wound shapes and depths. FORTIFY FLOWABLE Extracellular Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. FORTIFY FLOWABLE Extracellular Matrix is provided sterile and is intended for one-time use. It is a 510(k) cleared product. We began selling this product in early 2022.

VIM Amnion Matrix is a single layer sheet of amnion tissue that is minimally processed to decellularize the material while maintaining the structure and components of the extracellular matrix environment. All tissues are collected from consenting donors, tested for infectious diseases, and determined eligible for transplantation by a licensed Medical Director. It is provided in multiple sizes and terminally sterilized. The VIM Amnion Matrix is intended for homologous use as a wound covering or barrier in surgical, orthopedic, ophthalmic, and wound applications. It is air-dried for off-the-shelf room temperature storage with no product preparation. The graft is supplied sterile and is intended for one-time use in a single patient. We expect to begin selling the VIM product in 2022.

Beginning in early 2022, we began co-promoting the following products with Scendia Biologics, LLC: (i) TEXAGEN Amniotic Membrane Allograft, a multi-layer amniotic membrane allograft used as an anatomical barrier with robust handling that can be sutured if needed, (ii) BiFORM Bioactive Moldable Matrix, an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site, (iii) AMPLIFY Verified Inductive Bone Matrix, a 100% human allograft bone with conformable handling properties, and (iv) ALLOCYTE Advanced Cellular Bone Matrix, a human allograft cellular bone matrix (CBM) containing bone-derived progenitor cells and conformable bone fibers.

Sanara Technology-Based Services

We are currently developing the capability to offer various services addressing chronic wound and skin care through our subsidiary WounDerm, which has exclusive affiliations with three companies, which include DirectDerm, MGroup, and Precision Healing.

We anticipate that our various service offerings will allow us to collect large amounts of data on patient conditions and outcomes that will improve treatment protocols and ultimately lead to more evidence-based treatments to improve outcomes in the future. We believe our planned service offerings through WounDerm are complemented by our existing product portfolio to complete the comprehensive wound strategy.

WounDerm plans to offer the following services:

- ***EMR software platform for both wound and skin conditions***

  In 2020, we made a minority investment in Woundyne Medical, LLC ("Woundyne") to fund further development of Woundyne's imagery and data sharing platform designed to meet our specified virtual environment. In January 2021, we acquired the remaining interest of Woundyne. In June 2021, we invested in Canada-based Pixalere Healthcare, Inc. ("Pixalere"). In connection with this investment, Pixalere granted Pixalere Healthcare USA, LLC ("Pixalere USA"), our subsidiary, a royalty-free exclusive license to use the Pixalere software and platform in the United States. Pixalere provides a cloud-based wound care software tool that empowers nurses, specialists and administrators to deliver better care for patients. Pixalere developed a software system that combines the documentation functionality of wound care and dermatology EMRs with a Health Insurance Portability and Accountability Act of 1996 ("HIPAA")-secure online mobile application platform for provider and caregiver collaboration and the ability to perform virtual consultations via telemedicine. The software includes a complete wound and skin care specialty specific collaboration platform that allows for interoperability with client facing EMRs, reduce the burden of duplicate documentation, and improve the accuracy of assessments and treatment plans. We expect to have the EMR platform commercially available in mid-2022. Additionally, the collaboration platform is expected to integrate with the Precision Healing diagnostic imaging technology to gather images and clinical information. We anticipate that the proprietary software will provide for the correction of inaccurate initial measurements performed by caregivers, as well as adjustments for light and photo quality. We plan to have the Precision Healing technology integration complete and commercially available within our EMR platform in 2023.

- ***Virtual consultation services for both wound and skin care conditions***

  DirectDerm is a telemedicine company based in Palo Alto, California and has an exclusive network of dermatologists licensed across 32 states who have trained and/or teach at top U.S. medical institutions, and whose service is covered by many of the major health plans in the United States. WounDerm is working to integrate the DirectDerm platform into its collaboration platform to provide virtual consultations through DirectDerm's network of board-certified dermatologists to patients in all of WounDerm's healthcare markets.

  MGroup is a physician-owned and physician-led multispecialty wound care group focused on utilizing telehealth and associated technologies to build high-quality, cost-effective care delivery systems. MGroup currently holds active medical licenses in all 50 states. Our affiliation with MGroup will provide us with the ability to offer wound care telehealth services.

  During the fourth quarter of 2021, we conducted a pilot program with a large home health agency. The pilot program realized positive results and will expand to include the service offering to six more agencies in the first quarter of 2022.

- ***Diagnostic products and services for chronic wounds***

  The Precision Healing product platform is a diagnostic imaging and smart pad for assessing a patient's wound and skin conditions. This comprehensive skin and wound assessment technology is designed to quantify biochemical markers to determine the trajectory of a wound's condition to enable better diagnosis and treatment protocol. Precision Healing was formed by executives and imaging specialists at Lumicell Corporation as well as experienced wound care scientists and physicians. Precision Healing expects to have its imaging device and smart pad commercially available in 2023 and is currently being integrated into the WounDerm EMR.

Sales and Marketing

As of December 31, 2021, we employed thirty regional sales managers ("RSMs"). Our RSMs are recruited based on their previous industry experience and professional performance and are required to have a minimum of three years of experience successfully selling into similar markets. We constantly evaluate new markets and sales opportunities to add to our sales teams as warranted.

RSMs are initially trained through an internal learning management system, SanaraU, which gives them further product and surgical specialty training including wound etiology, operating room etiquette and credentialing requirements. After completing their internal training, new hire RSMs participate in field training with experienced RSM field trainers to get insights into best practice as well as real world training. The initial training period lasts approximately five weeks. RSMs are supported by regular updated training modules on product information and best practices.

A key component of our sales and marketing efforts involves working with physicians and clinicians to champion our products in their facilities. We work closely with surgeons and health system stakeholders to demonstrate the efficacy and beneficial impact of our surgical products and successfully navigate the hospital value analysis committee, (more commonly known as the "VAC"), approval process, allowing our products to be sold in those facilities. Similarly, we work with clinicians to demonstrate the efficacy of our wound care products in their respective care settings. If our sales and marketing efforts are successful, the clinicians then advocate for the use of our products when medically necessary.

Manufacturing, Supply, and Production

We do not own or operate and do not intend to establish our own manufacturing facilities. We rely on, and plan to continue relying on, contract manufacturing for our products. Our contract manufacturing strategy is intended to drive cost leverage and scale and avoid the high capital outlays and fixed costs associated with constructing and operating manufacturing facilities. Our manufacturing partners have internal compliance processes to maintain the high quality and reliability of our products. We believe our contract manufacturers are well-positioned to support future expansion of our product sales. We do source some packaging and marketing materials separate from our licensing partners.

Reimbursement, Clinical Validation, and Clinical Utility

We do not promote our products based on their reimbursement status, however we are mindful of the benefits of a favorable reimbursement coverage status to increase patient access and support our research and development efforts to supply the highest efficacy solutions.

Three of our chronic wound care products (BIAKŌS Antimicrobial Skin and Wound Gel, HYCOL Hydrolyzed Collagen Powder, and HYCOL Hydrolyzed Collagen Gel) have HCPCS A codes and are eligible for reimbursement through Medicare Part B. There is currently no reimbursement for BIAKŌS AWC, BIAKŌS Antimicrobial Skin and Wound Irrigation Solution, or CellerateRX Surgical.

We anticipate that our WounDerm services, once launched, will provide a wealth of patient data to help us measure our products' effectiveness on improving patient outcomes while simultaneously reducing healthcare costs. We believe our reimbursement strategy, including establishing the clinical validation, clinical utility and health economics of our products, will allow us to drive improved reimbursement coverage for our products and technologies.

Competition

The wound care market is served by several large, multi-product line companies as well as a number of small companies. Our products compete with primary dressings, advanced wound care products, collagen matrices and other biopharmaceutical products. Manufacturers and distributors of competitive products include Smith & Nephew plc, Medline Industries, Inc., ConvaTec Group plc, Mölnlycke Health Care AB, 3M Company, Integra LifeSciences Holdings Corporation (which acquired ACell Inc. on January 20, 2021) and numerous others. Many of our competitors are significantly larger than we are and have greater financial and personnel resources. We believe, however, that our products outperform our competitors' currently available equivalent products for the specific application in which they are intended by providing improved efficacy, better outcomes, and reduced cost of patient care.

WounDerm plans to offer a comprehensive wound care and dermatology strategy to expand cost-effective, high quality wound and skin care to all patients throughout the care setting continuum. Although novel in its comprehensive offerings and solutions, there are existing competitors for each of the verticals in which WounDerm plans to offer services and solutions.

Existing wound care imaging technology competitors include MolecuLight, Wound-Vision, HyperMed Imaging, Inc., SpectralMD, Inc., Kent and Tissue Analytics. However, we do not believe that any of these existing platforms offer a bioassay evaluation in combination with their imaging solution. In addition, there are existing wound care-specific EMR documentation and telemedicine communication platforms such as NetHealth, Swift Medical Inc., Corstrata, LLC and Intellicure, Inc.

The public health emergency caused by the COVID-19 pandemic has led to the widespread adoption of telemedicine for all health care clinical specialties, including wound care and dermatology. As such, any clinical wound care or dermatology physician and/or provider group that has incorporated telemedicine into their practice could be considered competitive. However, the majority of these groups are local or regional and do not incorporate the comprehensive national care delivery platform that WounDerm expects to offer. Examples of large wound care specialty practices include Vohra Physician Group, Healogics Specialty Physicians and WoundTech.

Licensing Agreements

We in-license the rights to market, sell, and distribute our current products from third parties.

CellerateRX Activated Collagen

On August 27, 2018, we entered into an exclusive, world-wide sublicense agreement with CGI Cellerate RX to distribute CellerateRX Surgical and HYCOL products into the wound care and surgical markets. We pay royalties of 3-5% of annual collected net sales of CellerateRX Surgical and HYCOL. As amended, the term of the sublicense extends through May 2050, with automatic year-to-year renewal terms thereafter so long as our Net Sales (as defined in the sublicense agreement) each year are equal to or in excess of $1,000,000. If our Net Sales fall below $1,000,000 for any year after the initial expiration date, CGI Cellerate RX will have the right to terminate the sublicense agreement upon written notice. Minimum royalties of $400,000 per year are payable for the first five years of the sublicense agreement.

BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser

On July 7, 2019, we executed a license agreement with Rochal, whereby we acquired an exclusive world-wide license to market, sell and further develop antimicrobial products for the prevention and treatment of microbes on the human body utilizing certain Rochal patents and pending patent applications (the "BIAKŌS License Agreement"). Currently, the products covered by the BIAKŌS License Agreement are BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser. Both products are 510(k) approved. Our Executive Chairman is a director of Rochal, and indirectly a significant shareholder of Rochal, and through the potential exercise of warrants, a majority shareholder of Rochal. Another one of our directors is also a director and significant shareholder of Rochal.

Future commitments under the terms of the BIAKŌS License Agreement include:

- We will pay Rochal a royalty of 2-4% of net sales. The minimum annual royalty due to Rochal was $100,000 in 2020 and will increase by 10% each subsequent calendar year up to a maximum amount of $150,000.

- We will pay additional royalty annually based on specific net profit targets from sales of the licensed products, subject to a maximum of $1,000,000 during any calendar year.

Unless previously terminated by the parties, the BIAKŌS License Agreement will expire with the related patents in December 2031.

CuraShield Antimicrobial Barrier Film and No Sting Skin Protectant

On October 1, 2019, we executed a license agreement with Rochal whereby we acquired an exclusive world-wide license to market, sell and further develop certain antimicrobial barrier film and skin protectant products for use in the human health care market utilizing certain Rochal patents and pending patent applications (the "ABF License Agreement"). Currently, the products covered by the ABF License Agreement are CuraShield Antimicrobial Barrier Film and a no sting skin protectant product.

Future commitments under the terms of the ABF License Agreement include:

- The Company will pay Rochal a royalty of 2-4% of net sales. The minimum annual royalty due to Rochal will be $50,000 beginning with the first full calendar year following the year in which first commercial sales of the products occur. The annual minimum royalty will increase by 10% each subsequent calendar year up to a maximum amount of $75,000.

- We will pay additional royalties annually based on specific net profit targets from sales of the licensed products, subject to a maximum of $500,000 during any calendar year.

Unless previously terminated or extended by the parties, the ABF License Agreement will terminate upon expiration of the last U.S. patent in October 2033. No commercial sales or royalty payments had been made under ABF License Agreement as of December 31, 2021.

Debrider License Agreement

On May 4, 2020, we executed a product license agreement with Rochal, whereby we acquired an exclusive world-wide license to market, sell and further develop a debrider for human medical use to enhance skin condition or treat or relieve skin disorders, excluding uses primarily for beauty, cosmetic, or toiletry purposes (the "Debrider License Agreement").

Future commitments under the terms of the Debrider License Agreement include:

- At the time Rochal issues a purchase order to its contract manufacturer for the first good manufacturing practice run of the licensed products, we will pay Rochal $600,000 in cash.

- Upon FDA clearance of the licensed products, we will pay Rochal $500,000 in cash and $1,000,000, which at our option may be paid in any combination of cash and our common stock.

- We will pay Rochal a royalty of 2-4% of net sales. The minimum annual royalty due to Rochal will be $100,000 beginning with the first full calendar year following the year in which first commercial sales of the licensed products occur and increase by 10% each subsequent calendar year up to a maximum amount of $150,000.

- We will pay additional royalty annually based on specific net profit targets from sales of the licensed products, subject to a maximum of $1,000,000 during any calendar year.

Unless previously terminated or extended by the parties, the Debrider License Agreement will expire in October 2034. No commercial sales or royalties had been recognized under the Debrider License Agreement as of December 31, 2021.

Cook Biotech Marketing and Distribution Agreement

On December 17, 2020, we entered into a marketing and distribution agreement with Cook Biotech whereby we were appointed as the exclusive distributor in the United States of three Cook advanced biologic products. The first two products, FORTIFY TRG Tissue Repair Graft and FORTIFY FLOWABLE Extracellular Matrix, are for use in the surgical wound care segment, and VIM Amnion Matrix is for use in the chronic wound care and surgical wound care segments. We expect to fully commercialize these products in 2022.

Under the terms of the agreement, we will purchase the products from Cook Biotech at initial transfer prices stipulated in the agreement. Cook Biotech may update the transfer prices annually based on changes in the US Producer's Price Index. Minimum annual order quantities will be agreed upon by both parties after the first year of the contract term. The agreement will terminate on the third anniversary of the date on which the first commercial sale to us from Cook Biotech is made, with automatic two-year renewal terms unless notice of non-renewal is given by one party at least one year prior to the end of the initial term or renewal term that is then in effect.

Resorbable Bone Hemostat

We acquired a patent in 2009 for a resorbable bone hemostat and delivery system for orthopedic bone void fillers. This patent is not part of our long-term strategic focus. We subsequently licensed the patent to a third party to market a bone void filler product for which we receive a 3% royalty on product sales over the life of the patent, which expires in 2023, with annual minimum royalties of $201,000. We pay two unrelated third parties a combined royalty equal to eight percent (8%) of our net revenues and royalties generated from products that utilize the acquired patented bone hemostat and delivery system. To date, royalties received by us related to this licensing agreement have not exceeded the annual minimum of $201,000 ($50,250 per quarter). Therefore, our annual royalty obligation under the terms of the license agreement has been $16,080 ($4,020 per quarter).

Government Regulation

Our operations are subject to comprehensive federal, state, and local laws and regulations in the jurisdictions in which we or our research and development partners or affiliates do business. The laws and regulations governing our business and interpretations of those laws and regulations and are subject to frequent change. Our ability to operate profitably will depend in part upon our ability, and that of our research and development partners and affiliates, to operate in compliance with applicable laws and regulations. The laws and regulations relating to medical products and healthcare services that apply to our business and that of our partners and affiliates continue to evolve, and we must, therefore, devote significant resources to monitoring developments in legislation, enforcement, and regulation in such areas. As the applicable laws and regulations change, we are likely to make conforming modifications in our business processes from time to time. We cannot provide assurance that a review of our business by courts or regulatory authorities will not result in determinations that could adversely affect our operations or that the regulatory environment will not change in a way that restricts our operations.

FDA Regulation

Our medical products and operations are regulated by the FDA and other federal and state agencies. The products we currently market are regulated as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as implemented and enforced by the FDA. The FDA regulates the development, testing, manufacturing, labeling, packaging, storage, installation, servicing, advertising, promotion, marketing, distribution, import, export, and market surveillance of our medical devices.

In addition, we have entered into agreements to market and distribute products regulated by FDA under Section 361 of the PHSA (42 U.S.C. § 264) and 21 C.F.R. Part 1271. These products include: (i) VIM Amnion Matrix, a tissue based product for use in the chronic wound care and surgical wound care segments, (ii) TEXAGEN Amniotic Membrane Allograft, a multi-layer amniotic membrane allograft used as an anatomical barrier with robust handling that can be sutured if needed, (iii) AMPLIFY Verified Inductive Bone Matrix, a 100% human allograft bone with conformable handling properties, and (iv) ALLOCYTE Advanced Cellular Bone Matrix, a human allograft cellular bone matrix (CBM) containing bone-derived progenitor cells and conformable bone fibers.

Device Premarket Regulatory Requirements

Before being introduced into the U.S. market, each medical device must obtain marketing clearance or approval from FDA through the 510(k) premarket notification process, the *de novo* classification process (summarized below under *De Novo Classification Process*), or the premarket approval application ("PMA") process, unless they are determined to be Class I devices or to otherwise qualify for an exemption from one of these available forms of premarket review and authorization by the FDA. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. Class I devices are those for which reasonable assurance of safety and effectiveness can be assured by adherence to general controls that include compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), as well as regulations requiring facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. The Class I designation also applies to devices for which there is insufficient information to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but that are not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and that do not present a potential unreasonable risk of illness of injury.

Class II devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish "special controls." These special controls can include performance standards, post-market surveillance requirements, patient registries and FDA guidance documents describing device-specific special controls. While most Class I devices are exempt from the 510(k) premarket notification requirement, most Class II devices require a 510(k) premarket notification prior to commercialization in the United States; however, the FDA has the authority to exempt Class II devices from the 510(k) premarket notification requirement under certain circumstances. As a result, manufacturers of most Class II devices must submit 510(k) premarket notifications to the FDA under Section 510(k) of the FDCA (21 U.S.C. § 360(k)) in order to obtain the necessary clearance to market or commercially distribute such devices. To obtain 510(k) clearance, manufacturers must submit to the FDA adequate information demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, meaning, (i) a device that was legally marketed prior to May 28, 1976 ("preamendments device") and for which a PMA is not required, (ii) a device that has been reclassified from Class III to Class II or I, or (iii) a device that was found substantially equivalent through the 510(k) process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If there is no adequate predicate to which the manufacturer can compare its proposed device, the proposed device is automatically classified as a Class III device. In such cases, the device manufacturer must then fulfill the more rigorous PMA requirements or can request a risk-based classification determination for the device in accordance with the *de novo* classification process.

The *de novo* classification process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its device to Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Under the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"), the FDA is required to classify a device within 120 days following receipt of the *de novo* classification request. If the manufacturer seeks reclassification into Class II, the classification request must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the classification request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

Devices that are intended to be life sustaining or life supporting, devices that are implantable, devices that present a potential unreasonable risk of harm or are of substantial importance in preventing impairment of health, and devices that are not substantially equivalent to a predicate device are placed in Class III and generally require FDA approval through the PMA process, unless the device is a preamendments device not yet subject to a regulation requiring premarket approval. The PMA process is more demanding than the 510(k) premarket notification process. For a PMA, the manufacturer must demonstrate through extensive data, including data from preclinical studies and clinical trials, that the device is safe and effective. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. Before approving a PMA, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the QSR.

Thus far, all of the medical devices that we currently market and distribute have been cleared through 510(k) premarket notifications filed by our third-party research and development partners, who are the manufacturers of such devices. We also are continuing to work through the development process for a number of products in our pipeline. Our debrider product, as well a novel dressing that delivers oxygen to the wound bed and a sterile BIAKŌS product, are currently under development, and we are in discussions concerning the best path for seeking clearance and approval for these products. We are also exploring new indications of use and improved formulas for a next generation CellerateRX and a next generation HYCOL.

Clinical trials are almost always required to support PMAs and are sometimes required to support 510(k) submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE"), regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," as defined by the FDA, the agency requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies the company that the investigation is on hold and may not begin until the sponsor provides supplemental information about the investigation that satisfies FDA's concerns. If the FDA determines that there are deficiencies or other concerns with an IDE that require modification of the study, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the study must be approved by, and conducted under the oversight of, an institutional review board ("IRB"), for each clinical site. If the device presents a non-significant risk to the patient according to criteria established by FDA as part of the IDE regulations, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate authorization from the FDA, but must still comply with abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

Device Post-market Regulatory Requirements

After a device is cleared or approved for commercialization, and prior to marketing, numerous regulatory requirements apply to the various entities responsible for preparing a device for distribution, including the manufacturer (including specification developer), contract manufacturers, relabelers/repackagers, sterilizers and initial importer, as applicable. These include:

- establishment registration and device listing;
- development of a quality management system, including establishing and implementing procedures to design and manufacture devices in compliance with the QSR (unless a device category is exempt from this requirement by the FDA, such as in the case of many Class I devices);
- labeling regulations that prohibit the promotion of products for uncleared or unapproved uses (known as off-label uses), as well as requirements to provide accurate and non-misleading information and adequate information on both risks and benefits of the device;
- FDA's unique device identification requirements that call for a unique device identifier ("UDI") on device labels, packages, and in some cases, on the device itself, and submission of data to the FDA's Global Unique Device Identification Database ("GUDID");
- medical device reporting regulations that require manufacturers to report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- corrections and removal reporting regulations that require manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and
- post-market surveillance regulations, which apply to Class II or III devices if the FDA has issued a post-market surveillance order and the failure of the device would be reasonably likely to have serious adverse health consequences, the device is expected to have significant use in the pediatric population, the device is intended to be implanted in the human body for more than one year, or the device is intended to be used to support or sustain life and to be used outside a user facility.

Our research and development partners and their contract manufacturers may be subject to periodic scheduled or unscheduled inspections by the FDA. If we are required to register with the FDA, by becoming the manufacturer or specification developer of any medical device for instance, then we also may be subject to such inspections by FDA. If the FDA believes we or any of our research and development partners or their contract manufacturers are not in compliance with the QSR, or other post-market requirements, it has broad authority to take significant enforcement actions to compel compliance. Specifically, if the FDA determines that we or our research and development partners or their contract manufacturers failed to comply with applicable regulatory requirements, the agency can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement or refunds;
- mandatory recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or approval of pre-market approval applications relating to new products or modified products;
- reclassifying a 510(k)-cleared device or withdrawing PMA approval;
- refusal to grant export approvals for our products; or
- pursuing criminal prosecution.

Any such enforcement action by the FDA would have a material adverse effect on our business. In addition, these regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction, and continued availability of new products.

HCT/P Regulatory Requirements

Human cells, tissues, and cellular and tissue-based products (“HCT/Ps”) are regulated by FDA’s Center for Biologics Evaluation and Research (“CBER”) or Center for Devices and Radiological Health (“CDRH”) depending on the type of product, how it is manufactured and its intended uses. HCT/Ps that meet all of the criteria described in 21 C.F.R. § 1271.10(a) are regulated by CBER under Section 361 of the PHSA (42 U.S.C. § 264) and 21 C.F.R. Part 1271 only (“361 products”). Although 361 products do not require premarket review by FDA prior to commercialization, manufacturers of 361 products must register with FDA, submit a list of HCT/Ps manufactured, and comply with current good tissue practices (“cGTP”), among other things.

We have entered into an agreement to market and distribute VIM Amnion Matrix, which is manufactured from amniotic membrane and will be marketed as a 361 product. Cook Biotech, as the manufacturer, must comply with all requirements of Section 361 of the PHSA and 21 C.F.R. Part 1271 that are applicable to the products and may be subject to periodic scheduled or unscheduled inspections by the FDA to ensure compliance with cGTP.

Federal Trade Commission Regulatory Oversight

Our advertising for our products and services is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission, or FTC, as well as comparable state consumer protection laws. Under the Federal Trade Commission Act (“FTC Act”), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution.

Fraud and Abuse and Transparency Laws and Regulations

Our business activities (and the business activities of our research and development partners and affiliates), including, but not limited to, research, sales, promotion, distribution and medical education, are subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States, including the Department of Justice, the Department of Health and Human Services and its various divisions, CMS, the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Our business activities must comply with numerous healthcare laws, including, but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations, which are described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, furnishing, or order of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs, in whole or in part. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Patient Protection and Affordable Care Act, of 2010, as amended (the "ACA"), modified the intent requirement under the Anti-Kickback Statute to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (the "FCA"). The ACA further created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

The federal civil FCA, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, or submission of inaccurate information required by government contracts, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a drug's label, and allegations as to misrepresentations with respect to the products supplied or services rendered. Several pharmaceutical and other healthcare companies have further been sued under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Intent to deceive is not required to establish liability under the civil FCA; however, a change in Department of Justice policy now prohibits enforcement actions for knowing violations of law based on non-compliance with agency subregulatory guidance. Civil FCA actions may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Since 2004, these FCA lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as $3.0 billion, regarding certain sales practices and promoting off label drug uses. Civil FCA liability may be imposed for Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act.

The government may further prosecute conduct constituting a false claim under the criminal FCA. The criminal FCA prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil FCA, requires proof of intent to submit a false claim. The civil monetary penalties statute is another potential statute under which drug and device companies may be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

HIPAA also created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. The ACA, as amended, modified the intent requirement under the certain portions of these federal criminal statutes such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it.

The ACA further created federal requirements for reporting, by applicable manufacturers of covered therapeutics, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers, and some have transparency laws that require reporting price increases and related information. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require drug manufacturers to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject to penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, debarment from receiving government contracts or refusal of new orders under existing contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Telemedicine Standards, and Related Laws and Guidelines

We have entered into a management agreement with MGroup, which is a physician-owned multispecialty wound care group with active medical licenses in all 50 states. Through this partnership, we expect to make available coordinated telemedicine services on our platform. In connection with this arrangement, we expect to administer non-clinical services to support the delivery of telemedicine services, including billing, scheduling and a wide range of other administrative and support services, and will be paid a pre-determined, fair market value amount for those services. We have also entered into a professional services agreement with and made a minority investment in DirectDerm, a dermatology telemedicine company based in California, which has an exclusive network of dermatologists licensed across 32 states.

The delivery of telemedicine services directly or through contractual relationships is subject to various federal, state, and local laws, regulations and approvals, relating to, among other things, the health provider licensure, adequacy and continuity of medical care, medical practice standards (including specific requirements when providing healthcare utilizing telemedicine technologies and consulting services among providers), medical records maintenance, personnel supervision, and prerequisites for the prescription of medication. The application of some of these laws to telemedicine is unclear and subject to differing interpretation. Further, laws and regulations specific to delivering medical services utilizing telemedicine technologies continues to evolve with some states incorporating modality and consent requirements for certain telemedicine encounters.

Telemedicine services also implicate state corporate practice of medicine and fee-splitting laws which vary from state to state and are not always consistent among states. In addition, these requirements are subject to broad powers of interpretation, enforcement discretion by state regulators, and, in some cases, dated (yet still valid) case law. Some of these requirements may apply to us or our partners, even if we do not have a physical presence in the state, based solely on the engagement of a provider licensed in the state or the provision of telemedicine to a resident of the state. However, regulatory authorities or other parties, including providers in our affiliated provider network, may assert that, despite these arrangements, we are engaged in the corporate practice of medicine or that our contractual arrangements with affiliated physician groups constitute unlawful fee-splitting. In this event, failure to comply could lead to adverse judicial or administrative action against us and/or our providers, civil or criminal penalties, receipt of cease-and-desist orders from state regulators, loss of provider licenses, or the need to make changes to the arrangements with our affiliated provider network; each of which could interfere with our business or prompt other materially adverse consequences.

U.S. Federal and State Health Information Privacy and Security Laws

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personally identifiable information ("PII"), including health information. In particular, HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act, and its respective implementing regulations establishes privacy and security standards that limit the use and disclosure of PHI, and require the implementation of administrative, physical, and technical safeguards to ensure the confidentiality, integrity and availability of individually identifiable health information in electronic form. Our affiliated network providers and our hospital, health system and other provider clients are all regulated as covered entities under HIPAA. Since the effective date of the HIPAA Omnibus Final Rule on September 23, 2013, HIPAA's requirements are also directly applicable to the independent contractors, agents and other "business associates" of covered entities that create, receive, maintain or transmit protected health information ("PHI") in connection with providing services to covered entities. We are a business associate under HIPAA when we are working on behalf of our affiliated providers.

Violations of HIPAA may result in civil and criminal penalties. The civil penalties range from $119 to $59,522 per violation, with a cap of $1.8 million per year for violations of the same standard during the same calendar year. However, a single breach incident can result in violations of multiple standards. We must also comply with HIPAA's breach notification rule. Under the breach notification rule, covered entities must notify affected individuals without unreasonable delay in the case of a breach of unsecured PHI, which may compromise the privacy, security or integrity of the PHI. In addition, notification must be provided to Health and Human Services ("HHS") and the local media in cases where a breach affects more than 500 individuals. Breaches affecting fewer than 500 individuals must be reported to HHS on an annual basis. The regulations also require business associates of covered entities to notify the covered entity of breaches by the business associate.

State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states. While HIPAA does not create a private right of action that would allow individuals to sue in civil court for a HIPAA violation, its standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the Civil Monetary Penalty fine paid by the violator. In light of the HIPAA Omnibus Final Rule, recent enforcement activity, and statements from HHS, we expect increased federal and state HIPAA privacy and security enforcement efforts.

HIPAA also required HHS to adopt national standards establishing electronic transaction standards that all healthcare providers must use when submitting or receiving certain healthcare transactions electronically.

Many states in which we or our research and development partners may operate also have laws that protect the privacy and security of sensitive and personal information, including health information. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, the laws of the State of California are more restrictive than HIPAA. Where state laws are more protective than HIPAA, we must comply with the state laws to which we are subject, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Not only may some of these state laws impose fines and penalties upon violators, but also some, unlike HIPAA, may afford private rights of action to individuals who believe their personal information has been misused. In addition, state laws are changing rapidly, and there is discussion of a new federal privacy law or federal breach notification law, to which we may be subject.

In addition to HIPAA, state health information privacy laws, we may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security and laws that place specific requirements on certain types of activities, such as data security and texting.

In recent years, there have been a number of well-publicized data breaches involving the improper use and disclosure of PII and PHI. Many states have responded to these incidents by enacting laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach, such as providing prompt notification of the breach to affected individuals and state officials. In addition, under HIPAA and pursuant to the related contracts that we enter into with our business associates, we must report breaches of unsecured PHI to our contractual partners following discovery of the breach. Notification must also be made in certain circumstances to affected individuals, federal authorities and others.

Employees

As of December 31, 2021, we had a staff of 63 full-time employees and 5 contractors.

Corporate Information

We were incorporated in Texas on December 14, 2001. Our principal executive offices are located at 1200 Summit Ave, Suite 414, Fort Worth, Texas 76102, telephone number (817) 529-2300. Our website address is www.sanaramedtech.com. Information accessed through our website is not incorporated into this annual report and is not a part of this annual report.

Available Information

The Company electronically files reports with the Securities and Exchange Commission (the "SEC"). The SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Copies of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished to the SEC are also available free of charge through the Company's website (http://www.sanaramedtech.com/), as soon as reasonably practicable after electronically filing with or otherwise furnishing such information to the SEC, and are available in print to any shareholder who requests it.

Item 1A. RISK FACTORS

The risks below are those that we believe are the material risks that we currently face, but are not the only risks facing us and our business. If any of these risks actually occur, our business, financial condition and results of operations could be materially adversely affected. Below is a summary of our risk factors with a more detailed discussion following.

- We have had a history of losses, which may continue as we expand our selling efforts.
- The COVID-19 pandemic in the United States has and may continue to negatively impact our business, financial condition and results of operations.
- Our revenue growth for a particular period is difficult to predict, and a shortfall in forecast revenues may harm our operating results.
- Our current comprehensive wound and skin care strategy involves growth through acquisitions and investments, which requires us to incur substantial costs and potential liabilities for which we may never realize the anticipated benefits.
- If we cannot meet our future capital requirements, our business will suffer.
- Failure to retain and recruit key personnel would harm our ability to meet key objectives.
- Failure to manage our growth strategy could harm our business.
- We operate in highly competitive markets and face competition from large, well-established medical device manufacturers and telehealth providers as well as new market entrants, and if we are unable to compete within our markets or our products and services do not gain market acceptance, our operating results and financial condition could suffer.
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.
- If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results or prevent fraud and our business may be harmed and our stock price may be adversely impacted.
- We rely heavily on our research and development partners to design, manufacture and supply the products we have licensed for marketing. If we or one of our partners fails to perform adequately or fulfill our needs, we may be required to incur significant costs. We also may face significant delays in our product introductions and commercialization.

- Certain of our product candidates are still under development, and there can be no assurance of successful commercialization of any of these product candidates.
- Our future success will largely depend on our ability to maintain and further grow clinical acceptance and adoption of our products, and we may be unable to adequately educate healthcare practitioners on the use and benefits of our products.
- Competitors could invent products superior to ours and cause our products and technologies to become obsolete.
- Disruption of, or changes in, our distribution model or customer base could harm our sales and margins.
- If we are unable to manage product inventory in an effective manner, our profitability could be impaired.
- Failure of any third-party assessments to demonstrate desired outcomes in proposed endpoints may result in adverse regulatory actions, reduce physician usage or adoption of our products, or reduce the price, coverage and/or reimbursement for our products, which could have a negative impact on our business performance.
- We may have exposure to product liability claims.
- Interruptions in the supply of our products or inventory loss may adversely affect our business, results of operations and financial condition.
- Our planned expansion into wound and skin care virtual consult and other services will require entrance into several markets in which we have little or no experience and is dependent on our relationships with affiliated professional entities to provide physician services.
- Recent and frequent state legislative and regulatory changes specific to telemedicine may present us with additional requirements and state compliance costs, with potential operational impacts in certain jurisdictions.
- If we are unable to adequately protect our intellectual property rights, we may not be able to compete effectively.
- CellerateRX Surgical no longer has patent protection. Accordingly, CellerateRX Surgical may be subject to competition from the sale of substantially equivalent products that could adversely affect our business and operations.
- We are heavily dependent on technologies and products we have licensed from third parties, and we may need to license technologies and products in the future, and if we fail to obtain licenses we need, or fail to comply with our payment obligations in the agreements under which we in-license intellectual property and other rights from third parties, we could lose our ability to develop and commercialize our products.
- We may be found to infringe on intellectual property rights of others.
- Our business is affected by numerous regulations relating to the development, manufacture, distribution, labeling, marketing and sale of our products.
- We are subject to various governmental regulations relating to the labeling, marketing and sale of our products.
- Delays in or changes to the FDA clearance and approval processes or ongoing regulatory requirements could make it more difficult for us to obtain FDA clearance or approval of new products or comply with ongoing requirements.
- Changes in reimbursement policies and regulations by governmental or other third-party payors may have an adverse impact on the use of our products.
- We heavily rely on our research and development partners to comply with applicable laws and regulations relating to product classification and when and what types of FDA marketing authorizations are needed to lawfully commercialize a new or updated medical product in the United States.

- We and our employees and contractors are subject, directly or indirectly, to federal, state and foreign healthcare fraud and abuse laws, including false claims laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

- We and our or our research and development partners' use and disclosure of personally identifiable information is subject to federal and state privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, business, financial condition and results of operations.

- If we fail to comply with extensive healthcare laws and government regulations, we could suffer penalties or be required to make significant changes to our operations.

- Our officers, employees, independent contractors, principal investigators and commercial partners may engage in activities that are improper under other laws and regulations, which would create liability for us.

- We could be adversely affected if healthcare reform measures substantially change the market for medical care or healthcare coverage in the United States.

- Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, litigation and negative publicity that could materially adversely affect our reputation, business, results of operations and financial condition.

- It is possible that we will require additional capital to meet our financial obligations and support business growth.

Risks Related to How We Operate Our Business

The COVID-19 pandemic in the United States has and may continue to negatively impact our business, financial condition and results of operations.

Beginning in March 2020, many states issued orders suspending elective surgeries in order to free-up hospital resources to treat COVID-19 patients. This resulted in a reduction in demand for our surgical products beginning in the second half of March 2020. Additionally, most states limited access to SNFs to only resident caregivers, which impeded our ability to provide education and product training to the clinicians who use our products in these facilities. These restrictions resulted in an overall decline in sales for the second quarter of 2020. During the second half of 2020 and the first half of 2021, we saw a strong rebound in product sales as restrictions on elective surgeries eased in its primary markets in Texas, Florida, and the southeastern United States. During the second half of 2021, the United States experienced a surge of COVID-19 cases as the Delta and Omicron variants of the virus impacted much of the country and negatively impacted our sales in Texas, the northeastern United States, and other markets.

The duration and effects of the pandemic remain uncertain; however, management believes that elective surgical procedures will continue to be performed with the exception of certain geographic hotspots. Additionally, management believes that the majority of surgical procedures impacted by COVID-19 and its variants will ultimately be performed. We continue to closely monitor the pandemic in order to ensure the safety of the Company's people and its ability to serve its customers and patients.

We have had a history of losses, which may continue as we expand our selling efforts.

We have incurred net losses in most years since we began our current operations in 2004. We plan to continue making significant investments in our sales force and clinical programs, which substantially increase our operating expenses. Consequently, we will need to continue our revenue growth to become profitable in future periods. We cannot offer any assurance that we will be able to generate future sales growth. If we fail to achieve profitability, our stock price may decline, and you may lose part or all of your investment.

Our revenue growth for a particular period is difficult to predict, and a shortfall in forecast revenues may harm our operating results.

Because we are a relatively small company, our revenue growth and, consequently, results of operations are difficult to predict. We plan our operating expense levels based primarily on forecasted revenue levels. A shortfall in revenue could lead to operating results being below expectations as we may not be able to quickly reduce our fixed expenses in response to short-term revenue shortfalls. We have experienced fluctuations in revenue and operating results from quarter to quarter and anticipate that these fluctuations will continue until we achieve a critical mass with our product and service sales. These fluctuations can result from a variety of factors, including:

- economic conditions worldwide, as well as economic conditions specific to the healthcare industry, which could affect the ability of surgical and post-acute facilities to purchase our products and could result in a reduction in elective operative procedures;
- governmental regulations, including those adopted in response to the COVID-19 pandemic;
- the uncertainty surrounding our ability to attract new customers and retain existing customers;
- changes in reimbursement rates for our products by government and private insurers;
- the length and variability of our sales cycle, especially gaining approvals for the use of our products in additional hospitals and surgery centers, which makes it difficult to forecast the quarter in which our sales will occur;
- issues including delays in the sourcing of our products;
- the timing of regulatory approvals;
- the timing of operating expense relating to the expansion of our business and operations;
- changes in the pricing of our products and those of our competitors;
- the development of new wound care products or product enhancements by our competitors; and
- actual events, circumstances, outcomes and amounts differing from assumptions and estimates used in preparing our operating plan and how well we execute our strategy and operating plans.

As a consequence, operating results for a particular future period are difficult to predict and prior results are not necessarily indicative of future results. Any of the foregoing factors, or any other factors discussed elsewhere herein, could have a material adverse effect on our business.

Our current comprehensive wound and skin care strategy involves growth through acquisitions and investments, which requires us to incur substantial costs and potential liabilities for which we may never realize the anticipated benefits.

We may be unable to continue implementing our growth strategy, and our strategy ultimately may be unsuccessful. We engage in evaluations of potential acquisitions and investments and are in various stages of discussion regarding possible acquisitions, certain of which, if consummated, could be significant to us. Any new acquisition or investment could result in material transaction expenses, increased interest and amortization expense, increased depreciation expense and increased operating expense, any of which could have a material adverse effect on our operating results. In addition, if we are unable to integrate businesses and operations that we acquire in the future, our profitability could suffer. These acquisitions and investments also involve other risks, including diversion of management resources otherwise available for the running of our business and the development of our business as well as risks associated with entering markets in which our marketing teams and sales force has limited experience or where experienced distribution alliances are not available. We may not be able to identify suitable acquisition or investment candidates in the future, obtain acceptable financing or consummate any future acquisitions or investments. In addition, certain potential acquisitions may be subject to antitrust and competition laws, which could impact our ability to pursue strategic acquisitions and could result in mandated divestitures. If we are unsuccessful in our current strategy to expand into wound and skin care virtual consult and other services, we may be unable to meet our financial targets and our financial performance could be materially and adversely affected.

If we cannot meet our future capital requirements, our business will suffer.

We have a history of operating losses and negative cash flow from operating activities, and future results of operations involve significant risks and uncertainties. Factors that could affect our future operating results and cause actual results to vary materially from expectations include, but are not limited to, demand for our products and services, new product and service offerings from competitors, regulatory approval of our new products, technological change, and dependence on key personnel. Although we have taken steps to improve our overall liquidity, if our cash flow is insufficient, we may be forced to seek additional debt or equity financing in order to:

- fund operating losses;
- increase marketing to address the market for surgical, wound and skin care products and services;
- take advantage of opportunities, including more rapid expansion or acquisitions of complementary products or businesses;
- hire, train and retain employees;
- develop and/or distribute new products; and/or
- respond to economic and competitive pressures.

If our capital needs are met through the issuance of equity or convertible debt securities, the percentage ownership of our current shareholders may be reduced which may have a negative impact on the market price of our common stock. Our future success may be determined in large part by our ability to obtain additional financing, and the incurrence of indebtedness would result in increased debt service obligations which could result in operating and financing covenants that would restrict our operations. There can be no assurance that such financing would be available or, if available, that such financing could be obtained upon terms acceptable to us. If adequate funds are not available, or are not available on acceptable terms, our operating results and financial condition may suffer.

Failure to retain and recruit key personnel would harm our ability to meet key objectives.

Our success depends, in large part, on our ability to attract and retain skilled executive, managerial, sales and marketing personnel. We compete for such personnel with other companies, some of which have greater financial resources than we do to recruit and retain personnel. There can be no assurance that we will be able to find and attract additional qualified employees or retain any such executive officers and other key personnel. The inability to hire qualified personnel or the loss of services of our executive officers or key personnel may have a material adverse effect on our business. Further, any inability on our part to enforce non-compete arrangements related to key personnel who have left our company or may leave our company in the future could have a material adverse effect on our business.

Failure to manage our growth strategy could harm our business.

Our ability to successfully implement our business plan and develop, market and sell our surgical, wound and skin care products and services requires an effective plan for managing our future growth. We plan to increase the scope of our operations at a rapid rate. Future expansion efforts will be expensive and may strain our internal operating resources. To manage future growth effectively, we must maintain and enhance our financial and accounting systems and controls, integrate new personnel and manage expanded operations. If we do not manage growth properly, it could harm our operating results and financial condition.

We operate in highly competitive markets and face competition from large, well-established medical device manufacturers and telehealth providers as well as new market entrants, and if we are unable to compete within our markets or our products and services do not gain market acceptance, our operating results and financial condition could suffer.

Competition from other medical device companies is significant and we could be significantly affected by new product introductions and other activities of market participants. We compete with other companies in acquiring rights to products or technologies from third-party developers. Although our products have performed well in customer evaluations, we are a relatively unknown brand in a market dominated by companies with extensive product lines and large customer bases. We may not, even with more efficacious products, be able to secure contracts and achieve significant growth with large national accounts.

In addition, if we launch our wound and skin care virtual consult and other service offerings, we will face competition from other telehealth providers. The public health emergency caused by the COVID-19 pandemic has led to the widespread adoption of telemedicine for most health care clinical specialties, including wound care and dermatology. As such, any clinical wound care or dermatology physician and/or provider group that has incorporated telemedicine into their practice could be considered competitive. If we are unable to compete with other telehealth providers, our operating results and financial condition may suffer.

Several factors may limit the market acceptance of our products and services, including the timing of regulatory approvals and market entry relative to competitive products and services, the availability of alternative products and services, the price of our products and services relative to alternative products and services, the availability of third-party reimbursement and the extent of marketing efforts by third-party distributors or agents that we retain. There can be no assurance that our products or services will receive market acceptance in a commercially viable period of time, if at all. Furthermore, there can be no assurance that we can develop products and services that are more effective or achieve greater market acceptance than competitive products and services, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete.

Our competitors enjoy several competitive advantages over us, including but not limited to:

- large and established distribution networks in the U.S. and/or in international markets;
- greater financial, managerial and other resources for products research and development, sales and marketing efforts and protecting and enforcing intellectual property rights;
- greater name recognition;
- larger consumer bases;
- more expansive portfolios of products and intellectual property rights; and
- greater experience in obtaining and maintaining regulatory approvals and/or clearances from the FDA and other regulatory agencies.

The presence of competition in our market may lead to pricing pressure which would make it more difficult to sell our products and services at a profitable price or may prevent us from selling our products at all. Our failure to compete effectively would have a material adverse effect on our business.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we use networks to collect and store sensitive data, including intellectual property, proprietary business information and important information of our customers, suppliers and business partners, as well as personally identifiable information of our customers and employees. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in the loss of existing customers, difficulty in attracting new customers, backlash from negative public relations, legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties. Further, such access, disclosure or loss may cause disruption of our operations and the services we provide to customers, damage to our reputation, and cause a loss of confidence in our products and services, which could adversely affect our business.

We have programs, processes and technologies in place to prevent, detect, contain, respond to and mitigate security related threats and potential incidents. We undertake considerable ongoing improvements to our systems, connected devices and information-sharing products in order to minimize vulnerabilities, in accordance with industry and regulatory standards. Because the techniques used to obtain unauthorized access change frequently and can be difficult to detect, anticipating, identifying or preventing these intrusions or mitigating them if and when they occur, may be challenging.

If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results or prevent fraud and our business may be harmed and our stock price may be adversely impacted.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and to effectively prevent fraud. Any inability to provide reliable financial reports or to prevent fraud could harm our business. The Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) requires management to evaluate and assess the effectiveness of our internal control over financial reporting. In order to comply with the requirements of the Sarbanes-Oxley Act, we are required to continuously evaluate and, where appropriate, enhance our policies, procedures and internal controls. If we fail to maintain the adequacy of our internal controls over financial reporting, we could be subject to litigation or regulatory scrutiny and investors could lose confidence in the accuracy and completeness of our financial reports. We cannot provide any assurance that in the future we will be able to fully comply with the requirements of the Sarbanes-Oxley Act or that management will conclude that our internal control over financial reporting is effective. If we fail to fully comply with the requirements of the Sarbanes-Oxley Act, our business may be harmed and our stock price may decline. In addition, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

For instance, our assessment, testing and evaluation of the design and operating effectiveness of our internal control over financial reporting resulted in our conclusion that as of December 31, 2019, our internal control over financial reporting was not effective, due to our small size and limited segregation of duties. As a result of such determination, we implemented additional controls, including the hiring of an additional full-time accounting professional in January 2020, which enabled us to properly segregate duties, and concluded that the material weakness was remediated as of June 30, 2020. While we have concluded that the material weakness has been remediated, projections of any evaluation of the effectiveness of internal control over financial reporting for future periods are subject to the risk that controls may become inadequate because of changes in conditions or if the degree of compliance with the policies or procedures deteriorate over time.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

Our net operating loss ("NOL") carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax laws. NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act (the "Jobs Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), NOLs arising in taxable years beginning after December 31, 2017, and before January 1, 2021, may be carried back to each of the five tax years preceding the tax year of such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under the Jobs Act, NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2021, not all states have conformed to the Jobs Act and CARES Act.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" (as defined under Section 382 of the Code ("Section 382") and applicable treasury regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. After applying the provisions of Section 382 of the Internal Revenue Code, the unexpired net operating loss ("NOL") carry forward at December 31, 2021 was approximately $20.7 million, of which, approximately $5.1 million, generated in 2017 and prior, will expire between 2022 and 2037. Under the Jobs Act, the NOL of approximately $15.6 million during the years 2018 through 2021, will have an indefinite carryforward period but can generally only be used to offset 80% of taxable income in any particular year. We may be subject to certain limitations in our annual utilization of NOL carry forwards to off-set future taxable income pursuant to Section 382, which could result in NOLs expiring unused.

Risks Related to Our Products and our Product Pipeline

We rely heavily on our research and development partners to design, manufacture and supply the products we have licensed for marketing. If we or one of our partners fails to perform adequately or fulfill our needs, we may be required to incur significant costs. We may also face significant delays in our product introductions and commercialization.

On July 14, 2021, we entered into an asset purchase agreement with Rochal Industries LLC ("Rochal"), effective July 1, 2021, pursuant to which we purchased certain assets of Rochal, including, among others, intellectual property, FDA 510(k) clearances for four medical devices (Bioshield Silicone Film, Antimicrobial Wound Cleanser, No Sting Skin Protectant, and Antimicrobial Barrier Film), rights to license certain product candidates and technologies currently under development, equipment, and supplies. Through the asset purchase, our pipeline now contains products and product candidates intended for mitigation of opportunistic pathogens and biofilm, wound re-epithelialization and closure, necrotic tissue debridement, and cell compatible substrates. In addition, we have hired all Rochal employees. While we expect to have the capability to develop certain of our pipeline in-house, we rely heavily on our research and development partners, from whom we license most of the products we currently commercialize, to design, manufacture and supply such products

We and our research and development partners responsible for manufacturing our products and their contract manufacturers are obliged to operate in accordance with FDA's current good manufacturing practices ("cGMP"), current good tissue practices ("cGTP"), and the Quality System Regulation ("QSR"), as applicable, as well as other regulations applicable to medical product manufacturers. The manufacture of regulated medical products in compliance with cGMP, cGTP, and the QSR, as applicable, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including product stability and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced regulatory requirements, other federal and state regulatory requirements and foreign regulations. If we or our research and development partners or their contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to commercialize our products would be jeopardized. Any delay or interruption in the supply of products could have a material adverse effect on our business.

We and the manufacturers of certain of our products may be unable to comply with applicable FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of regulated products. We have little control over the manufacturers' compliance with these regulations and standards. Our failure or a failure of any of our current or future research and development partners or their contract manufacturers to establish and follow cGMP, cCTP, and the QSR, as applicable, and to document their adherence to such practices may lead to significant delays in obtaining marketing authorization of future products or the ultimate launch of products. Failure by us or our current or future partners or manufacturers to comply with applicable regulations could also result in sanctions being imposed on us or our partners, including fines, injunctions, civil penalties, failure of the government to grant marketing authorization, delays, suspension or withdrawal of authorization, seizures or recalls of products, operating restrictions, and criminal prosecutions. If the safety of any product supplied is compromised due to the manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize our products. Any of these factors could cause a delay of commercialization of our products, entail higher costs or impair our reputation.

Certain of our product candidates are still under development, and there can be no assurance of successful commercialization of any of these product candidates.

Our pipeline contains products and product candidates for mitigation of opportunistic pathogens and biofilm, wound re-epithelialization and closure, necrotic tissue debridement, and cell compatible substrates. We may also decide to develop other product candidates. Certain of our research and development programs are in developmental stages. One or more of our product candidates may fail to meet safety and efficacy standards in human testing, even if those product candidates are found to be effective in animal studies. To develop and commercialize product candidates, we must provide the FDA and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate adequate safety and effectiveness. To generate this data, we will have to subject our product candidates to significant additional research and development efforts, including extensive non-clinical studies and clinical testing. Our approach to product discovery may not be effective or may not result in the development of any product. It can take several years for a product to be approved and we may not be successful in bringing any therapeutic candidates to the market. A new product candidate may appear promising at an early stage of development or after clinical trials and never reach the market, or it may reach the market and not sell, for a variety of reasons. For example, the product may:

- be shown to be ineffective or to cause harmful side effects during preclinical testing or clinical trials;
- fail to receive regulatory approval on a timely basis or at all;
- be difficult to manufacture on a large scale;
- not be economically viable;
- not be prescribed by doctors or accepted by patients;
- fail to receive a sufficient level of reimbursement from government, insurers or other third-party payors; or
- infringe on intellectual property rights of any other party.

If our delivery platform technologies or product development efforts fail to generate product candidates that lead to the successful development and commercialization of products, or if the product candidates we have (or may in the future) acquired are not approved or cleared for commercialization in the United States or, otherwise, experience adverse regulatory action, our business and financial condition will be materially adversely affected.

Our future success will largely depend on our ability to maintain and further grow clinical acceptance and adoption of our products, and we may be unable to adequately educate healthcare practitioners on the use and benefits of our products.

Healthcare practitioners play a significant role in determining the course of a patient's treatment and, ultimately, the type of products, if any, that will be used to treat the patient. As a result, our commercial success is heavily dependent on our ability to educate practitioners on the use of our products in both surgical and post-acute care settings. Acceptance and adoption of our products in our markets depends on educating healthcare practitioners as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products, including potential comparisons to our competitors' products, and on training healthcare practitioners in the proper application of our products. If we are not successful in convincing healthcare practitioners of the merits and advantages of our products compared to our competitors' products, they may not use our products and we will be unable to increase our sales and sustain growth or profitability.

Convincing healthcare practitioners to dedicate the time and energy necessary to properly train to use new products and techniques is challenging, and we may not be successful in these efforts. In particular, as healthcare resources are strained due to the ongoing COVID-19 pandemic, it may be more difficult to convince healthcare practitioners to commit their time and resources to learning to use a new product. If healthcare practitioners are not properly trained, they may use our products ineffectively, resulting in unsatisfactory patient outcomes, negative publicity or lawsuits against us. Accordingly, even if our products show superior benefits, safety or efficacy, based on head-to-head clinical trials, in comparison to alternative treatments, our success will depend on our ability to gain and maintain market acceptance for our products. If we fail to do so, our sales will not grow and our business, financial condition and results of operations will be adversely affected. We may not have adequate resources to effectively educate the medical community and our efforts may not be successful due to physician resistance or negative perceptions regarding our products.

Healthcare practitioners may be hesitant to change their medical treatment practices for the following reasons, among others:

- lack or perceived lack of evidence supporting greater efficacy versus standard of care;
- perceived liability risks generally associated with the use of new products and procedures;
- limited or lack of availability of coverage and reimbursement within healthcare payment systems;
- existing sole-source supply contracts with purchasing entities, such as hospital systems and group purchasing organizations, that do not use our products;
- pressure to contain costs and use lower cost alternatives to our products; and
- the time commitment that may be required for training to use new products or technologies.

Competitors could invent products superior to ours and cause our products and technologies to become obsolete.

The wound care sector of the medical products industry is characterized by a multitude of technologies and intense competition. Our competitors currently manufacture and distribute a variety of products that are, in many respects, comparable to our products. Many suppliers of competing products are considerably larger and have much greater resources than we have. In addition, many specialized products companies have formed collaborations with large, established companies to support research, development and commercialization of wound care products which may be competitive with ours. Academic institutions, government agencies and other public and private research organizations are also conducting research activities and may commercialize wound care products on their own or through joint ventures. It is possible that these competitors may develop technologies and products that are more effective than any we currently have. If this occurs, any of our products and technology affected by these developments could become obsolete.

Disruption of, or changes in, our distribution model or customer base could harm our sales and margins.

If we fail to manage the distribution of our products properly, or if the financial condition or operations of our reseller channels weaken, there may be a material adverse effect on our business. Furthermore, a change in the mix of our customers between service provider and enterprise, or a change in the mix of direct and indirect sales, could adversely affect our business.

Several factors could also result in disruption of or changes in our distribution model or customer base, which could harm our sales and margins, including the following:

- in some instances, we compete with some of our resellers through our direct sales, which may lead these channel partners to use other suppliers that do not compete; and
- some of our resellers may have insufficient financial resources and may not be able to withstand changes in business conditions.

If we are unable to manage product inventory in an effective and efficient manner, our profitability could be impaired.

Many factors affect the efficient use and planning of product inventory, such as effectiveness of predicting demand, effectiveness of preparing manufacturing to meet demand, efficiently meeting product mix and product demand requirements and product expiration. Our products have a shelf life of between 18 months and three years. If we are unable to manage our product inventory efficiently or within expected budget goals, or keep sufficient finished and in-process product on hand to meet demand, our operating margins and long-term growth prospects could be impaired.

We place orders with our suppliers based on forecasts of demand and, in some instances, may acquire additional inventory to accommodate anticipated demand. Our forecasts are based on management’s judgment and assumptions, each of which may introduce error into our estimates. If we overestimate customer demand, our excess or obsolete inventory may increase significantly, which would reduce our gross margin and adversely affect our financial results. Conversely, if we underestimate customer demand or if insufficient manufacturing capacity is available, we would miss revenue opportunities and potentially lose market share and damage our customer relationships.

Failure of any third-party assessments to demonstrate desired outcomes in proposed endpoints may result in adverse regulatory actions, reduce physician usage or adoption of our products, or reduce the price, coverage and/or reimbursement for our products, which could have a negative impact on our business performance.

Our collaborators regularly conduct clinical studies designed to test a variety of endpoints associated with product performance and use across a number of applications. If a clinical study conducted by us or our collaborators fails to demonstrate statistically significant results supporting performance, use benefits or compelling health economic outcomes from using our products, physicians may elect not to use our products as a treatment for conditions that may benefit from them. Furthermore, in the event of an adverse clinical study outcome, our products may not achieve "standard-of-care" designations, where they exist, for the conditions in question, which could deter the adoption of our products. Also, if serious adverse events are reported during the conduct of a study, it could affect continuation of the study, product marketing authorization by regulatory authorities and product adoption by healthcare professionals or could cause regulatory authorities to impose other restrictions on the product or require additional warning or precaution statements to appear on the product labeling. If we or our collaborators are unable to develop a body of statistically significant evidence from our clinical studies, whether due to adverse results or the inability to complete properly designed studies, public and private payors could refuse to cover our products, limit the manner in which they cover our products, or reduce the price they are willing to pay or reimburse for our products.

We may have exposure to product liability claims.

Although we have contractual indemnity from the manufacturers of our current products for certain liability claims related to their production, we could face a product liability claim outside of the scope of the contractual indemnities, or liability claims related to products we manufacture or may manufacture in the future. We do not have, and do not anticipate obtaining, contractual indemnification from parties supplying raw materials or parties marketing the products we sell. In any event, indemnification from the manufacturers of our products or from any other party is limited by the terms of the indemnity and by the creditworthiness of the indemnifying party. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer as result of a product liability claim, which could have a material adverse effect on our business.

Product liability insurance for the healthcare industry may become prohibitively expensive, to the extent it is available at all. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage as commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. In the event that we do not have adequate insurance or contractual indemnification, product liability claims relating to defective products could have a material adverse effect on our business.

Interruptions in the supply of our products or inventory loss may adversely affect our business, results of operations and financial condition.

Our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements including stability requirements or specifications. Most of our products must be stored and transported within a specified temperature range. For example, if environmental conditions deviate from that range, our products' remaining shelf-lives could be impaired or their safety and efficacy could be adversely affected, making them unsuitable for use. These deviations may go undetected. Severe weather conditions and natural disasters may make compliance with these processes and maintenance of these standards more difficult, and climate change threatens more extreme weather events, which could increase our production risks. The occurrence of actual or suspected production and distribution problems can lead to lost inventories, and in some cases recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays and result in substantial additional expenses. Any unforeseen failure in the storage of our products or loss in supply could result in a loss of our market share and negatively affect our revenues and operations.

Increased prices for, or unavailability of, raw materials used in our products could adversely affect our business, results of operations and financial condition.

Our profitability is affected by the prices of the raw materials used in the manufacture of our products. These prices may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel related delivery costs, competition, import duties, excises and other indirect taxes, currency exchange rates, and government regulation. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third-party payors, we may be unable to pass along cost increases for key components or raw materials through higher prices to our customers. If the cost of key components or raw materials increases, and we are unable fully to recover these increased costs through price increases or offset these increases through other cost reductions, we could experience lower margins and profitability. Significant increases in the prices of raw materials that cannot be recovered through productivity gains, price increases or other methods could adversely affect our business, results of operations and financial condition.

Risks Related to Our Planned Expansion into Wound and Skin Care Virtual Consult and Other Services

Our planned expansion into wound and skin care virtual consult and other services could have a material adverse effect on our business, financial condition or results of operations.

Our planned expansion into wound and skin care virtual consult and other services subjects us to risks associated with the use of new and novel technologies, operational, financial, regulatory, legal and reputational risks, as well as the risk that we may be unable to timely or successfully launch our service offerings. The success of these operations depends upon our ability to commercialize our service offerings, and our failure to do so could negatively affect our ability to generate revenue from these activities.

Our planned expansion into wound and skin care virtual consult and other services will require entrance into several markets in which we have little or no experience, which may not be successful and could be costly.

As part of our planned expansion into wound and skin care virtual consult services, we will be required to enter into other markets in which we have little to no experience, including EMR, telehealth and healthcare diagnostics. While we intend to expand our staff with individuals with more experience in the EMR, telehealth and diagnostic markets and will closely scrutinize individuals we engage, we cannot provide assurance that we will be able to retain or continue to hire well-qualified and experienced individuals or that our assessment of individuals we retain will be accurate. As we enter new markets, we will face new technological and operational risks and challenges with which we are unfamiliar and may incur significant costs. Entering new markets requires substantial management efforts and skills to mitigate these risks and challenges. Our lack of experience with certain of these new markets may result in unsuccessful new market entries. If we do not manage our entry into new markets properly, these costs and risks could harm our business, financial condition or results of operations.

Our planned expansion into the telehealth business is dependent on our relationships with affiliated professional entities to provide physician services, and our business would be adversely affected if those relationships were disrupted.

There is a risk that U.S. state authorities in some jurisdictions may find that any future contractual relationships we enter into with our affiliated professional entities who provide telehealth services violate laws prohibiting the corporate practice of medicine and professional fee-splitting laws. These laws generally prohibit the practice of medicine by lay persons or entities or sharing of professional fees with lay persons and are intended to prevent unlicensed persons or entities from interfering with or inappropriately influencing a physician's professional judgment. The corporate practice of medicine prohibition exists in some form, by statute, regulation, board of medicine or attorney general guidance, or case law, in most states and is subject to change and to evolving interpretations by state boards of medicine, state attorneys general and state courts. As such, we will be required to continually monitor our compliance with laws in every jurisdiction in which we plan to operate, and we cannot guarantee that subsequent interpretation of the corporate practice of medicine laws will not circumscribe our future business operations. State corporate practice of medicine doctrines could also subject physicians to penalties for aiding the corporate practice of medicine, which could discourage physicians from participating in our network of providers.

Due to the prevalence of the corporate practice of medicine doctrine, including in the states where we plan to conduct our telehealth business, we expect to continue contracting with provider-entities through management services agreements. Although we expect that these relationships will continue, we cannot guarantee that they will. A material change in our relationships with these provider entities, whether resulting from a dispute among the parties, a change in government regulation, or the loss of these affiliations, could impair our ability to provide services to our future clients and could have a material adverse effect on our business, financial condition and results of operations. Any scrutiny, investigation or litigation with regard to our future arrangements with these professional entities could have a material adverse effect on our business, financial condition, and results of operations.

Recent and frequent state legislative and regulatory changes specific to telemedicine may present us with additional requirements and state compliance costs, with potential operational impacts in certain jurisdictions.

The state laws and regulations specific to telemedicine vary from state to state and are continually evolving. In some cases, these laws and regulations target "direct to consumer" telehealth service offerings rather than specialty consultative services, such as our planned acute telemedicine service offerings, and incorporate informed consent, modality, medical records and follow up care and other requirements. Thus, where new legislation and regulations apply to our planned expansion into telemedicine services, we may incur costs to monitor, evaluate, and modify operational processes for compliance. All such activities will increase our costs and could, in certain circumstances, impact our ability to make telemedicine services available in a particular state.

Risks Related to Intellectual Property

If we are unable to adequately protect our intellectual property rights, we may not be able to compete effectively.

Part of our success depends on our and our research development partners' ability to protect proprietary rights to technologies used in certain of our products. We and our research development partners rely on patents, copyrights, trademarks and trade secret laws to establish and maintain proprietary rights in our technology and products. However, these legal means afford only limited protection and may not adequately protect our or our research development partners' rights or permit us to gain or keep a competitive advantage. Patents and patent applications for the products we have may not be broad enough to prevent competitors from introducing similar products into the market. Our or our research development partners' patents or attempts to enforce them may not be upheld by the courts. Efforts to enforce any of our or our research development partners' proprietary rights could be time-consuming and expensive, which could adversely affect our business and prospects and divert management's attention. There can be no assurance that our or our research and development partners' proprietary rights will not be challenged, invalidated or circumvented or that such rights will in fact provide competitive advantages to us.

CellerateRX Surgical is not currently protected by any pending patent application nor any unexpired patent. Accordingly, CellerateRX Surgical may be subject to competition from the sale of substantially equivalent products that could adversely affect our business and operations.

CellerateRX Surgical has no patent protection, and therefore, in order to continue to obtain commercial benefits from CellerateRX Surgical, we will rely on product manufacturing trade secrets, know-how and related non-patent intellectual property. The effect of CellerateRX Surgical's lack of patent protection depends, among other things, upon the nature of the market and the position of our products in the market from time to time, the size of the market, the complexities and economics of manufacturing a competitive product and applicable regulatory approval requirements. In the event that competition develops substantially equivalent products, this competition could have a material adverse effect on our business, financial condition and operating results. The entrance into the market of a product substantially equivalent to CellerateRX Surgical may erode our product's market share, which may have a material adverse effect on our business, financial condition and results of operations.

We are heavily dependent on technologies and products we have licensed from third parties, and we may need to license technologies and products in the future, and if we fail to obtain licenses we need, or fail to comply with our payment obligations in the agreements under which we in-license intellectual property and other rights from third parties, we could lose our ability to develop and commercialize our products.

We are heavily dependent on licenses from our research and development partners for all of our technologies and products and are party to a sublicense agreement with CGI Cellerate RX, license agreements with Rochal and a marketing and distribution agreement with Cook Biotech. Our sublicense agreement and license agreements require that we pay royalties to the sublicensor or licensor, as applicable, based on our net sales of the sublicensed and licensed products.

No assurance can be given that our existing sublicense agreement, license agreements or marketing and distribution agreement will be extended on reasonable terms or at all. In addition, we expect we will need to license intellectual property, technology and products from third parties in the future and that these licenses will be material to our business. No assurance can be given that we will meet our minimum performance obligations or generate sufficient revenue or raise additional financing to meet our payment obligations in our agreements with CGI Cellerate RX, Rochal and Cook Biotech or other license or marketing and distribution agreements we enter into with third parties in the future. Any failure to meet our minimum performance obligations or make the payments required by our agreements may permit the licensor or supplier to terminate the agreement. If we were to lose or otherwise be unable to maintain these licenses or marketing and distribution agreements for any reason, it would halt our ability to commercialize our pipeline products. Furthermore, such loss of these licenses or marketing and distribution agreements may enable development of new products that may compete with our pipeline products, and our competitors may gain proprietary position. Any of the foregoing could result in a material adverse effect on our business or results of operations.

We may be found to infringe on intellectual property rights of others.

Third parties, including customers, may in the future assert claims or initiate litigation related to exclusive patent, copyright, trademark and other intellectual property rights to technologies and related standards that are relevant to us. These assertions may emerge over time as a result of our growth and the general increase in the pace of patent claim assertions, particularly in the U.S. Because of the existence of a large number of patents in the healthcare field, the secrecy of some pending patent applications and the rapid rate of issuance of new patents, we believe that it is not economically practical or even possible to determine in advance whether a product or any of its components infringes or will infringe the patent rights of others. The asserted claims or initiated litigation can include claims against us or our manufacturers, suppliers or customers alleging infringement of their proprietary rights with respect to our existing or future products or components of those products. Regardless of the merit of these claims, they can be time-consuming, result in costly litigation and diversion of technical and management personnel, or require us to develop a non-infringing technology or enter into license agreements. Where claims are made by customers, resistance even to unmeritorious claims could damage customer relationships. There can be no assurance that licenses will be available on acceptable terms and conditions, if at all, or that our indemnification by our suppliers will be adequate to cover our costs if a claim were brought directly against us or our customers. Furthermore, because of the potential for high court awards that are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims settled for significant amounts. If any infringement or other intellectual property claim made against us by any third party is successful, or if we fail to develop non-infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business could be materially and adversely affected.

Risks Related to Regulations

Our business is affected by numerous regulations relating to the development, manufacture, distribution, labeling, marketing and sale of our products.

Government regulation by the FDA and similar agencies in other countries is a significant factor in the development, manufacturing and marketing of our products and in the acquisition or licensing of new products. Complying with government regulations is often time consuming and expensive and may involve delays or actions adversely impacting the marketing and sale of our current or future products.

Following initial regulatory approval or clearance of any products that we or our research and development partners may develop, we and/or our research and development partners will be subject to continuing regulatory review, including, but not limited to:

- establishment registration and device listing requirements;
- QSR, which governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices;
- labeling requirements, which mandate the inclusion of certain content in medical device labels and labeling, and when fully implemented, will generally require the label and package of medical devices to include a unique device identifier, and which also prohibit the promotion of products for uncleared or unapproved, i.e., “off-label,” indications;
- the Medical Device Reporting regulation, which requires that manufacturers and importers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- the Reports of Corrections and Removals regulation, which requires that manufacturers and importers report to the FDA recalls (i.e., corrections or removals) if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health and that manufacturers and importers keep records of recalls that they determine to be not reportable.

Failure to comply with applicable regulatory requirements can result in, among other things, the FDA or other governmental authorities:

- imposing fines and penalties on us;
- preventing us from manufacturing or selling our products;
- delaying or denying pending applications for approval or clearance of our products or of new uses or modifications to our existing products, or withdrawing or suspending current approvals or clearances;
- ordering or requesting a recall of our products;
- issuing warning letters, untitled letters, or “It has Come to Our Attention” letters;
- imposing operating restrictions, including a partial or total shutdown of production or investigation of any or all of our products;

- refusing to permit to import or export of our products;
- detaining or seizing our products;
- obtaining injunctions preventing us from manufacturing or distributing any or all of our products;
- commencing criminal prosecutions or seeking civil penalties; and
- requiring changes in our advertising and promotion practices.

The manufacturing facilities we or our research and development partners use (and may use) to make any of our FDA-regulated products are or may become subject to periodic review and inspection by the FDA. If a previously unknown problem with a product or a manufacturing or laboratory facility used or contracted by us or one of our research and development partners is discovered, the FDA may impose restrictions on that product or on the manufacturing facility, including requiring us and/or our research and development partner to withdraw the product from the market. Any changes to an approved or cleared product, including the way it is manufactured or promoted, often requires FDA review and separate approval or clearance before the product, as modified, may be marketed. In addition, for products we develop in the future, we and our contract manufacturers may be subject to ongoing FDA requirements for submission of safety and other post-market approval information. If we violate regulatory requirements at any stage, whether before or after marketing approval or clearance is obtained, we may be fined, be forced to remove a product from the market or experience other adverse consequences, which would materially harm our financial results. Additionally, due to limitations imposed on us by the scope of the cleared or approved indications or intended use of our products and by FDA and Federal Trade Commission ("FTC") regulations relating to promotional claims, we may not be able to obtain the labeling claims necessary or desirable for product promotion.

Distribution of our products outside the United States is subject to extensive government regulation. These regulations, including the requirements for marketing authorizations or product licenses necessary to bring a medical product to market, the time required for regulatory review and the sanctions imposed for violations, vary from country to country. We do not know whether we will obtain the marketing authorizations or product licenses necessary to market our products in such countries or that we will not be required to incur significant costs in obtaining or maintaining these regulatory approvals.

We are subject to various governmental regulations relating to the labeling, marketing and sale of our products.

Both before and after a product is commercially released, we have ongoing responsibilities under regulations promulgated by the FDA, the Federal Trade Commission, and similar U.S. and foreign regulations governing product labeling and advertising, distribution, sale and marketing of our products.

Medical devices and biological products may only be marketed or promoted for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against companies that promoted products for "off-label" uses (i.e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for "off-label" uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off-label promotion. The failure to comply with prohibitions on "off-label" promotion can result in significant monetary penalties, revocation or suspension of a company's business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S. government that imposes significant administrative obligations and costs.

If we fail to obtain or experience significant delays in obtaining regulatory clearances or approvals to market future medical device products, we will be unable to commercialize these products until such clearance or approval is obtained.

The developing, testing, manufacturing, marketing and selling of medical devices is subject to extensive regulation by governmental authorities in the U.S. and other countries. The process of obtaining regulatory clearance and approval of certain medical technology products is costly and time consuming. Inherent in the development of new medical products is the potential for delay because product testing, including clinical evaluation, is typically required, especially for drugs, biologics and high-risk devices, before such products can be approved for human use. With respect to medical devices, such as those that we currently market, before a new medical device, or a new indicated use of, or claim for, an existing product can be marketed (unless it is a Class I device), it must first receive either premarket clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or approval of a PMA from the FDA, or be reclassified and receive marketing authorization through the de novo classification process, unless an exemption applies.

In the 510(k)-clearance process, the FDA must determine that the proposed device is "substantially equivalent" to a Class I or II device legally on the market, known as a "predicate" device, with respect to intended use, technology, safety and effectiveness to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence for certain device types. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. If a device is novel and there is no appropriate predicate to which the applicant can demonstrate substantial equivalence, the device will be automatically classified as a Class III device and require approval through the PMA process prior to commercialization, unless the applicant submits a *de novo* classification request demonstrating that the novel device should be reclassified into Class I or II. Demonstrating that a novel device should be reclassified to Class I or II from Class III typically requires extensive information and data on the benefits and risks of the device, including performance data and frequently data from one or more clinical studies. The 510(k), PMA and *de novo* classification approval processes can be expensive and lengthy.

Failure to comply with applicable regulatory requirements can result in, among other things, suspension or withdrawal of clearances or approvals, seizure or recall of products, injunctions against the manufacture, holding, distribution, marketing and sale of a product and civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory clearances or approvals. Meeting regulatory requirements and evolving government standards may delay marketing of any new products developed by us for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us.

We cannot assure you that the FDA or other regulatory agencies will clear or approve any products developed by us on a timely basis, if at all, or, if granted, that clearance or approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

Changes to the FDA clearance and approval processes or ongoing regulatory requirements could make it more difficult for us to obtain FDA clearance or approval of new products or comply with ongoing requirements.

New government regulations may be enacted and changes in FDA policies and regulations and, their interpretation and enforcement, could prevent or delay regulatory clearance or approval of new products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. Therefore, we do not know whether we or our research and development partners will be able to continue to comply with such regulations or whether the costs of such compliance will have a material adverse effect on our business. Changes could, among other things, require different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, or limitations on product distribution. These changes, or others required by the FDA could have an adverse effect on our business, and specifically, on the sales of affected products. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements. If we or our research and development partners are not able to maintain regulatory compliance, we may not be permitted to market our products and our business would suffer.

Modifications to our current products may require new marketing clearances or approvals or require us to cease marketing or recall the modified products until such clearances or approvals are obtained.

Any modification to an FDA-cleared product that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its indicated use, requires a new FDA 510(k) clearance or, possibly, a PMA. In addition, any significant modification to an FDA-approved product, such as a new indication for use, labeling changes, or manufacturing changes, requires submission of a PMA supplement or 30-day notice for changes to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of the product. The FDA requires every manufacturer to make its own determination as to whether a modification requires a new 510(k) clearance or PMA, but the FDA may review and disagree with any decision reached by the manufacturer. In the future, we or our research and development partners may make additional modifications to our products after they have received FDA clearance or approval and, in appropriate circumstances, determine that new clearance or approval is unnecessary. Regulatory authorities may disagree with our or our research and development partners' decisions not to seek new clearance or approval and may require us or the research and development partner that controls the marketing authorization for the respective device to obtain clearance or approval for previous modifications to our products. If that were to occur for a previously cleared or approved product, we may be required to cease marketing or recall the modified device until we obtain, or our research and development partner obtains, the necessary clearance or approval. Under these circumstances, we may also be subject to significant regulatory fines or other penalties. If any of the foregoing were to occur, our financial condition and results of operations could be negatively impacted.

Failure to obtain or maintain adequate reimbursement or insurance coverage for drugs, if any, could limit our ability to market those drugs and decrease our ability to generate revenue. Changes in reimbursement policies and regulations by governmental or other third-party payors may have an adverse impact on the use of our products.

The pricing, coverage, and reimbursement of our products, if any, must be sufficient to support our commercial efforts and other development programs, and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford medical treatments. Sales of our products depend substantially, both domestically and abroad, on the extent to which the costs of our products, if any, will be paid for or reimbursed by health maintenance, managed care, and similar healthcare management organizations, or government payers and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide medical products for free or we may not be able to successfully commercialize our products.

A significant portion of our wound care products are purchased principally for the Medicare and Medicaid eligible population by hospital outpatient clinics, wound care clinics, durable medical equipment ("DME") suppliers and SNFs, which typically bill various third-party payors, primarily state and federal healthcare programs (e.g., Medicare and Medicaid), and managed care plans, for the products and services provided to their patients. Although the majority of our wound care products are currently eligible for reimbursement under Medicare Part B, adjustments to our reimbursement amounts or a change in CMS's reimbursement policies could have an adverse effect on our market opportunities in this area. The ability of our customers to obtain appropriate reimbursement for products and services from third-party payors is critical to the success of our business because reimbursement status affects which products our customers purchase. In addition, our ability to obtain reimbursement approval in foreign jurisdictions may affect our ability to expand our product offerings internationally.

Third-party payors have adopted, and are continuing to adopt, a number of policies intended to curb rising healthcare costs. These policies include the imposition of conditions of payment by foreign, state and federal healthcare programs as well as private insurance plans, and the reduction in reimbursement amounts applicable to specific products and services.

Changes in healthcare systems in the U.S. or internationally in a manner that significantly reduces reimbursement for procedures using our products or denies coverage for these procedures would also have an adverse impact on the acceptance of our products and the prices which our customers are willing to pay for them.

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new medical products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with our products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs or biologics in particular, has and is expected to continue to increase in the future. As a result, profitability of our current or future products, may be more difficult to achieve.

We heavily rely on our research and development partners to comply with applicable laws and regulations relating to product classification and what types of FDA marketing authorizations are needed to lawfully commercialize a new or updated medical product in the United States.

We heavily rely on our research and development partners, from whom we license most of the products we currently commercialize, to determine the appropriate classification for each such product and to comply with applicable regulations related to obtaining the proper marketing authorization. With respect to each medical device product we license, our respective research and development partner designs the product and determines whether the device should be classified as a Class I, II, or III device and the appropriate FDA marketing authorization pathway to pursue (i.e., 510(k), PMA or *de novo* classification). In addition, we rely on our research and development partners to determine whether specific legal or regulatory definitions or exemptions apply to particular medical products, which individually may be subject to FDA oversight as a device, drug, biologic or human cellular or tissue-based product. The FDA has broad regulatory authority to interpret and enforce the laws and regulations that govern medical products in commercial distribution, and any adverse determination by the FDA relating to one of our licensed products could require significant cost and effort to comply.

For example, our research and development partner, Cook Biotech, from whom we have the right to exclusively distribute three biologic products for surgical and wound care applications, has determined that one such product, VIM Amnion Matrix, is intended for homologous use as a wound covering or barrier. It is possible that the FDA, after evaluating the product, promotional claims, and other information pertinent to the FDA's determination of the product's intended use, may not agree with Cook Biotech's conclusion that the VIM Amnion Matrix product is intended for homologous use, which would change the legal framework under which the product is regulated and may require Cook Biotech and us to incur substantial costs and expend significant effort to bring the product into compliance with applicable regulations. Such action by the FDA may also require us to cease marketing operations relating to the VIM Amnion Matrix product until the appropriate corrections are complete.

Similarly, some of the devices that we market under a license (or that we have acquired or have, otherwise, obtained commercialization rights in the United States) have been updated or modified since their initial 510(k) clearance. Depending on the nature of the updates or modifications made to a 510(k)-cleared device, the FDA may require the submission (and clearance) of a new 510(k). More specifically, any modification that could significantly affect the cleared device's safety or effectiveness, or that would constitute a significant change in its intended use, will require a new 510(k) clearance. The FDA requires device manufacturers to make the initial determination as to whether a
proposed modification to a cleared device requires a new 510(k) submission, but the FDA can review any such decision not to submit a new 510(k) (if it becomes aware of the modifications during an inspection or otherwise) and may disagree with the manufacturer's determination that the given modification(s) did not require new clearance. If the FDA finds that a manufacturer has improperly marketed a modified device (for which the FDA has determined that a new 510(k) is required) under the original device's 510(k), the FDA may mandate that the manufacturer cease marketing and/or recall the modified device until the requisite clearance is obtained, in addition to one or more other enforcement actions. FDA may disagree with our partners' decisions not to submit new 510(k) notifications for those of our 510(k)-cleared devices that have been updated or modified since their initial clearance, in which case, we may be subject to a wide range of FDA enforcement actions, including, but not limited to, warning letters, fines, and other penalties, and our business will be adversely affected, as we would likely be required to cease commercialization (and, possibly, conduct a recall) of the modified product(s) at-issue and may incur additional expenses in connection with the preparation and submission of a new 510(k).

We and our employees and contractors are subject, directly or indirectly, to federal, state and foreign healthcare fraud and abuse laws, including false claims laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations are subject to various federal, state and foreign fraud and abuse laws. These laws may affect our operations, including the financial arrangements and relationships through which we market, sell and distribute our products. U.S. federal and state laws that affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent;

- Section 242 of HIPAA codified at 18 U.S.C. § 1347, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program (i.e., public or private);

- federal transparency laws, including the so-called federal "sunshine" law, which requires the tracking and disclosure to the federal government by pharmaceutical and medical device manufacturers of payments and other transfers of value to physicians and teaching hospitals as well as ownership and investment interests that are held by physicians and their immediate family members; and
- state law equivalents of each of these federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical and medical device companies to comply with their industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict certain payments that may be made to healthcare providers and other potential referral sources, state laws that require drug and medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that prohibit giving gifts to licensed healthcare professionals and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

In particular, activities and arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, waste and other abusive practices. These laws and regulations may restrict or prohibit a wide range of activities or other arrangements related to the development, marketing or promotion of products, including pricing and discounting of products, provision of customer incentives, provision of reimbursement support, other customer support services, provision of sales commissions or other incentives to employees and independent contractors and other interactions with healthcare practitioners, other healthcare providers and patients.

Because of the breadth of these laws and the narrow scope of the statutory or regulatory exceptions and safe harbors available, our business activities could be challenged under one or more of these laws. Relationships between medical product manufacturers and health care providers are an area of heightened scrutiny by the government. We engage in various activities, including the conduct of speaker programs to educate physicians, the provision of reimbursement advice and support to customers, and the provision of customer and patient support services, that have been the subject of government scrutiny and enforcement action within the medical device industry.

Government expectations and industry best practices for compliance continue to evolve and past activities may not always be consistent with current industry best practices. Further, there is a lack of government guidance as to whether various industry practices comply with these laws, and government interpretations of these laws continue to evolve, all of which create compliance uncertainties. Any non-compliance could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation. Although we have a comprehensive compliance program designed to ensure that our employees' and commercial partners' activities and interactions with healthcare professionals and patients are appropriate, ethical, and consistent with all applicable laws, regulations, guidelines, policies and standards, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

If a government entity opens an investigation into possible violations of any of these laws (which may include the issuance of subpoenas), we would have to expend significant resources to defend ourselves against the allegations. Allegations that we, our officers, or our employees violated any one of these laws can be made by individuals called "whistleblowers" who may be our employees, customers, competitors or other parties. Government policy is to encourage individuals to become whistleblowers and file a complaint in federal court alleging wrongful conduct. The government is required to investigate all of these complaints and decide whether to intervene. If the government intervenes and we are required to pay damages, which in such cases are typically set at three times the actual monetary damages, to the government, the whistleblower, as a reward, is awarded a percentage of such damages or any settlement amount. If the government declines to intervene, the whistleblower may proceed on her own and, if she is successful, she will receive a percentage of any judgment or settlement amount the company is required to pay. The government may also initiate an investigation on its own. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable business. In particular, if our operations are found to be in violation of any of the laws described above or if we agree to settle with the government without admitting to any wrongful conduct or if we are found to be in violation of any other governmental regulations that apply to us, we, our officers and employees may be subject to sanctions, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, the curtailment or restructuring of our operations and the imposition of a corporate integrity agreement, any of which could adversely affect our business, results of operations and financial condition.

We and our research and development partners' use and disclosure of personally identifiable information, including health information, is subject to federal and state privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, business, financial condition and results of operations.

Numerous state and federal laws and regulations, including HIPAA, govern the collection, dissemination, use, privacy, confidentiality, security, availability and integrity of PII, including protected health information. HIPAA establishes a set of basic national privacy and security standards for the protection of PHI by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services, which likely includes us. HIPAA requires healthcare providers and business associates to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical, and technical safeguards to protect such information. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims. HIPAA imposes mandatory penalties for certain violations. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts will be able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities or business associates for compliance with the HIPAA Privacy and Security Standards. HIPAA further requires that patients be notified of any unauthorized acquisition, access, use or disclosure of their unsecured PHI that compromises the privacy or security of such information, with certain exceptions related to unintentional or inadvertent use or disclosure by employees or authorized individuals. HIPAA specifies that such notifications must be made without unreasonable delay and in no case later than 60 calendar days after discovery of the breach. If a breach affects 500 patients or more, it must be reported to HHS without unreasonable delay, and HHS will post the name of the breaching entity on its public web site. Breaches affecting 500 patients or more in the same state or jurisdiction must also be reported to the local media. If a breach involves fewer than 500 people, the covered entity must record it in a log and notify HHS at least annually.

Numerous other federal and state laws protect the confidentiality, privacy, availability, integrity and security of PII, including PHI. These laws in many cases are more restrictive than, and may not be preempted by, the HIPAA rules and may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our clients and potentially exposing us to additional expense, adverse publicity and liability. In addition, new health information standards, whether implemented pursuant to HIPAA, congressional action or otherwise, could have a significant effect on the manner in which we must handle healthcare related data, and the cost of complying with standards could be significant. If we do not comply with existing or new laws and regulations related to PHI, we could be subject to criminal or civil sanctions.

Because of the extreme sensitivity of the PII we or our partners may store and transmit, the security features of our technology platforms are very important. If our security measures, some of which may be managed by third parties, are breached or fail, unauthorized persons may be able to obtain access to sensitive client and patient data, including HIPAA-regulated PHI. As a result, our reputation could be severely damaged, adversely affecting client or investor confidence. Clients may curtail their use of or stop using our products and services, which would cause our business to suffer. In addition, we could face litigation, damages for contract breach, penalties and regulatory actions for violation of HIPAA and other applicable laws or regulations and significant costs for remediation, notification to individuals and for measures to prevent future occurrences. Any potential security breach could also result in increased costs associated with liability for stolen assets or information, repairing system damage that may have been caused by such breaches, incentives offered to client or other business partners in an effort to maintain our business relationships after a breach and implementing measures to prevent future occurrences, including organizational changes, deploying additional personnel and protection technologies, training employees and engaging third-party experts and consultants. While we maintain insurance covering certain security and privacy damages and claim expenses, our coverage may not be sufficient to compensate for all liability.

Government regulation of healthcare creates risks and challenges with respect to our compliance efforts and our business strategies.

The healthcare industry is highly regulated and is subject to changing political, legislative, regulatory, and other influences. Existing and new laws and regulations affecting the healthcare industry could create unexpected liabilities for us, could cause us to incur additional costs, and could restrict our operations. Many healthcare laws are complex, and their application to specific products and services may not be clear. In particular, many existing healthcare laws and regulations, when enacted, did not anticipate the services that we aim to provide. However, these laws and regulations may nonetheless be applied to our business. Our failure to accurately anticipate the application of these laws and regulations, or other failure to comply, could create liability for us, result in adverse publicity and materially affect its business, financial condition, and results of operations.

If we fail to comply with extensive healthcare laws and government regulations, we could suffer penalties or be required to make significant changes to our operations.

The healthcare industry is required to comply with extensive and complex laws and regulations at the federal, state and local government levels relating to, among other things:

- licensure of health providers, certification of organizations and enrollment with government reimbursement programs;

- necessity and adequacy of medical care;
- relationships with physicians and other referral sources and referral recipients;
- billing and coding for services;
- properly handling overpayments;
- quality of medical equipment and services;
- qualifications of medical and support personnel;
- confidentiality, maintenance, data breach, identity theft and security issues associated with health-related and personal information and medical records; and
- communications with patients and consumers.

Among these laws are the federal Stark Law, the federal Anti-Kickback Statute, the FCA, and similar state laws. If we fail to comply with applicable laws and regulations, we could suffer civil sanctions and criminal penalties, including the loss of our ability to participate in the Medicare, Medicaid and other federal and state healthcare programs. While we endeavor to ensure that our financial relationships with referral sources such as hospitals and physicians comply with the applicable laws (including applicable safe harbors and exceptions), evolving interpretations or enforcement of these laws and regulations could subject our current practices to allegations of impropriety or illegality or could require us to make changes in our operations. A determination that we have violated these or other laws, or the public announcement that we are being investigated for possible violations of these or other laws, could have a material adverse effect on our business, financial condition, results of operations or prospects, and our business reputation could suffer significantly. In addition, other legislation or regulations at the federal or state level may be adopted that adversely affect our business.

Our officers, employees, independent contractors, principal investigators, consultants, and commercial partners may engage in misconduct or activities that are improper under other laws and regulations, which would create liability for us.

We are exposed to the risk that our officers, employees, independent contractors (including contract research organizations CROs), principal investigators, consultants and commercial partners may engage in fraudulent conduct or other illegal activity and/or may fail to disclose unauthorized activities to us. Misconduct by these parties could include, but is not limited to, intentional, reckless and/or negligent failures to comply with:

- the laws and regulations of the FDA and its foreign counterparts requiring, among other things, compliance with good manufacturing practice and/or quality system requirements, post-market vigilance reporting, product marketing authorization requirements, facility registration requirements, the reporting of true, complete and accurate information to such regulatory bodies, including but not limited to safety problems associated with the use of our products;
- laws and regulations of the FDA and its foreign counterparts concerning the conduct of clinical trials and the protection of human research subjects, including but not limited to good clinical practices;
- other laws and regulations of the FDA and its foreign counterparts relating to the manufacture, processing, packing, holding, investigating or distributing in commerce of medical devices, biological products and/or HCT/Ps;
- manufacturing standards we have established; or
- healthcare fraud and abuse laws, including but not limited to, the Anti-Kickback Statute, the Stark Law, the FCA, and state law equivalents.

In particular, companies involved in the manufacture of medical products are subject to laws and regulations intended to ensure that medical products that will be used in patients are safe and effective, and, specifically, that they are not adulterated or misbranded, that they are properly labeled, and have the identity, strength, quality and purity that which they are represented to possess. Further, companies involved in the research and development of medical products are subject to extensive laws and regulations intended to protect research subjects and ensure the integrity of data generated from clinical trials and of the regulatory review process. Any misconduct in any of these areas, whether by our own employees or by contractors, vendors, business associates, consultants, or other entities acting as our agents, could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation. Although we have a comprehensive compliance program designed to ensure that our employees', CRO partners', principal investigators', consultants', and commercial partners' activities and interactions with healthcare professionals and patients are appropriate, ethical, and consistent with all applicable laws, regulations, guidelines, policies and standards, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, or our CRO partners, principal investigators, consultants, or commercial partners, those actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable business.

We could be adversely affected if healthcare reform measures substantially change the market for medical care or healthcare coverage in the United States.

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (P.L. 111-148) and on March 30, 2010, the signed the Health Care and Education Reconciliation Act (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the system for paying for healthcare in the United States, including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the healthcare industry in the United States and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals and medical devices. This attention may result in our current commercial products, products we may commercialize or promote in the future, and our therapeutic candidates, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare and Medicaid), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for medical services and procedures, prescribed drugs, biologics and medical devices, including our current commercial products, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for the products we currently commercialize or promote, any product we may commercialize or promote, or approved therapeutic candidates is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with any pharmaceutical product we commercialize or promote are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U.S. federal government, which may force significant additional changes to the healthcare system in the United States. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including our current commercial products, our development or commercialization partners or any product or medical service we may commercialize or promote), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for our current commercial products, any product we may commercialize or promote or for which we receive marketing approval or clearance in the future, could have a material adverse effect on our reputation, business, financial condition, or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the Healthcare Reform Law at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, the states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the Healthcare Reform Law and judicial challenges continue. We cannot predict the impact on our business of future legislative and legal challenges to the Healthcare Reform Law or other changes to the current laws and regulations. The uncertainty around the future of the Healthcare Reform Law, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of medical products and services. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

While in office, President Trump supported the repeal of all or portions of the Healthcare Reform Law. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Healthcare Reform Law and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Healthcare Reform Law to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the Healthcare Reform Law, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the Healthcare Reform Law's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the Healthcare Reform Law and was intended to reduce the rate of growth in Medicare spending).

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S. or the effect of any future legislation or regulation. Furthermore, we cannot predict what actions the Biden administration will implement in connection with the Healthcare Reform Law. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the U.S. in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we currently, or intend to, commercialize in the U.S. or that reduce medical procedure volumes could adversely affect our operations and/or future business plans.

Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, litigation and negative publicity that could materially adversely affect our reputation, business, results of operations and financial condition.

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Quality and safety issues may occur with respect to any of our products, and our future operating results will depend on our ability to maintain an effective quality control system and effectively train and manage our workforce with respect to our quality system. The development, manufacture and control of medical devices are subject to extensive and rigorous regulation by numerous government agencies, including the FDA and similar foreign agencies. Compliance with these regulatory requirements, including but not limited to the FDA's QSR, good manufacturing practices and adverse events/recall reporting requirements in the United States and other applicable regulations worldwide, is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory authorities. The FDA and foreign regulatory authorities may also require post-market testing and surveillance to monitor the performance of products cleared or approved for use in their jurisdictions. Our manufacturing facilities and those of our suppliers and independent sales agencies are also subject to periodic regulatory inspections. If the FDA or other regulatory authority were to conclude that we or our suppliers have failed to comply with any of these requirements, it could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions, such as product recalls or seizures, withdrawals, monetary penalties, consent decrees, injunctive actions to halt the manufacture or distribution of products, import detentions of products made outside the United States, export restrictions, restrictions on operations or other civil or criminal sanctions. Civil or criminal sanctions could be assessed against our officers, employees, or us. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing, and selling our products.

In addition, we cannot predict the results of future legislative activity or future court decisions, any of which could increase regulatory requirements, subject us to government investigations or expose us to unexpected litigation. Any regulatory action or litigation, regardless of the merits, may result in substantial costs, divert management's attention from other business concerns and place additional restrictions on our sales or the use of our products. In addition, negative publicity, including regarding a quality or safety issue, could damage our reputation, reduce market acceptance of our products, cause us to lose customers and decrease demand for our products. Any actual or perceived quality issues may also result in issuances of physician's advisories against our products or cause us to conduct voluntary recalls. Any product defects or problems, regulatory action, litigation, negative publicity or recalls could disrupt our business and have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Ownership of Our Common Stock

The issuance of shares upon the exercise of derivative securities may cause immediate and substantial dilution to our existing shareholders.

In the future, we may issue additional shares of common stock or other securities convertible into or exchangeable for shares of common stock. For instance, certain of the product license agreements we have entered into with third parties require us to make payments to such third parties upon the occurrence of certain events. Pursuant to these product license agreements, we may choose to make such payments in shares of our common stock. The issuance of additional shares of our common stock may substantially dilute the ownership interests of our existing shareholders. Furthermore, sales of a substantial amount of our common stock in the public market, or the perception that these sales may occur, could reduce the market price of our common stock. This could also impair our ability to raise additional capital through the sale of our securities.

It is possible that we will require additional capital to meet our financial obligations and support business growth.

We intend to continue to make significant investments to support our business growth and expect to require additional funds to respond to business challenges. Accordingly, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through future issuances of equity or convertible debt securities, our existing shareholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing that we secure in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when and if we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly impaired, and our business may be harmed.

The trading price of the shares of our common stock is highly volatile, and purchasers of our common stock could incur substantial losses.

The market price of our common stock has been and is likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or by our competitors, including announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships or capital commitments;
- additions or departures of key personnel;
- changes in expectations as to our future financial performance;
- the continued impact of the COVID-19 pandemic on our business operations;
- sales of our common stock;
- our ability to execute our business plan;
- loss of any strategic relationship;
- industry developments;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- general market conditions, including market volatility;

- fluctuations in stock market prices and trading volumes of similar companies;
- economic, political and other external factors;
- period-to-period fluctuations in our financial results;
- applicable regulatory developments in the United States and foreign countries, both generally or specific to us and our products; and
- intellectual property, product liability or other litigation against us.

Although publicly traded securities are subject to price and volume fluctuations, it is likely that our common stock will experience these fluctuations to a greater degree than the securities of more established and better capitalized organizations.

Our common stock does not have a vigorous trading market, and you may not be able to sell your securities at or near ask prices, or at all.

Although there is a public market for our common stock, trading volume has been historically low, which could impact our stock price and your ability to sell shares of our common stock at or near ask prices, or at all. We can give no assurance that a more active and liquid public market for the shares of our common stock will develop in the future.

The potential sale of large amounts of common stock may have a negative effect upon the market value of our shares.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price of our common stock.

We have not paid, and we are unlikely to pay, cash dividends on our securities in the near future. Because we have no current plans to pay cash dividends on our common stock for the foreseeable future, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We have not paid and do not currently intend to pay dividends on our common stock, which may limit the current return available on an investment in our stock. Future dividends on our stock, if any, will depend on our future earnings, capital requirements, financial condition and such other factors as our management may consider relevant. Currently, we intend to retain earnings, if any, to increase our net worth and reserves. Consequently, shareholders will only realize an economic gain on their investment in our common stock if the price appreciates. Shareholders should not purchase our common stock expecting to receive cash dividends. Because we currently do not pay dividends, and there may be limited trading in our common stock, shareholders may not have any manner to liquidate or receive any payment on their common stock. Therefore, our failure to pay dividends may cause shareholders to not see any return on their common stock even if we are successful in our business operations. In addition, because we do not pay dividends, we may have trouble raising additional funds, which could affect our ability to expand our business operations.

A few of our existing shareholders own a large percentage of our voting stock and have control over matters requiring shareholder approval and may delay or prevent a change in control or otherwise lead to actual or potential conflicts of interest.

As of March 30, 2022, our directors controlled through their affiliates more than 50% of our outstanding common stock. As a result, our directors and their affiliates could have the ability to exert substantial influence over all matters requiring approval by our shareholders, including (i) the election and removal of directors, (ii) any proposed merger, consolidation, or sale of all or substantially all of our assets as well as other corporate transactions and (iii) any amendment to our Certificate of Formation, as amended (the "Certificate of Formation"). This concentration of control could be disadvantageous to other shareholders having different interests. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors sometimes perceive disadvantages in owning stock in companies with controlling shareholders.

In addition, our Certificate of Formation contains a provision which under the Texas Business Organizations Code (the "TBOC") could allow the shareholders who own a majority of our common stock to approve certain major transactions without the approval of other shareholders that otherwise would be required under Texas corporation law.

Our Certificate of Formation includes provisions limiting the personal liability of our directors for breaches of fiduciary duties under Texas law.

Our Certificate of Formation contains a provision eliminating a director's personal liability to the fullest extent permitted under Texas law. Pursuant to the TBOC, a corporation has the power to indemnify its directors and officers against judgments and certain expenses other than judgments that are actually and reasonably incurred in connection with a proceeding, provided that there is a determination that the individual acted in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal proceeding, had no reasonable cause to believe the individual's conduct was unlawful. However, no indemnification may be made in respect of any proceeding in which such individual is liable to the corporation or improperly received a personal benefit and is found liable for willful misconduct, breach of the duty of loyalty owned to the corporation, or an act or omission deemed not to be committed in good faith.

The principal effect of the limitation on liability provision is that a shareholder will be unable to prosecute an action for monetary damages against a director unless the shareholder can demonstrate a basis for liability for which indemnification is not available under the TBOC. This provision, however, should not limit or eliminate our rights or any shareholder's rights to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of a director's fiduciary duty. This provision will not alter a director's liability under federal securities laws. The inclusion of this provision in our Certificate of Formation may discourage or deter shareholders or management from bringing a lawsuit against directors for a breach of their fiduciary duties, even though such an action, if successful, might otherwise have benefited us and our shareholders.

Texas law and our Certificate of Formation and bylaws contain anti-takeover provisions that could delay or discourage takeover attempts that shareholders may consider favorable.

Under our Certificate of Formation, our board of directors can authorize the issuance of preferred stock, which could diminish the rights of holders of our common stock and make a change of control of the Company more difficult even if it might benefit our shareholders. The board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our shareholders.

In addition, provisions of our Certificate of Formation and Bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which shareholders might otherwise receive a premium for their shares, or transactions that our shareholders might otherwise deem to be in their best interests. For example, our Certificate of Formation and bylaws (i) do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose), (ii) require that special meetings of the shareholders be called by the Chairman of the board of directors, the President or the board of directors, or by the holders of not less than ten percent (10%) of all the shares issued, outstanding and entitled to vote, (iii) permit our board of directors to alter, amend or repeal our bylaws or to adopt new bylaws, and (iv) enable our board of directors to increase the number of persons serving as directors and to fill vacancies created as a result of the increase by a majority vote of the directors present at a meeting of directors.

While we are subject to the provisions of Title 2, Chapter 21, Subchapter M of the TBOC, which provides that a Texas corporation that qualifies as an "issuing public corporation" (as defined in the TBOC) may not engage in specified types of business combinations, including mergers, consolidations and asset sales, with a person, or an affiliate or associate of that person, who is an "affiliated shareholder," the restrictions in Title 2, Chapter 21, Subchapter M of the TBOC do not apply to us because we have elected, in the manner provided under the TBOC, not to be subject to such provisions.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

Our shares of common stock are currently listed for trading on The Nasdaq Capital Market under the symbol "SMTI." If we fail to satisfy the continued listing requirements of The Nasdaq Stock Market, LLC ("Nasdaq"), such as the corporate governance requirements, the shareholder's equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting or even notification of failure to comply with such requirements would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we expect that we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any buildings or other real property. We have two material operating leases for office space. Our leased office space in Fort Worth, Texas consists of 5,877 square feet of rentable space located in Summit Office Park, a twin-building, mid-rise, 242,000 square foot office park located on the perimeter of the Fort Worth central business district. The lease has a remaining lease term of thirty months as of December 31, 2021. The monthly base rental payments for our Fort Worth office lease are as follows:

From	Through	Monthly Base Rental
July 1, 2021	June 30, 2022	$ 12,489
July 1, 2022	June 30, 2023	$ 12,734
July 1, 2023	June 30, 2024	$ 12,978

Our leased office space in San Antonio, Texas consists of 7,289 square feet of rentable space located in a 14,500 square foot office park in an industrial district in San Antonio, Texas. This lease expires August 31, 2022. The base monthly rent was $8,504 through August 31, 2021, then increased to $8,808 for the remainder of the lease. The Company intends to renew this lease in mid-2022.

As of December 31, 2021, our operating leases have a weighted average remaining lease term of 2.2 years and a weighted average discount rate of 5.9%.

We periodically enter into operating lease contracts for office space and equipment. Arrangements are evaluated at inception to determine whether such arrangements constitute a lease. In accordance with the transition guidance of Accounting Standards Codification (“ASC”) Topic No. 842, such arrangements are included in our balance sheet as of January 1, 2020.

See **Note 7** to the financial statements for additional information on our operating leases.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in claims and legal actions that arise in the ordinary course of business. To our knowledge, there are no material pending legal proceedings to which we are a party or of which any of our property is the subject.

ITEM 4. MINE SAFETY DISCLOSURES

This item is not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on The Nasdaq Capital Market under the trading symbol "SMTI." The closing price of our common stock as reported by Nasdaq on March 29, 2022 was $27.78.

Record Holders

As of March 30, 2022, there were 238 shareholders of record and there were 7,813,738 shares of common stock issued and outstanding. The number of shareholders of record does not reflect the number of persons or entities who held stock in nominee or street name through various brokerage firms.

Dividends

We have never declared or paid any cash dividends on our common stock and we do not intend to pay cash dividends in the foreseeable future. We currently expect to retain any future earnings to fund our operations and the expansion of our business.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during the year ended December 31, 2021 that were not previously reported on a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2021.

ITEM 6. [RESERVED]

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

The following discussion and analysis contains forward-looking statements about future revenues, operating results, plans and expectations. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in Part I, "Item 1A. Risk Factors." Also, please read the "Cautionary Statement Regarding Forward-Looking Statements" set forth at the beginning of this Annual Report on Form 10-K.

In addition, the following discussion should be read in conjunction with Part I of this Annual Report on Form 10-K as well as our consolidated financial statements and the related Notes contained elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical technology company focused on developing and commercializing transformative technologies to improve clinical outcomes and reduce healthcare expenditures in the surgical and chronic wound and skin care markets. Our portfolio of products and services will allow us to deliver comprehensive wound and skin care solutions for patients in all care settings, including acute (hospitals and long-term acute care hospitals ("LTACHs")) and post-acute (wound care clinics, physician offices, skilled nursing facilities ("SNFs"), home health, hospice, and retail). Each of our products, services, and technologies contributes to our overall goal of achieving better clinical outcomes at a lower overall cost for patients regardless of where they receive care. We strive to be one of the most innovative and comprehensive providers of effective wound and skin care products and technologies and are continually seeking to expand our offerings for patients requiring wound and skin care treatments across the entire continuum of care in the United States.

We currently market several products across surgical and chronic wound care applications and have multiple products in our pipeline. We license our products from Applied Nutritionals, LLC ("AN") (through a sublicense with CGI Cellerate RX, LLC ("CGI Cellerate RX"), an affiliate of The Catalyst Group, Inc. ("Catalyst")) and Rochal Industries, LLC ("Rochal") and have the right to exclusively distribute certain products manufactured by Cook Biotech Inc. ("Cook Biotech").

In June 2020, we formed a subsidiary, United Wound and Skin Solutions LLC ("UWSS", or "WounDerm"), to hold certain investments and operations in wound and skin care virtual consult services. We anticipate that our various service offerings will allow clinicians/physicians utilizing our technologies to collect and analyze large amounts of data on patient conditions and outcomes that will improve treatment protocols and ultimately lead to more evidence-based formulary to improve patient outcomes. Through a combination of our WounDerm services and our Sanara products, we believe we will be able to offer patient care solutions at every step in the continuum of wound and skin care from diagnosis through healing.

Effective July 1, 2021, we acquired certain assets from Rochal, including, among others, intellectual property, four FDA 510(k) clearances, rights to license certain products and technologies currently under development, equipment and supplies. As a result of the asset purchase, our pipeline now contains product candidates for mitigation of opportunistic pathogens and biofilm, wound re-epithelialization and closure, necrotic tissue debridement and cell compatible substrates.

Impact of the COVID-19 Pandemic

Beginning in March 2020, many states issued orders suspending elective surgeries in order to free-up hospital resources to treat COVID-19 patients. This resulted in a reduction in demand for our surgical products beginning in the second half of March 2020. Additionally, most states limited access to SNFs to only resident caregivers, which impeded our ability to provide education and product training to the clinicians who use our products in these facilities. These restrictions resulted in an overall decline in sales for the second quarter of 2020. During the second half of 2020 and the first quarter of 2021, we saw a strong rebound in product sales as restrictions on elective surgeries eased in our primary markets in Texas, Florida, and the southeastern United States. During the second half of 2021, the United States experienced a surge of COVID-19 cases as the Delta and Omicron variants of the virus impacted much of the country and negatively impacted our sales in Texas, the northeastern United States, and other markets.

The duration and effects of the pandemic remain uncertain; however, management believes that elective surgical procedures will continue to be performed with the exception of certain geographic hotspots. Additionally, management believes that the majority of surgical procedures impacted by COVID-19 and its variants will ultimately be performed. We will continue to closely monitor the pandemic in order to ensure the safety of our people and our ability to serve our customers and patients.

Components of Results of Operations

Sources of Revenues

Our revenue is derived primarily from sales of our surgical wound care products to hospitals and other acute care facilities, and sales of our chronic wound care products to customers across the post-acute continuum of care. Our revenue is driven by direct orders shipped by us to our customers, and to a lesser extent, direct sales to customers through delivery at the time of procedure by one of our sales representatives. We generally recognize revenue when our product is received by the customer.

The vast majority of our product sales revenue is derived from sales of CellerateRX surgical powder. Revenue streams from product sales and royalties are summarized below for the years ended December 31, 2021 and 2020. All revenue was generated in the United States.

	Year Ended December 31,	
	2021	**2020**
Product sales revenue	$ 23,942,919	$ 15,385,976
Royalty revenue	201,000	201,000
Total Revenue	$ 24,143,919	$ 15,586,976

We recognize royalty revenue from a development and licensing agreement with BioStructures, LLC. We record revenue each calendar quarter as earned per the terms of the agreement, which stipulates that we will receive quarterly royalty payments of at least $50,250. Under the terms of the development and license agreement, royalties of 2.0% are recognized on sales of products containing our patented resorbable bone hemostasis. The minimum annual royalty due to us is $201,000 per year throughout the life of the patent, which expires in 2023. These royalties are payable in quarterly installments of $50,250. To date, royalties related to this development and licensing agreement have not exceeded the annual minimum of $201,000 ($50,250 per quarter).

Cost of Goods Sold

Cost of goods sold consists of the acquisition costs from the manufacturers of our licensed products, raw material costs for certain components sourced directly by our Company, and all royalties related due as a result of the sale of our products. Our gross profit represents total revenue less the cost of goods sold, and gross margin is gross profit expressed as a percentage of total revenue.

Operating Expenses

Selling, general and administrative expenses ("SG&A") consist primarily of salaries, sales commissions, benefits, bonuses, and stock-based compensation. SG&A also includes outside legal counsel, audit fees, insurance premiums, rent, and other corporate expenses. We expense all SG&A expenses as incurred. We expect our SG&A expenses to increase in absolute dollars and decrease as a percent of revenue as we grow our commercial organization.

Research and development expenses ("R&D") include costs related to enhancements to our currently available products and additional investments in our product and platform development pipelines. This includes personnel-related expenses, including salaries and benefits for all personnel directly engaged in R&D activities, contracted services, materials, prototype expenses and allocated overhead, which is comprised of lease expense and other facilities-related costs. We expense R&D costs as incurred. We generally expect that R&D expenses will increase as we continue to support product enhancements as well as to bring new products to market.

Other Income (Expense)

Other income (expense) is primarily comprised of gains or losses on equity method investments, interest income, interest expense and other non-operating activities. Interest income consists of interest earned on our cash and cash equivalents.

Results of Operations

Revenues. For the year ended December 31, 2021, we generated revenues of $24,143,919 compared to revenues of $15,586,976 for the year ended December 31, 2020, a 55% increase from the prior year. The higher revenues in 2021 were due to increased sales of surgical wound care products as we continued the execution of our strategy to expand our sales force and independent distribution network in both new and existing U.S. markets. As discussed above under "—Impact of the COVID-19 Pandemic," our sales have been adversely impacted in 2020 and 2021 as a result of the COVID-19 pandemic, and the duration and future impact of the pandemic remain uncertain.

Cost of goods sold. Cost of goods sold for the year ended December 31, 2021 was $2,311,221, compared to costs of goods sold of $1,616,625 for the year ended December 31, 2020. The increase over the prior year was primarily due to higher sales volume. Gross margins were approximately 90% for both years ended December 31, 2021 and 2020.

Selling, general and administrative expenses **("SG&A").** SG&A expenses for the year ended December 31, 2021 were $28,053,176, compared to SG&A expenses of $18,673,404 for the year ended December 31, 2020. The higher SG&A expenses in 2021 were primarily due to increased selling costs resulting from sales force expansion and operational support, higher sales commission expense as a result of higher product sales, higher non-cash equity compensation costs, higher payroll costs related to the mid-year addition of the Rochal workforce, and higher costs associated with the launch of our WounDerm technology platform. In addition, costs related to travel and in-person promotional activities increased in 2021 compared to 2020 as many in-person activities were cancelled or postponed in 2020 as a result of the COVID-19 pandemic. As part of our continued strategy to expand our sales reach in new and existing markets, we employed eleven additional field sales managers since December 31, 2020. As of December 31, 2021, we had a total of 30 field sales managers.

Research and development expenses. R&D expenses for the year ended December 31, 2021 were $558,704 compared to $40,190 for the year ended December 31, 2020. The higher R&D expenses in 2021 were due to costs associated with several development projects for our currently licensed products and technologies.

Depreciation and amortization expense. Depreciation and amortization expense for the period ended December 31, 2021 was $596,975 compared to $291,370 for the year ended December 31, 2020. The higher depreciation and amortization expense in 2021 was due to the amortization of internal use software placed into service in 2021, and due to additional amortization related to the patents acquired from Rochal.

Other expense. Other expense for the year ended December 31, 2021 was $617,638 compared to other income of $589,468 for the year ended December 31, 2020. The higher expense in 2021 was due to the recognition of a non-cash loss of $616,927 from our equity method investment in Precision Healing Inc. ("Precision Healing"). Interest expense was $711 for the year ended December 31, 2021, as compared to $11,528 for the year ended December 31, 2020. The higher interest expense in 2020 was due to interest expense associated with our unsecured promissory note under the Paycheck Protection Program (described in further detail below), and interest on a convertible promissory note which was converted to common stock in early 2020.

Net income / loss. For the year ended December 31, 2021, we had a net loss of $7,993,795, compared to net loss of $4,445,145 for the year ended December 31, 2020. The higher net loss in 2021 was due to increased SG&A costs described above, higher R&D expenses, and the recognition of losses on our equity method investment.

Liquidity and Capital Resources

Cash on hand at December 31, 2021 was $18,652,841, compared to $455,366 at December 31, 2020. Historically, we have financed our operations primarily from the sale of equity securities. In 2020, our principal sources of liquidity were cash generated from operations, availability of our bank line of credit, and cash provided by an unsecured promissory note under the Paycheck Protection Program in the principal amount of $583,000 (the "PPP Loan") to Cadence Bank, N.A. ("Cadence"). All principal and interest under the PPP Loan were forgiven in 2020. On February 12, 2021, we closed an underwritten public offering of 1,265,000 shares of our common stock (including 165,000 shares of common stock issued pursuant to the full exercise by the underwriters of their option to purchase additional shares of common stock) at a public offering price of $25.00 per share, resulting in gross proceeds of $31,625,000, before deducting underwriting discounts and commissions and offering expenses. We expect our future needs for cash to include expanding our salesforce, further development of our products, services and technologies pipeline, clinical studies and general corporate purposes, including working capital and acquisitions. Based on our current plan of operations, including potential acquisitions, we believe our cash on hand, when combined with expected cash flows from operations, will be sufficient to fund our growth strategy and to meet our anticipated operating expenses and capital expenditures for at least the next twelve months. However, our ability to generate sufficient cash flows from operations or fund any potential future acquisitions or other similar transactions depends on operating and economic conditions, some of which are beyond our control. If additional capital is needed, we may not be able to obtain debt or equity financing on terms favorable to us, or at all. We are continuing to evaluate all uses of cash, including opportunistic acquisitions, and whether to pursue growth opportunities and whether such growth opportunities, additional sources of liquidity, including equity and/or debt financings, are appropriate to fund any such growth opportunities.

On January 15, 2021, we entered into a new loan agreement with Cadence (the "Loan Agreement"), providing for a $2.5 million revolving line of credit. Pursuant to the terms of the Loan Agreement, the revolving line of credit was set to mature on January 13, 2023 and was secured by substantially all of our assets.

On February 11, 2021, we made an $800,000 draw on the revolving line of credit. On February 19, 2021, we paid down the entire balance of the revolving line of credit. Effective March 25, 2022, we terminated Loan Agreement and released Cadence from any obligation to make advances under the Loan Agreement. No amounts of principal, interest or other fees and expenses were owed by the Company as of the termination date. There is no assurance that we will enter into an additional loan agreement with Cadence or with another bank on similar terms, or at all.

On November 9, 2020, we entered into agreements to purchase shares of Series A Convertible Preferred Stock (the "Series A Stock") of Precision Healing for an aggregate purchase price of $600,000. In 2021, we made additional purchases of Series A Stock as follows: $600,000 in February, $500,000 in June, $500,000 in October, and $600,000 in December of 2021.

On July 7, 2019, we executed a license agreement with Rochal whereby we acquired an exclusive world-wide license to market, sell and further develop antimicrobial products for the prevention and treatment of microbes on the human body utilizing certain Rochal patents and pending patent applications (the "BIAKŌS License Agreement"). Under the terms of the BIAKŌS License Agreement, we agreed to pay Rochal $750,000 upon the completion of a capital raise, on or before December 31, 2022, of at least $10,000,000 through the sale of our common stock or assets. In March 2021, we issued 20,834 shares of our common stock to Rochal as full payment of the $750,000, which became due upon the completion of our capital raise in February 2021.

On June 3, 2021, we invested $2,084,278 for 278,587 Class A Preferred Shares (the "Shares") of Canada based Pixalere Healthcare, Inc. ("Pixalere"). The Shares are convertible into 28.6% of the outstanding equity of Pixalere. Pixalere provides a cloud-based wound care software tool that empowers nurses, specialists and administrators to deliver better care for patients. In connection with our purchase of the Shares, Pixalere granted Pixalere Healthcare USA, LLC ("Pixalere USA"), our subsidiary, a royalty-free exclusive license to use the Pixalere software and platform in the United States. In conjunction with the grant of the license, we issued Pixalere a 27.3% equity ownership interest in Pixalere USA.

On July 14, 2021, we entered into an asset purchase agreement with Rochal, effective July 1, 2021, pursuant to which we purchased certain assets of Rochal, including, among others, certain of Rochal's intellectual property, furniture and equipment, supplies, rights and claims, other than certain excluded assets, and assumed certain liabilities upon the terms and subject to the conditions set forth in the asset purchase agreement. In exchange for the acquired assets, we paid Rochal (i) $496,100 in cash and (ii) 14,369 shares of common stock.

On July 17, 2020, we purchased Series B-2 Preferred Shares of Direct Dermatology Inc. for $500,000. We made additional investments in the Series B-2 Preferred Shares in the amounts of $125,000 in November 2021 and $125,000 in December of 2021.

For the year ended December 31, 2021, net cash used in operating activities was $4,814,526 compared to $4,034,518 used in operating activities for the year ended December 31, 2020. The higher use of cash in 2021 was primarily due to higher operating expenses related to sales force expansion, research and development, and the launch of our WounDerm technology platform.

For the year ended December 31, 2021, net cash used in investing activities was $5,284,731 compared to $2,744,374 used in investing activities during the year ended December 31, 2020. The cash used in investing activities during 2021 included $496,100 for the Rochal asset acquisition, and our investments in non-marketable equity securities including $2.2 million for Precision Healing Inc. Series A-2 Preferred Shares, $2.0 million for Pixalere Healthcare Inc. Class A Preferred Shares, and $250,000 for DirectDerm Series B-2 Preferred Shares.

For the year ended December 31, 2021, net cash provided by financing activities was $28,296,732 as compared to $622,330 provided by financing activities for the year ended December 31, 2020. The higher cash provided by financing activities in 2021 was due to proceeds received pursuant to an underwritten public offering of 1,265,000 shares of our common stock at a public offering price of $25.00 per share resulting in gross proceeds of $31,625,000, before underwriting discounts, commissions and other offering expenses.

Material Transactions with Related Parties

CellerateRx Sublicense Agreement

We have an exclusive, world-wide sublicense to distribute CellerateRX products into the wound care and surgical markets from an affiliate of Catalyst, CGI Cellerate RX, which licenses the rights to CellerateRX from AN. Sales of CellerateRX comprise the vast majority of our sales. On January 26, 2021, we amended the term of the sublicense agreement to extend the term to May 17, 2050, with automatic one-year renewals so long as annual net sales of CellerateRX exceed $1,000,000. We pay royalties based on our annual net sales of CellerateRX consisting of 3% of all collected net sales each year up to $12,000,000, 4% of all collected net sales each year that exceed $12,000,000 up to $20,000,000, and 5% of all collected net sales each year that exceed $20,000,000. Minimum royalties of $400,000 per year are payable for the first five years of the sublicense agreement, which was entered on August 27, 2018. For the years ended December 31, 2021 and 2020, royalty expense recognized under the terms of this agreement totaled $856,755 and $479,809, respectively.

Ronald T. Nixon, our Executive Chairman, is the founder and managing partner of Catalyst. Mr. Nixon and Catalyst, collectively with their affiliates, including CGI Cellerate RX, beneficially owned 3,519,019 shares, or 46%, of our common stock as of December 31, 2021.

Convertible Notes Payable

In connection with the Cellerate Acquisition, we issued a 30-month convertible promissory note to CGI Cellerate RX, an affiliate of Catalyst, in the principal amount of $1,500,000, bearing interest at 5% per annum, compounded quarterly. Interest on the promissory note was payable quarterly but could have been deferred at our election to the maturity of the promissory note. Outstanding principal and interest were convertible at CGI Cellerate RX's option into shares of our common stock at a conversion price of $9.00 per share.

On February 7, 2020, CGI Cellerate RX converted its $1,500,000 promissory note, including accrued interest of $111,911, into 179,101 shares of our common stock.

Payables

We had outstanding payables to related parties totaling $155,817 at December 31, 2021, and $223,589 at December 31, 2020.

Receivables

We had outstanding receivables to a related party totaling $79,787 at December 31, 2021, and $0 at December 31, 2020.

Product License Agreements

On July 7, 2019, the Company executed a license agreement with Rochal, a related party, whereby the Company acquired an exclusive world-wide license to market, sell and further develop antimicrobial products for the prevention and treatment of microbes on the human body utilizing certain Rochal patents and pending patent applications (the "BIAKŌS License Agreement"). Currently, the products covered by the BIAKŌS License Agreement are BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser. Both products are 510(k) approved. The Company's Executive Chairman is a director of Rochal, and indirectly a significant shareholder of Rochal, and through the potential exercise of warrants, a majority shareholder of Rochal. Another one of the Company's directors is also a director and significant shareholder of Rochal.

On October 1, 2019, the Company executed a license agreement with Rochal whereby the Company acquired an exclusive world-wide license to market, sell and further develop certain antimicrobial barrier film and skin protectant products for use in the human health care market utilizing certain Rochal patents and pending patent applications (the "ABF License Agreement"). Currently, the products covered by the ABF License Agreement are CuraShield Antimicrobial Barrier Film and a no sting skin protectant product.

On May 4, 2020, The Company executed a product license agreement with Rochal, whereby the Company acquired an exclusive world-wide license to market, sell and further develop a debrider for human medical use to enhance skin condition or treat or relieve skin disorders, excluding uses primarily for beauty, cosmetic, or toiletry purposes.

Manufacturing and Technical Services Agreements

On September 9, 2020, we executed a manufacturing agreement with Rochal. Under the terms of the manufacturing agreement, Rochal agreed to manufacture, package, and label products we licensed from Rochal. The manufacturing agreement includes customary terms and conditions. The term of the agreement is for a period of five years unless extended by the mutual consent of the parties. For the year ended December 31, 2021, we incurred no inventory manufacturing costs with Rochal. The Company terminated this agreement on August 12, 2021.

On September 9, 2020, we executed a technical services agreement with Rochal. Under the terms of the technical services agreement, Rochal will provide its expertise and services on technical service projects identified by us for wound care, skin care and surgical site care applications. The technical services agreement includes customary terms and conditions for our industry. For the year ended December 31, 2021, we incurred $337,746 of costs for Rochal technical services. The Company terminated this agreement on August 12, 2021.

Ronald T. Nixon, our Executive Chairman, is also a director of Rochal, and indirectly a significant shareholder of Rochal, and through the potential exercise of warrants a majority shareholder of Rochal. Ann Beal Salamone, a director, is a significant shareholder, the former president and current Chairman of the Board of Rochal.

Rochal Asset Acquisition

As noted above, on July 14, 2021, we entered into an asset purchase agreement with Rochal, effective July 1, 2021, pursuant to which we purchased certain assets of Rochal, including, among others, certain of Rochal's intellectual property, furniture and equipment, supplies, rights and claims, other than certain excluded assets, and assumed certain liabilities upon the terms and subject to the conditions set forth in the asset purchase agreement. In exchange for the acquired assets, we paid Rochal (i) $496,100 in cash and (ii) 14,369 shares of common stock.

Consulting Agreement

Concurrent with the Rochal asset purchase, on July 14, 2021, the Company entered into a consulting agreement with Ann Beal Salamone pursuant to which Ms. Salamone agreed to provide the Company with consulting services with respect to, among other things, writing new patents, conducting patent intelligence, and participating in certain grant and contract reporting. In consideration for the consulting services to be provided to the Company, Ms. Salamone is entitled to receive an annual consulting fee of $177,697, with payments to be paid once per month. The consulting agreement has an initial term of three years, unless earlier terminated by the Company, and is subject to renewal. Ms. Salamone is a director of the Company and is the current Chair of the board of directors of Rochal.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The results of these assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Under different assumptions or conditions, actual results may differ from these estimates. We have identified certain significant accounting policies and estimates which involve a higher degree of judgment and complexity in making certain estimates and assumptions that affect amounts reported in our consolidated financial statements, as summarized below.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, which we adopted on January 1, 2018 using the modified retrospective method. Revenues are recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to receive in exchange for transferring those goods or services. Revenue is recognized based on the following five step model:

- Identification of the contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, we satisfy a performance obligation

Impairment of Long-Lived Assets

Long-lived assets, including certain identifiable intangibles held and to be used by our Company, are reviewed for impairment whenever events or changes in circumstances, including the COVID-19 pandemic, indicate that the carrying amount of such assets may not be recoverable. We continuously evaluate the recoverability of our long-lived assets based on estimated future cash flows and the estimated liquidation value of such long-lived assets and provide for impairment if such undiscounted cash flows are insufficient to recover the carrying amount of the long-lived assets. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, undiscounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. No impairment was recorded during the years ended December 31, 2021 and 2020.

Investment in Equity Securities

Our equity investments consist of non-marketable equity securities in privately held companies without readily determinable fair values. Unless accounted for under the equity method of accounting, the investments are reported at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer.

We apply the equity method of accounting to investments when it has significant influence, but not controlling interest, in the investee. Judgment regarding the level of influence over each equity method investment includes considering key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions and material intercompany transactions. Our proportionate share of the net income (loss) resulting from these investments is reported under the line item captioned "Share of losses from equity method investment" in our consolidated statements of operations. Our equity method investments are adjusted each period for our share of the investee's income or loss and dividend paid, if any. We classify distributions received from equity method investments using the cumulative earnings approach on the consolidated statements of cash flows.

We have reviewed the carrying value of our investments and have determined there was no impairment or observable price changes as of December 31, 2021.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost computed on a first-in, first-out basis. Inventories consist of finished goods and related packaging components. We recorded inventory obsolescence expense of $251,826 for the year ended December 31, 2021 and $318,076 for the year ended December 31, 2020. The allowance for obsolete and slow-moving inventory had a balance of $333,850 at December 31, 2021, and $276,603 at December 31, 2020. We considered the impact of COVID-19 on its recorded value of inventory and determined no additional adjustment was necessary as of December 31, 2021.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect amounts reported in the financial statements and accompanying notes. The extent to which the COVID-19 pandemic may directly or indirectly impact our business, financial condition, and results of operations is highly uncertain and subject to change. We considered the potential impact of the COVID-19 pandemic on our estimates and assumptions and determined there was not a material impact on our estimates and assumptions used in preparing our consolidated financial statements as of and for the years ended December 31, 2021 and 2020; however, actual results could differ from those estimates and there may be changes to our estimates in future periods.

Income Taxes

We account for income taxes in accordance with ASC Topic No. 740, “Income Taxes.” This standard requires us to provide a net deferred tax asset or liability equal to the expected future tax benefit or expense of temporary reporting differences between book and tax accounting and any available operating loss or tax credit carry forwards.

After applying the provisions of Section 382 of the Internal Revenue Code, the unexpired net operating loss (“NOL”) carry forward at December 31, 2020 was approximately $20.7 million, of which, approximately $5.1 million generated in 2017 and prior, will expire between 2022 and 2037. Under the Tax Cuts and Jobs Act, the NOL generated during the years 2018 through 2021 of approximately $15.6 million will have an indefinite carryforward period but can generally only be used to offset 80% of taxable income in any particular year. We may be subject to certain limitations in our annual utilization of NOL carry forwards to off-set future taxable income pursuant to Section 382 of the Internal Revenue Code, which could result in NOLs expiring unused.

The components of the deferred income tax assets and liabilities consisted of the following:

	2021	2020
Deferred tax assets		
Net operating loss carry forwards	$ 4,352,201	2,827,835
Inventory reserves	70,221	58,087
Bad debt and other reserves	561,944	562,248
Accrued expenses	35,579	16,817
Other temporary differences	1,134	630
Total deferred tax assets	5,021,079	3,465,617
Deferred tax liabilities		
Depreciation and amortization	(17,001)	(32,657)
Valuation allowance	(5,004,078)	(3,432,960)
Net deferred tax asset	$ -	$ -

A 100% valuation allowance has been provided for all deferred tax assets, as our ability to generate sufficient taxable income in the future is uncertain.

Off-Balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide this information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

SANARA MEDTECH INC.
AND SUBSIDIARIES
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Sanara MedTech Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Sanara MedTech Inc. and subsidiaries (collectively, the Company) as of December 31, 2021, and the related statements of operations, changes in shareholders' equity and cash flows for the year 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 the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on the entity's financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Acquisition of Rochal Assets – Refer to Note 3 to the financial statements

Critical Accounting Matter Description

The Company entered into an asset purchase agreement with Rochal Industries, LLC, a related party, to acquire certain assets during the year ended December 31, 2021. Management has recorded this transaction as an asset acquisition due to its determination that substantially all of the fair value of the assets acquired was concentrated in a group of similar identifiable assets. Management has determined the estimated fair value of acquired intangible assets for purposes of making this determination.

We identified the determination of the relative fair values of the acquired intangible assets as a critical audit matter because of the subjective process when developing the estimated fair values. This in turn led to significant auditor judgment and subjectivity in performing procedures relating to the valuation of acquired intangible assets and significant audit effort was necessary in evaluating the significant assumptions relating to the estimates, including the timing and amounts of future cash flows. In addition, the audit effort involved the use of professionals with specialized skill and knowledge.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Company's estimated fair values included the following, among others:

- We obtained an understanding of the design and implementation of management's controls over the acquisition of Rochal assets.
- We obtained and evaluated the relevant asset purchase agreements to evaluate the completeness of the identified assets.
- With the assistance of our internal fair value specialists, we evaluated the appropriateness of the methodologies applied in determining the fair values of the acquired intangible assets, and the reasonableness of the significant inputs and assumptions used by management. This testing included inquiries with management, consideration of positive and negative evidence impacting management's forecasts, and evaluation of relevant market and industry factors.
- We evaluated management's determination of similar assets that were acquired and management's conclusion that the acquired assets did not meet the definition of a business.

/s/ Weaver and Tidwell, L.L.P.
We have served as the Company's auditor since 2021
Austin, Texas
March 30, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Sanara MedTech Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Sanara MedTech Inc. and its subsidiaries (collectively, the "Company") as of December 31, 2020, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year 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, 2020, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2014.
Houston, Texas
March 30, 2021

SANARA MEDTECH INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash	$ 18,652,841	$ 455,366
Accounts receivable, net of allowances of $99,278 and $100,189	2,861,014	2,217,533
Accounts receivable - related party	79,787	-
Royalty receivable	49,344	49,344
Inventory, net of allowance for obsolescence of $333,850 and $276,603	2,048,191	1,148,253
Prepaid and other assets	917,318	611,817
Total current assets	**24,608,495**	**4,482,313**
Long-term assets		
Property and equipment, net of accumulated depreciation of $342,574 and $124,691	1,629,845	678,589
Right of use assets – operating leases	412,770	467,653
Intangible assets, net of accumulated amortization of $1,203,512 and $827,108	4,727,970	3,097,666
Investment in equity securities	5,017,351	1,100,000
Total long-term assets	**11,787,936**	**5,343,908**
Total assets	**$ 36,396,431**	**$ 9,826,221**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 438,154	$ 271,251
Accounts payable – related parties	155,817	223,589
Accrued royalties and expenses	706,196	502,191
Accrued bonus and commissions	4,518,817	2,417,277
Operating lease liability - current	203,292	125,587
Total current liabilities	**6,022,276**	**3,539,895**
Long-term liabilities		
Operating lease liability – long term	222,151	355,797
Other long-term liabilities	-	90,293
Total long-term liabilities	**222,151**	**446,090**
Total liabilities	**6,244,427**	**3,985,985**
Commitments and contingencies (Note 6)		
Shareholders' equity		
Common Stock: $0.001 par value, 20,000,000 shares authorized; 7,676,662 issued and outstanding as of December 31, 2021 and 6,297,008 issued and outstanding as of December 31, 2020	7,677	6,297
Additional paid-in capital	45,867,768	13,176,576
Accumulated deficit	(15,235,044)	(7,032,242)
Total Sanara MedTech shareholders' equity	**30,640,401**	**6,150,631**
Equity (deficit) attributable to noncontrolling interest	(488,397)	(310,395)
Total shareholders' equity	**30,152,004**	**5,840,236**
Total liabilities and shareholders' equity	**$ 36,396,431**	**$ 9,826,221**

The accompanying notes are an integral part of these consolidated financial statements.

SANARA MEDTECH INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2021	**2020**
Net Revenue	**$ 24,143,919**	**$ 15,586,976**
Cost of goods sold	**2,311,221**	**1,616,625**
Gross profit	**21,832,698**	**13,970,351**
Operating expenses		
Selling, general and administrative expenses	28,053,176	18,673,404
Research and development	558,704	40,190
Depreciation and amortization	596,975	291,370
Total operating expenses	**29,208,855**	**19,004,964**
Operating loss	**(7,376,157)**	**(5,034,613)**
Other income / (expense)		
Other income	-	14,822
Interest expense	(711)	(11,528)
Share of losses from equity method investment	(616,927)	-
Debt forgiveness	-	586,174
Total other income / (expense)	**(617,638)**	**589,468**
Net loss	**(7,993,795)**	**(4,445,145)**
Less: Net loss attributable to noncontrolling interest	(71,881)	(88,705)
Net loss attributable to Sanara MedTech common shareholders	**$ (7,921,914)**	**$ (4,356,440)**
Net loss per share of common stock, basic and diluted	$ (1.08)	$ (0.76)
Weighted average number of common shares outstanding, basic and diluted	7,341,580	5,734,537

The accompanying notes are an integral part of these consolidated financial statements.

SANARA MEDTECH INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

	Preferred Stock Series F $10 par value		Common Stock $0.001 par value		Additional Paid-In Capital	Accumulated Income/(Deficit)	Noncontrolling Interest	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	1,136,815	$ 11,368,150	3,571,001	$ 3,571	$ (2,081,829)	$ (2,675,802)	$ (221,690)	$ 6,392,400
Conversion of Preferred Shares to Common Stock	(1,136,815)	(11,368,150)	2,273,630	2,274	11,365,876	-	-	-
Conversion of Promissory Note to Common Stock	-	-	179,101	179	1,611,732	-	-	1,611,911
Issuance of Common Stock for intangible asset	-	-	60,000	60	749,940	-	-	750,000
Employee stock purchase program			3,735	4	39,326			39,330
Share-based compensation	-	-	209,541	209	1,491,531	-	-	1,491,740
Net loss	-	-	-	-	-	(4,356,440)	(88,705)	(4,445,145)
Balance at December 31, 2020	-	$ -	6,297,008	$ 6,297	$13,176,576	$ (7,032,242)	$ (310,395)	$ 5,840,236
Issuance of common stock for asset acquisitions	-	-	64,739	65	2,334,179	-	-	2,334,244
Issuance of common stock in equity offering	-	-	1,265,000	1,265	28,937,992	-	-	28,939,257
Share-based compensation	-	-	59,933	60	1,580,648	-	-	1,580,708
Net settlement and retirement of equity-based awards	-	-	(10,018)	(10)	(161,627)	(280,888)	-	(442,525)
Distribution to noncontrolling interest member	-	-	-	-	-	-	(200,000)	(200,000)
Capital contribution of noncontrolling interest member	-	-	-	-	-	-	93,879	93,879
Net loss	-	-	-	-	-	(7,921,914)	(71,881)	(7,993,795)
Balance at December 31, 2021	-	$ -	7,676,662	$ 7,677	$45,867,768	$ (15,235,044)	$ (488,397)	$ 30,152,004

The accompanying notes are an integral part of these consolidated financial statements.

SANARA MEDTECH INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (7,993,795)	$ (4,445,145)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	596,975	291,370
Interest expense on convertible debt	-	8,354
Interest expense on PPP loan	-	3,174
Loss on disposal of asset	41	2,897
Bad debt expense	51,536	30,000
Inventory obsolescence	251,826	318,076
Share-based compensation	2,668,892	1,402,897
Noncash lease expense	174,955	117,598
Loss on equity method investment	616,927	-
Debt forgiveness, including interest	-	(586,174)
Changes in operating assets and liabilities:		
Accounts receivable	(695,018)	(961,462)
Accounts receivable - related party	(79,787)	-
Inventory	(1,151,764)	(719,810)
Prepaid and other assets	(305,501)	(449,915)
Accounts payable	166,903	(66,253)
Accounts payable - related parties	(67,772)	154,921
Accrued royalties and expenses	204,005	(25,870)
Accrued bonus and commissions	747,051	890,824
Net cash used in operating activities	(4,814,526)	(4,034,518)
Cash flows from investing activities:		
Purchase of property and equipment	(171,867)	(544,374)
Purchase of intangible assets	(578,586)	(1,100,000)
Investment in equity securities	(4,534,278)	(1,100,000)
Net cash used in investing activities	(5,284,731)	(2,744,374)
Cash flows from financing activities:		
Draw on line of credit	800,000	-
Pay off line of credit	(800,000)	-
Proceeds from PPP Loan	-	583,000
Public offering net proceeds	28,939,257	-
Net settlement of equity-based awards	(442,525)	-
Common stock issued for Employee Stock Purchase Plan	-	39,330
Distribution to noncontrolling interest member	(200,000)	-
Net cash provided by financing activities	28,296,732	622,330
Net increase (decrease) in cash	18,197,475	(6,156,562)
Cash, beginning of period	455,366	6,611,928
Cash, end of period	$ 18,652,841	$ 455,366
Cash paid during the period for:		
Interest	$ 711	$ -
Income taxes	-	-
Supplemental noncash investing and financing activities:		
Common stock issued for conversion of Series F Preferred Stock	-	11,368,150
Common stock issued for conversion of related party debt and interest	-	1,611,911
Common stock issued for asset acquisitions	2,334,244	750,000
License agreement as capital contribution from noncontrolling interest member	93,879	-

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 – NATURE OF BUSINESS AND BACKGROUND

Sanara MedTech Inc. ("we", "our", the "Company") is a medical technology company focused on developing and commercializing transformative technologies to improve clinical outcomes and reduce healthcare expenditures in the surgical and chronic wound and skin care markets. The Company's portfolio of products and services allows the Company to deliver comprehensive wound and skin care solutions for patients in all care settings, including acute (hospitals and long-term acute care hospitals) and post-acute (wound care clinics, physician offices, skilled nursing facilities ("SNFs"), home health, hospice, and retail). Each of the Company's products, services, and technologies contributes to its overall goal of achieving better clinical outcomes at a lower overall cost for patients regardless of where they receive care. The Company strives to be one of the most innovative and comprehensive providers of effective wound and skin care products and technologies and are continually seeking to expand our offerings for patients requiring wound and skin care treatments across the entire continuum of care in the United States.

Impact of the COVID-19 Pandemic

Beginning in March 2020, many states issued orders suspending elective surgeries in order to free-up hospital resources to treat COVID-19 patients. This resulted in a reduction in demand for the Company's surgical products beginning in the second half of March 2020. Additionally, most states limited access to SNFs to only resident caregivers, which impeded the Company's ability to provide education and product training to the clinicians who use its products in these facilities. These restrictions resulted in an overall decline in sales for the second quarter of 2020. During the second half of 2020 and the first quarter of 2021, the Company saw a strong rebound in product sales as restrictions on elective surgeries eased in its primary markets in Texas, Florida, and the southeastern United States. During the second half of 2021, the United States experienced a surge of COVID-19 cases as the Delta and Omicron variants of the virus impacted much of the country and negatively impacted the Company's sales in Texas, the northeastern United States, and other markets.

The duration and effects of the pandemic remain uncertain; however, management believes that elective surgical procedures will continue to be performed with the exception of certain geographic hotspots. Additionally, management believes that the majority of surgical procedures impacted by COVID-19 and its variants will ultimately be performed. The Company will continue to closely monitor the pandemic in order to ensure the safety of its people and its ability to serve its customers and patients.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Sanara MedTech Inc., its wholly owned and majority-owned subsidiaries, as well as other entities in which the Company has a controlling financial interest. All significant intercompany profits, losses, transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect amounts reported in the financial statements and accompanying notes. The extent to which the COVID-19 pandemic may directly or indirectly impact the Company's business, financial condition, and results of operations is highly uncertain and subject to change. The Company considered the potential impact of the COVID-19 pandemic on its estimates and assumptions and determined there was not a material impact on its estimates and assumptions used in preparing its consolidated financial statements as of and for the year ended December 31, 2021. However, actual results could differ from those estimates and there may be changes to the Company's estimates in future periods.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Income / Loss Per Share

The Company computes income per share in accordance with Accounting Standards Codification ("ASC") Topic 260, Earnings per Share, which requires the Company to present basic and dilutive income per share when the effect is dilutive. Basic income per share is computed by dividing income available to common shareholders by the weighted average number of shares of common stock outstanding. Diluted income per share is computed similar to basic income per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the potential shares of common stock had been issued and if the additional shares of common stock were dilutive. All convertible instruments were excluded from the current and prior period calculations as their inclusion would have been anti-dilutive during the years ended December 31, 2021 and 2020 due to the Company's net loss.

The calculation of basic and diluted net loss per share for the years ended December 31, 2021 and 2020 are as follows:

	December 31,	
	2021	2020
Numerator for basic and diluted net loss per share:		
Net loss attributable to Sanara MedTech common shareholders	$ (7,921,914)	$ (4,356,440)
Denominator for basic and diluted net loss per share:		
Weighted average shares used to compute diluted net loss per share	7,341,580	5,734,537
Basic and diluted net loss per share attributable to common shareholders	$ (1.08)	$ (0.76)

The following table summarizes the shares of common stock that were potentially issuable but were excluded from the computation of diluted net loss per share for the years ended December 31, 2021 and 2020 as such shares would have had an anti-dilutive effect:

	As of December 31,	
	2021	2020
Stock options	11,500	11,500
Unvested restricted stock	161,450	170,178

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"), which the Company adopted on January 1, 2018 using the modified retrospective method. Revenues are recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to receive in exchange for transferring those goods or services. Revenue is recognized based on the following five step model:

- Identification of the contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, the Company satisfies a performance obligation

Details of this five-step process are as follows:

Identification of the contract with a customer

Customer purchase orders are generally considered to be contracts under ASC 606. Purchase orders typically identify specific terms of products to be delivered, create the enforceable rights and obligations of both parties, and result in commercial substance. No other forms of contract revenue recognition, such as the completed contract or percentage of completion methods, were utilized by the Company in either 2020 or 2021.

Performance obligations

The Company's performance obligation is generally limited to delivery of the requested items to its customers at the agreed upon quantities and prices.

Determination and allocation of the transaction price

The Company has established prices for its products. These prices are effectively agreed to when customers place purchase orders with the Company. Rebates and discounts, if any, are recognized in full at the time of sale as a reduction of net revenue. Allocation of transaction prices is not necessary where one performance obligation exists.

Recognition of revenue as performance obligations are satisfied

Product revenues are recognized when the products are delivered, and control of the goods and services passes to the customer.

Disaggregation of Revenue

Revenue streams from product sales and royalties are summarized below for the years ended December 31, 2021 and 2020. All revenue was generated in the United States; therefore, no geographical disaggregation was necessary.

	For the Year Ended December 31,	
	2021	**2020**
Product sales revenue	$ 23,942,919	$ 15,385,976
Royalty revenue	201,000	201,000
Total Revenue	$ 24,143,919	$ 15,586,976

The Company recognizes royalty revenue from a development and licensing agreement between BioStructures, LLC and the Company. The Company records revenue each calendar quarter as earned per the terms of the agreement which stipulates the Company will receive quarterly royalty payments of at least $50,250. Under the terms of the development and license agreement, royalties of 2.0% are recognized on sales of products containing the Company's patented resorbable bone hemostasis. The minimum annual royalty due to the Company is $201,000 per year throughout the life of the patent which expires in 2023. These royalties are payable in quarterly installments of $50,250. To date, royalties related to this development and licensing agreement have not exceeded the annual minimum amount of $201,000 ($50,250 per quarter).

Contract Assets and Liabilities

The Company does not have any contract assets or contract liabilities.

Accounts Receivable Allowances

The Company establishes an allowance for doubtful accounts to ensure accounts receivable are not overstated due to uncollectible accounts. The Company recorded bad debt expense of $51,536 and $30,000 in 2021 and 2020, respectively. The allowance for doubtful accounts at December 31, 2021 was $64,899 and $64,989 at December 31, 2020. Bad debt reserves are maintained based on a variety of factors, including the length of time receivables are past due and a detailed review of certain individual customer accounts. The Company also establishes other allowances to ensure accounts receivable are not overstated due to customer rebates and product returns. These allowances totaled $34,379 at December 31, 2021 and $35,200 at December 31, 2020. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. The Company considered the impact of COVID-19 in its analysis of receivables and determined its accounts receivable allowances were appropriate at December 31, 2021.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost computed on a first-in, first-out basis. Inventories consist of finished goods and related packaging components. The Company recorded inventory obsolescence expense of $251,826 in 2021 and $318,076 in 2020. The allowance for obsolete and slow-moving inventory had a balance of $333,850 at December 31, 2021, and $276,603 at December 31, 2020. The Company considered the impact of COVID-19 on its recorded value of inventory and determined no adjustment was necessary as of December 31, 2021.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the related assets, ranging from three to ten years. Below is a summary of property and equipment for the periods presented:

	December 31, 2021	December 31, 2020
Computers	$ 104,568	$ 87,252
Office equipment	21,731	22,597
Furniture and fixtures	221,565	205,871
Leasehold improvements	2,030	2,030
Internal use software	1,622,525	485,530
	1,972,419	803,280
Less accumulated depreciation	(342,574)	(124,691)
Property and equipment, net	**$ 1,629,845**	**$ 678,589**

Depreciation expense related to property and equipment was $220,571 for the year ended December 31, 2021, and $67,842 for the year ended December 31, 2020.

The Company considered the impact the COVID-19 pandemic may have had on the carrying value of its property and equipment and determined that no impairment loss had occurred as of December 31, 2021. The Company will continue to assess the COVID-19 pandemic's impact on its business including any indicators of impairment of property and equipment.

Internal Use Software

The Company accounts for costs incurred to develop computer software for internal use in accordance with ASC 350-40. The Company capitalizes the costs incurred during the application development stage, which generally includes third-party developer fees to design the software configuration and interfaces, coding, installation, and testing.

The Company begins capitalization of qualifying costs when both the preliminary project stage is completed, and management has authorized further funding for the completion of the project. Costs incurred during the preliminary project stage along with post implementation stages of internal-use computer software are expensed as incurred. The Company also capitalizes costs related to specific upgrades and enhancements when it is probable the expenditures will result in additional functionality. Capitalized development costs are classified as property and equipment, net in the consolidated balance sheets and are amortized over the estimated useful life of the software, which is generally five to seven years.

Intangible Assets

Intangible Assets are stated at cost of acquisition less accumulated amortization and impairment loss, if any. Cost of acquisition includes purchase price and any cost directly attributable to bringing the asset to its working condition for the intended use. The Company amortizes its intangible assets on a straight-line basis over the useful life of the respective assets which is generally the life of the related patents (if applicable).

See **Note 4** for more information on intangible assets.

Impairment of Long-Lived Assets

Long-lived assets, including certain identifiable intangibles held and to be used by the Company, are reviewed for impairment whenever events or changes in circumstances, including the COVID-19 pandemic, indicate that the carrying amount of such assets may not be recoverable. The Company continuously evaluates the recoverability of its long-lived assets based on estimated future cash flows and the estimated liquidation value of such long-lived assets and provides for impairment if such undiscounted cash flows are insufficient to recover the carrying amount of the long-lived assets. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, undiscounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. No impairment was recorded during the years ended December 31, 2021 and 2020.

Investments in Equity Securities

The Company's equity investments consist of non-marketable equity securities in privately held companies without readily determinable fair values. Unless accounted for under the equity method of accounting, the investments are reported at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer.

The Company applies the equity method of accounting to investments when it has significant influence, but not controlling interest, in the investee. Judgment regarding the level of influence over each equity method investment includes considering key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions and material intercompany transactions. The Company's proportionate share of the net income (loss) resulting from these investments is reported under the line item captioned "Share of losses from equity method investment" in the consolidated statements of operations. The Company's equity method investments are adjusted each quarter for the Company's share of the investee's income or loss and dividend paid, if any. The Company classifies distributions received from equity method investments using the cumulative earnings approach on the consolidated statements of cash flows.

The Company has reviewed the carrying value of its investments and has determined there was no impairment or observable price changes as of December 31, 2021.

Fair Value Measurement

As defined in ASC Topic 820, Fair Value Measurement ("ASC 820"), fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company utilizes market data or assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated, or generally unobservable. ASC 820 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (level 3 measurement). This fair value measurement framework applies at both initial and subsequent measurement.

The three levels of the fair value hierarchy defined by ASC 820 are as follows:

Level 1 – Quoted prices are available in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis. Level 1 primarily consists of financial instruments such as exchange-traded derivatives, marketable securities and listed equities.

Level 2 – Pricing inputs are other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reported date. Level 2 includes those financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including quoted forward prices for commodities, time value, volatility factors, and current market and contractual prices for the underlying instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace throughout the full term of the instrument, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Instruments in this category generally include non-exchange-traded derivatives such as commodity swaps, interest rate swaps, options and collars.

Level 3 – Pricing inputs include significant inputs that are generally less observable from objective sources. These inputs may be used with internally developed methodologies that result in management's best estimate of fair value.

The carrying amounts of cash, accounts receivable, accounts payable and accrued expenses approximate fair value because of the short-term nature of these instruments. The Company does not have any assets or liabilities that are required to be measured and recorded at fair value on a recurring basis.

Income Taxes

Income taxes are accounted for under the asset and liability method, whereby deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax asset will not be realized.

Advertising Expense

In accordance with ASC Topic No. 720-35-25-1, the Company recognizes advertising expenses the first time the advertising takes place. Such costs are expensed immediately if such advertising is not expected to occur.

Share-based Compensation

The Company accounts for stock-based compensation to employees and nonemployees in accordance with Accounting Standards Update ("ASU") 2018-07 Topic 718. Stock-based compensation is measured at the grant date, based on the fair value of the award, and is recognized as expense over the stipulated vesting period (if any). The Company estimates the fair value of stock-based payments using the Black-Scholes option-pricing model for common stock options and warrants, and the closing price of the Company's common stock for common stock issuances including restricted stock grants.

Research and Development Costs

Research and development ("R&D") expenses consist of personnel-related expenses, including salaries and benefits for all personnel directly engaged in R&D activities, contracted services, materials, prototype expenses and allocated overhead which is comprised of lease expense and other facilities related costs. R&D expenses include costs related to enhancements to the Company's currently available products, and additional investments in the product and platform development pipeline. The Company expenses R&D costs as incurred.

Recently Adopted Accounting Pronouncements

There were no new material accounting standards adopted in 2021 fiscal year.

Recently Issued Accounting Pronouncements

The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board on the Company's financial statements as well as material updates to previous assessments, if any, from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. There were no new material accounting standards issued in fiscal 2021 that impacted the Company.

NOTE 3 – ROCHAL ASSET ACQUISITION

On July 14, 2021, the Company entered into an asset purchase agreement with Rochal, effective July 1, 2021, pursuant to which the Company purchased certain assets of Rochal, including, among others, certain of Rochal's intellectual property, furniture and equipment, supplies, rights and claims, other than certain excluded assets, all as more specifically set forth in the asset purchase agreement, and assume certain liabilities upon the terms and subject to the conditions set forth in the asset purchase agreement. In exchange for the acquired assets, the Company paid Rochal (i) $496,100 in cash and (ii) 14,369 shares of the Company's common stock. Based on the trading price of the Company's common stock on July 14, 2021, the fair value of the equity consideration transferred was determined to be $584,244. The total purchase price as determined by the Company is as follows:

Description		Amount
Net cash consideration	$	496,100
Equity consideration (fair value)		584,244
Net liabilities assumed		3,900
Transaction costs		78,586
Total purchase consideration	**$**	**1,162,830**

Prior to the transaction, the Company entered into product license agreements with Rochal, pursuant to which the Company acquired exclusive world-wide licenses to market, sell and further develop certain antimicrobial barrier film and skin protectant products, antimicrobial products for the prevention and treatment of microbes on the human body utilizing certain of Rochal's patents and a debrider for human medical use to enhance skin condition or treat or relieve skin disorders. Pursuant to the asset purchase agreement, each of the foregoing licenses were retained by Rochal and were excluded from the purchased assets.

Pursuant to the asset purchase agreement, for the three-year period after the effective date, Rochal is entitled to receive consideration for any new product relating to the business that is directly and primarily based on an invention conceived and reduced to practice by a member or members of Rochal's science team. For the three-year period after the effective date, Rochal is also entitled to receive an amount in cash equal to twenty-five percent of the proceeds actually received for any Grant (as defined in the asset purchase agreement) by either the Company or Rochal. In addition, the Company agreed to use commercially reasonable efforts to perform Minimum Development Efforts (as defined in the asset purchase agreement) with respect to certain products under development, which if obtained, will entitle the Company to intellectual property rights from Rochal in respect of such products.

In connection with the asset purchase agreement, the Company hired certain employees of Rochal on an "at will" basis, with the terms of such employment being consistent with the Company's current employment agreements.

Concurrent with the asset purchase, on July 14, 2021, the Company entered into a consulting agreement with Ann Beal Salamone pursuant to which Ms. Salamone agreed to provide the Company with consulting services with respect to, among other things, writing new patents, conducting patent intelligence, and participating in certain grant and contract reporting. In consideration for the consulting services to be provided to the Company, Ms. Salamone is entitled to receive an annual consulting fee of $177,697, with payments to be paid once per month. The consulting agreement has an initial term of three years, unless earlier terminated by the Company, and is subject to renewal. Ms. Salamone is a director of the Company and is the current Chair of the board of directors of Rochal.

Based on guidance provided by ASC Topic 805, Business Combinations, the Company has recorded the Rochal asset purchase as an asset acquisition due to the determination that substantially all of the fair value of the assets acquired was concentrated in a group of similar identifiable assets. The Company believes the "substantially all" criterion was met with respect to the acquired intellectual property (i.e., patents, patent applications, and patent applications to be written) based on the Company's internal valuation models. These models assigned value to the acquired intellectual property based on estimated future cash flows over the life of the respective patents and patent applications. Accordingly, the Company accounted for the acquisition of the purchased net assets as an asset acquisition.

The purchase consideration, plus transaction costs, was allocated to the individual assets according to their fair values as a percentage of the total fair value of the assets purchased, with no goodwill recognized. Based on the Company's internal valuation performed, the total fair value of the net assets acquired was attributable to the intellectual property (i.e., patents) and assembled workforce. Due to the de minimis estimated fair value of furniture and equipment acquired, the Company did not allocate any amounts to such assets. The total purchase consideration was allocated based on the relative estimated fair value of such assets as follows:

Description	Amount	Percent of Total
Patents and Intellectual Property	$ 1,099,801	94.6%
Assembled Workforce	63,029	5.4%
Total purchase consideration	**$ 1,162,830**	**100.0%**

NOTE 4 – INTANGIBLE ASSETS

The carrying values of the Company's finite-lived intangible assets were as follows:

	December 31, 2021			December 31, 2020		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Product Licenses	$ 4,193,879	$ (586,541)	$ 3,607,338	$ 3,350,000	$ (264,909)	$ 3,085,091
Patents and Other IP	1,610,111	(551,285)	1,058,826	510,310	(510,310)	-
Software and Other	127,492	(65,686)	61,806	64,464	(51,889)	12,575
Total	**$ 5,931,482**	**$ (1,203,512)**	**$ 4,727,970**	**$ 3,924,774**	**$ (827,108)**	**$ 3,097,666**

In March 2021, the Company issued 20,834 shares of its common stock to Rochal Industries, LLC ("Rochal") for a $750,000 milestone payment required per the terms of a licensing agreement with Rochal. The payment became due upon the Company's public offering of common stock in February 2021. The milestone payment was recorded as an addition to intangible assets.

As of December 31, 2021, the weighted-average amortization period for all intangible assets was 12.7 years. Amortization expense related to intangible assets was $376,404 for the year ended December 31, 2021 and $223,528 for the year ended December 31, 2020. The estimated remaining amortization expense as of December 31, 2021 is as follows:

2022	$	437,678
2023		432,598
2024		432,598
2025		432,598
2026		432,598
Thereafter		2,559,900
Total	$	4,727,970

The Company has reviewed the carrying value of intangible assets due to the events and circumstances surrounding the COVID-19 pandemic. The Company does not believe the impact of COVID-19 or other matters have created an impairment loss on the Company's intangible assets as of December 31, 2021. Accordingly, there was no impairment loss recognized on the Company's intangible assets during the years ended December 31, 2021 or 2020.

NOTE 5 – CUSTOMERS AND SUPPLIERS

The Company had no customers in 2021 that accounted for at least 10% of the Company's annual sales and one customer whose accounts receivable balance exceeded 10% of the year-end balance. The Company had no customers in 2020 that accounted for at least 10% of Company's annual sales or whose accounts receivable exceeded 10% of the year-end balance.

The Company's principal revenue producing products are purchased from one manufacturer. If this supplier became unable to provide finished goods inventory in a timely manner, the Company's business, operating results, and financial condition could be materially adversely affected.

NOTE 6 - COMMITMENTS AND CONTINGENCIES

License Agreements and Royalties

CellerateRX Activated Collagen

On August 27, 2018, the Company entered into an exclusive, world-wide sublicense agreement with CGI Cellerate RX to distribute CellerateRX Surgical and HYCOL products into the wound care and surgical markets. The Company pays royalties of 3-5% of annual collected net sales of CellerateRX Surgical and HYCOL. As amended, the term of the sublicense extends through May 2050, with automatic year-to-year renewal terms thereafter so long as the Company's Net Sales (as defined in the sublicense agreement) each year are equal to or in excess of $1,000,000. If the Company's Net Sales fall below $1,000,000 for any year after the initial expiration date, CGI Cellerate RX will have the right to terminate the sublicense agreement upon written notice. Minimum royalties of $400,000 per year are payable for the first five years of the sublicense agreement.

For the years ended December 31, 2021 and 2020, royalty expense recognized under the terms of this agreement totaled $856,755 and $479,809 respectively.

BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser

On July 7, 2019, the Company executed a license agreement with Rochal, a related party, whereby the Company acquired an exclusive world-wide license to market, sell and further develop antimicrobial products for the prevention and treatment of microbes on the human body utilizing certain Rochal patents and pending patent applications (the "BIAKŌS License Agreement"). Currently, the products covered by the BIAKŌS License Agreement are BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser. Both products are 510(k) approved. The Company's Executive Chairman is a director of Rochal, and indirectly a significant shareholder of Rochal, and through the potential exercise of warrants, a majority shareholder of Rochal. Another one of the Company's directors is also a director and significant shareholder of Rochal.

Future commitments under the terms of the BIAKŌS License Agreement include:

- The Company will pay Rochal a royalty of 2-4% of net sales. The minimum annual royalty due to Rochal was $100,000 in 2020 and will increase by 10% each subsequent calendar year up to a maximum amount of $150,000.

- The Company will pay additional royalty annually based on specific net profit targets from sales of the licensed products, subject to a maximum of $1,000,000 during any calendar year.

Unless previously terminated by the parties, the BIAKŌS License Agreement will expire with the related patents in December 2031.

For the years ended December 31, 2021 and 2020, royalty expense recognized under this agreement was $110,000 and $100,000, respectively.

CuraShield Antimicrobial Barrier Film and No Sting Skin Protectant

On October 1, 2019, the Company executed a license agreement with Rochal whereby the Company acquired an exclusive world-wide license to market, sell and further develop certain antimicrobial barrier film and skin protectant products for use in the human health care market utilizing certain Rochal patents and pending patent applications (the "ABF License Agreement"). Currently, the products covered by the ABF License Agreement are CuraShield Antimicrobial Barrier Film and a no sting skin protectant product.

Future commitments under the terms of the ABF License Agreement include:

- The Company will pay Rochal a royalty of 2-4% of net sales. The minimum annual royalty due to Rochal will be $50,000 beginning with the first full calendar year following the year in which first commercial sales of the products occur. The annual minimum royalty will increase by 10% each subsequent calendar year up to a maximum amount of $75,000.

- The Company will pay additional royalties annually based on specific net profit targets from sales of the licensed products, subject to a maximum of $500,000 during any calendar year.

Unless previously terminated or extended by the parties, the ABF License Agreement will terminate upon expiration of the last U.S. patent in October 2033.

No commercial sales or royalties have been recognized under this agreement as of December 31, 2021.

Debrider License Agreement

On May 4, 2020, The Company executed a product license agreement with Rochal, whereby the Company acquired an exclusive world-wide license to market, sell and further develop a debrider for human medical use to enhance skin condition or treat or relieve skin disorders, excluding uses primarily for beauty, cosmetic, or toiletry purposes (the "Debrider License Agreement").

Future commitments under the terms of the Debrider License Agreement include:

- At the time a purchase order is issued to a contract manufacturer for the first good manufacturing practice run of the licensed products, the Company will pay Rochal $600,000 in cash.

- Upon FDA clearance of the licensed products, the Company will pay Rochal $500,000 in cash and $1,000,000, which at the Company's option may be paid in any combination of cash and its common stock.

- The Company will pay Rochal a royalty of 2-4% of net sales. The minimum annual royalty due to Rochal will be $100,000 beginning with the first full calendar year following the year in which first commercial sales of the licensed products occur and increase by 10% each subsequent calendar year up to a maximum amount of $150,000.

- The Company will pay additional royalty annually based on specific net profit targets from sales of the licensed products, subject to a maximum of $1,000,000 during any calendar year.

Unless previously terminated or extended by the parties, the Debrider License Agreement will expire in October 2034.

No commercial sales or royalties have been recognized under this agreement as of December 31, 2021.

Resorbable Bone Hemostat

The Company acquired a patent in 2009 for a resorbable bone hemostat and delivery system for orthopedic bone void fillers. This patent is not part of the Company's long-term strategic focus. The Company subsequently licensed the patent to a third party to market a bone void filler product for which the Company receives a 3% royalty on product sales over the life of the patent, which expires in 2023, with annual minimum royalties of $201,000. The Company pays two unrelated third parties a combined royalty equal to eight percent (8%) of the Company's net revenues or minimum royalties generated from products that utilize the Company's acquired patented bone hemostat and delivery system. To date, royalties received by the Company related to this licensing agreement have not exceeded the annual minimum of $201,000 ($50,250 per quarter). Therefore, the Company's annual royalty obligation under the terms of the license agreement has been $16,080 ($4,020 per quarter).

Other Commitments

At the time of the formation of Sanara Pulsar in 2019, it and Wound Care Solutions, Limited ("WCS"), entered into a supply agreement whereby Sanara Pulsar became the exclusive distributor in the United States of certain wound care products that utilize intellectual property developed and owned by WCS. In 2019, the Company advanced to WCS $200,000 and recorded the payment as a reduction of non-controlling interests. In the event WCS's Form K-l from Sanara Pulsar for the year 2020 does not allocate to WCS net income of at least $200,000 (the "Target Net Income"), then Cellerate, LLC will, within 30 days after such determination, pay WCS the amount of funds representing the difference between the Target Net Income and the actual amount of net income shown on WCS's Form K-1 for the year 2020. In March 2021, the Company paid WCS $200,000 for the year 2020. For each of the years 2021 through 2024 the Target Net Income will increase by 10%, and in the event WCS's Form K-1 for any of those years does not allocate to WCS net income in an amount at least equal to the Target Net Income for such year, then Cellerate, LLC will, within 30 days after such determination, pay WCS the amount of funds representing the difference between the Target Net Income and the actual amount of net income shown on WCS's Form K-1 for the applicable year. All other distributions made by Sanara Pulsar to its members, not including tax distributions, will be made exclusively to Cellerate, LLC until such time as Cellerate, LLC has received an amount of distributions equal to all such advances to WCS.

NOTE 7 - OPERATING LEASES

The Company periodically enters into operating lease contracts for office space and equipment. Arrangements are evaluated at inception to determine whether such arrangements constitute a lease.

Right of use assets, which we refer to as "ROU assets," represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities were recognized on the transition date based on the present value of lease payments over the respective lease term, with the office space ROU asset adjusted for deferred rent liability.

The Company has two active operating leases: an office space lease with a remaining lease term of 30 months and a facility lease with a remaining term of eight months as of December 31, 2021. All other leases are short-term leases, which for practical expediency, the Company has elected to not recognize as ROU assets and lease liabilities.

Effective July 1, 2021, the Company assumed an office lease pursuant to the Rochal asset purchase agreement. This lease expires August 31, 2022. The base monthly rent was $8,504 through August 31, 2021, then increased to $8,808 for the remainder of the lease. As the implicit rate in the lease was not determinable, the discount rate applied to determine the present value of lease payments was the 4% borrowing rate on our line of credit as of the assumption date. Additionally, the Company assumed the subleasing of a portion of the office space to a subtenant at a monthly rate of $975. Sublease income is recognized on a straight-line basis over the term of the sublease agreement, whose expiration corresponds to that of the master lease agreement, and presented as a reduction of general and administrative expense in the Company's Statement of Operations. Sublease income totaled $5,850 during the fiscal year ended December 31, 2021.

In accordance with ASC Topic 842, the Company has recorded lease assets of $412,770 and a related lease liability of $425,443 as of December 31, 2021. The Company recorded lease expense of $202,498 for the year ended December 31, 2021 for its leased assets. Cash paid for amounts included in the measurement of operating lease liabilities as of December 31, 2021 was $203,555. The present value of our operating lease liabilities as of December 31, 2021 is shown below.

Maturity of Operating Lease Liabilities

	For the Years Ended
2022	$ 221,793
2023	154,271
2024	77,870
2025	-
2026	-
Thereafter	-
Total lease payments	453,934
Less imputed interest	(28,491)
Present Value of Lease Liabilities	$ 425,443
Operating lease liability - current	203,292
Operating lease liability – long term	222,151

As of December 31, 2021, our operating leases have a weighted average remaining lease term of 2.2 years and a weighted average discount rate of 5.9%.

NOTE 8 – SHAREHOLDERS' EQUITY

Preferred Stock

On February 7, 2020, CGI Cellerate RX, an affiliate of Catalyst, converted its entire holdings of its 30-month $1,500,000 convertible promissory note and 1,136,815 shares of Series F Convertible Preferred Stock into shares of the Company's common stock. The Company issued an aggregate of 2,452,731 shares of common stock in the conversions. Ronald T. Nixon, our Executive Chairman, is the founder and managing partner of Catalyst. Mr. Nixon and Catalyst, collectively with their affiliates, including CGI Cellerate RX, beneficially owned 3,519,019 shares of the Company's common stock which represented 46.0% of the 7,676,662 shares of common stock outstanding as of December 31, 2021.

On December 30, 2020, the Company, following the approval of the Company's board of directors, filed a Resolution Relating to a Series of Shares (the "Resolution") with the Secretary of State of the State of Texas, which was effective upon filing, for the purpose of eliminating the Company's Series F Convertible Preferred Stock. No shares of the Series F Convertible Preferred Stock were outstanding at the time the Resolution was filed. Following the filing of the Resolution, the shares previously authorized under the Series F Convertible Preferred Stock resumed the status of authorized but unissued shares of preferred stock of the Company.

Common Stock

On February 21, 2020, the Company filed a Registration Statement on Form S-8 which registered an aggregate of 2,000,000 shares of its common stock that may be issued under the Sanara MedTech Inc. 2014 Omnibus Long-Term Incentive Plan. The Registration Statement on Form S-8 also covers such additional and indeterminate number of securities as may become issuable pursuant to the provisions of the plan relating to adjustments for changes resulting from a share dividend, share split or similar change. At the Company's Annual Meeting of Shareholders held on July 9, 2020, the Company approved the Restated 2014 Omnibus Long-Term Incentive Plan (the "LTIP Plan") in which the Company's directors, officers, employees and consultants are eligible to participate. A total of 308,209 shares had been issued under the LTIP Plan and 1,691,791 were available to issue as of December 31, 2021.

On January 18, 2021, the Company entered into an Equity Exchange Agreement (the "Exchange Agreement"), effective as of January 14, 2021, with two individuals who each owned 50% of the outstanding equity interests in Woundyne Medical, LLC ("Woundyne"). Pursuant to the Exchange Agreement, the Company acquired 100% of the issued and outstanding equity interests of Woundyne in exchange for the issuance of an aggregate of 29,536 shares of the Company's common stock with a fair value of $1,000,000. The acquisition of the outstanding equity interests of Woundyne was accounted for as an asset acquisition. The primary asset acquired by the Company is the Woundyne software platform which allows data related to surgical and chronic wounds to be tracked, monitored, and interfaced with the software user's electronic medical records. Woundyne has no other material assets, liabilities, or revenues. The issuance of these shares was capitalized as internal use software. The Company subsequently changed the name of Woundyne Medical, LLC to WounDerm, LLC.

On February 12, 2021, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cantor Fitzgerald & Co. as representative of several underwriters named therein (collectively, the "Underwriters"), pursuant to which the Company agreed to issue and sell an aggregate of 1,100,000 shares of the Company's common stock to the Underwriters at a price to the public of $25.00 per share, less underwriting discounts and commissions (the "Offering"). Pursuant to the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to an additional 165,000 shares of common stock at the public offering price, less underwriting discounts and commissions, which the Underwriters exercised in full. The Offering, including the purchase of the 165,000 additional shares of common stock, closed on February 17, 2021.

The net proceeds to the Company from the Offering were $28.9 million, after (i) giving effect to the Underwriters' full exercise of its option to purchase additional shares of common stock, and (ii) deducting the underwriting discounts and commissions and offering expenses payable by the Company. Through an insured cash sweep service, the net proceeds have been deposited in accounts insured by the Federal Deposit Insurance Corporation.

Following the closing of the Offering in February of 2021, the Company made the $750,000 Post Capital Raise Payment (as defined in the BIAKŌS License Agreement) to Rochal in the form of 20,834 shares of the Company's common stock (see **Notes** 4 and 6 for more information).

On July 14, 2021, the Company entered into an asset purchase agreement with Rochal, effective July 1, 2021, pursuant to which the Company purchased certain assets of Rochal, including, among others, certain of Rochal's intellectual property, furniture and equipment, supplies, rights and claims, other than certain excluded assets, all as more specifically set forth in the asset purchase agreement. In exchange for the acquired assets, the Company paid Rochal $496,100 in cash and (ii) 14,369 shares of the Company's common stock and assumed certain net liabilities of $3,900. Based on the trading price of the Company's common stock on July 14, 2021, the fair value of the equity consideration transferred was determined to be $584,244. See **Note 3** for more information regarding this transaction.

Restricted Stock Awards

During the year ended December 31, 2021, the Company issued restricted share awards under the LTIP Plan which are subject to certain vesting provisions and other terms and conditions set forth in each recipient's restricted stock agreement. The Company granted and issued 59,933 shares, net of forfeitures, of restricted common stock to Company employees, directors, and certain consultants of the Company. The fair value of these awards is based on the closing price of the Company's common stock on the respective grant dates; then, is recognized as compensation expense on a straight-line basis over the vesting period of the award.

Share-based compensation expense of $2,668,892 was recognized in selling, general and administrative expenses during the year ended December 31, 2021, compared to $1,402,897 recognized during the year ended December 31, 2020. For the year ended December 31, 2021, our share-based compensation expense of $2,668,892 included $1,088,184 which was recorded as a liability at December 31, 2021 as the awards were to be settled in a variable number of shares at a future date. The related shares for this liability were issued in early 2022 and were reclassified into equity at that time.

At December 31, 2021, there was $1,704,130 of total unrecognized share-based compensation expense related to unvested share-based equity awards. Unrecognized share-based compensation expense is expected to be recognized over a weighted-average period of 0.7 years.

Below is a summary of restricted stock activity for the year ended December 31, 2021:

	For the Year Ended December 31, 2021	
	Shares	Weighted Average Grant Date Fair Value
Non-vested at beginning of period	170,178	$ 14.20
Granted	64,719	28.99
Vested	(68,661)	18.99
Forfeited	(4,786)	13.03
Non-vested at December 31, 2021	161,450	$ 18.13

Stock Options

A summary of the status of outstanding stock options at December 31, 2021 and changes during the year then ended is presented below:

	For the Year Ended December 31, 2021		
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Outstanding at beginning of period	11,500	$ 6.00	
Granted	-	-	
Exercised	-	-	
Forfeited	-	-	
Expired	-	-	
Outstanding at December 31, 2021	11,500	$ 6.00	1.0
Exercisable at December 31, 2021	11,500	$ 6.00	1.0

NOTE 9 – INCOME TAXES

The Company accounts for income taxes in accordance with ASC Topic No. 740, "Income Taxes." This standard requires the Company to provide a net deferred tax asset or liability equal to the expected future tax benefit or expense of temporary reporting differences between book and tax accounting and any available operating loss or tax credit carry forwards.

After applying the provisions of Section 382 of the Internal Revenue Code, the unexpired net operating loss ("NOL") carry forward at December 31, 2021 was approximately $20.7 million, of which, approximately $5.1 million generated in 2017 and prior, will expire between 2022 and 2037. Under the Tax Cuts and Jobs Act, the NOL generated during the years 2018 through 2021 of approximately $15.6 million will have an indefinite carryforward period but can generally only be used to offset 80% of taxable income in any particular year. We may be subject to certain limitations in our annual utilization of NOL carry forwards to off-set future taxable income pursuant to Section 382 of the Internal Revenue Code, which could result in NOLs expiring unused.

The non-current deferred tax asset is summarized below:

	2021	2020
Deferred tax assets		
Net operating loss carry forwards	$ 4,352,201	$ 2,827,835
Inventory reserves	70,221	58,087
Bad debt and other reserves	561,944	562,248
Accrued expenses	35,579	16,817
Other temporary differences	1,134	630
Total deferred tax assets	5,021,079	3,465,617
Deferred tax liabilities		
Depreciation and amortization	(17,001)	(32,657)
Valuation allowance	(5,004,078)	(3,432,960)
Net deferred tax asset	$ -	$ -

A 100% valuation allowance has been provided for all deferred tax assets, as the ability of the Company to generate sufficient taxable income in the future is uncertain.

Reconciliations of the expected federal income tax benefit based on the statutory income tax rate of 21% to the actual benefit for the years ended December 31, 2021 and 2020 are listed below.

	2021	2020
Expected federal income tax benefit	$ 1,663,601	$ 914,852
NOL carryover adjusted for expiration	(29,730)	111,345
Equity method investment loss	(129,555)	-
Meals and entertainment	(7,439)	(24,859)
Stock-based compensation	120,924	(103,657)
PPP Loan Forgiveness	-	122,430
Other temporary differences	(46,683)	-
Change in valuation allowance	(1,571,118)	(1,020,111)
Income tax expense (benefit)	$ -	$ -

All tax years starting with 2018 are open for examination.

NOTE 10 – DEBT AND CREDIT FACILITIES

Revolving Line of Credit

On January 15, 2021, the Company entered into a loan agreement (the "Loan Agreement") with Cadence providing for a $2.5 million revolving line of credit. Pursuant to the terms of the Loan Agreement, the revolving line of credit was set to mature on January 13, 2023, and was secured by substantially all of the Company's assets.

On February 11, 2021, the Company made an $800,000 draw on the revolving line of credit. On February 19, 2021, the Company paid down the entire balance of the revolving line of credit. As of December 31, 2021, there were no outstanding amounts owed by the Company under the Loan Agreement. Effective March 25, 2022, the Company terminated the Loan Agreement and released Cadence from any obligation to make advances under the Loan Agreement. No amounts of principal, interest or other fees and expenses were owed by the Company as of the termination date.

Promissory Note – Paycheck Protection Program

On April 22, 2020, the Company executed an unsecured promissory note (the "PPP Loan") to Cadence pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The Company used the PPP Loan proceeds for covered payroll costs and other costs in accordance with the relevant terms and conditions of the CARES Act.

The PPP Loan was in the principal amount of $583,000 and bore interest at a fixed rate of 1.00% per annum. Under the terms of the PPP and the CARES Act, the Company applied for forgiveness of the full amount due on the PPP Loan. In November 2020, full amount of the PPP Loan, including accrued interest, was forgiven and reported under Other income in the consolidated statements of operations.

NOTE 11 – INVESTMENT IN EQUITY SECURITIES

The Company's equity investments consist of non-marketable equity securities in privately held companies without readily determinable fair values. Unless accounted for under the equity method of accounting, the investments are reported at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer.

The Company made a $500,000 long-term investment in July 2020 to purchase certain non-marketable securities consisting of 7,142,857 Series B-2 Preferred Shares of Direct Dermatology Inc. ("DirectDerm"), representing 2.9% ownership of DirectDerm at that time. Through this investment, the Company received exclusive rights to utilize DirectDerm's technology in all acute and post-acute care settings such as skilled nursing facilities, home health, and wound clinics. The Company does not have the ability to exercise significant influence over DirectDerm's operating and financial activities. In 2021, the Company purchased an additional 3,571,430 shares of DirectDerm's Series B-2 Preferred for $250,000. The Company's ownership of DirectDerm was 6.5% as of December 31, 2021.

On November 9, 2020, the Company entered into agreements to purchase certain non-marketable securities consisting of 150,000 shares of Series A Convertible Preferred Stock (the "Series A Stock") of Precision Healing Inc. ("Precision Healing") for an aggregate purchase price of $600,000. The Series A Stock is convertible into 150,000 shares of common stock of Precision Healing and has a senior liquidation preference relative to the common shareholders. This initial investment represented 12.6% ownership of Precision Healing's outstanding voting securities.

In February 2021, the Company invested $600,000 to purchase 150,000 additional shares of Series A Stock which is convertible into 150,000 shares of common stock of Precision Healing. This resulted in ownership of 22.4% of Precision Healing's outstanding voting securities. With this level of significant influence and the Preferred Shares deemed to be in-substance common stock as the investee had only issued Preferred Stock at this point, the Company transitioned to the equity method of accounting for this investment. On June 17, 2021, the Company invested $500,000 for 125,000 additional shares of Series A Stock which increased the Company's ownership of Precision Healing's outstanding voting securities to 29.0%. In October and in December of 2021, 125,000 and 150,000 more shares of Series A Stock were purchased for $500,000 and $600,000, respectively. The Company's ownership of Precision Healing was 40.3% at December 31, 2021. For the year ended December 31, 2021, the Company recorded $616,927 as its share of losses from this equity method investment.

On June 3, 2021, the Company invested $2,084,278 to purchase 278,587 Class A Preferred Shares (the "Shares") of Pixalere Healthcare, Inc. ("Pixalere"). The Shares are convertible into 28.6% of the outstanding equity of Pixalere. Pixalere provides a cloud-based wound care software tool that empowers nurses, specialists and administrators to deliver better care for patients. In connection with the Company's purchase of the Shares, Pixalere granted Pixalere Healthcare USA, LLC ("Pixalere USA"), a subsidiary of the Company, a royalty-free exclusive license to use the Pixalere software and platform in the United States. In conjunction with the grant of the license, the Company issued Pixalere a 27.3% equity ownership interest in Pixalere USA valued at $93,879.

The Company has reviewed the characteristics of the Shares in accordance with ASC Topic 323, Investments – Equity Method and Joint Ventures. Due to the substantive liquidation preferences of the Shares over Pixalere's common stock, the Shares are not "in-substance" common stock, and therefore, the Company will not utilize the equity method of accounting for this investment. In accordance with ASC Topic 321, Investments - Equity Securities, this investment was reported at cost as of December 31, 2021.

The following summarizes the Company's investments:

	December 31, 2021		December 31, 2020	
	Carrying Amount	Economic Interest	Carrying Amount	Economic Interest
Equity Method Investment				
Precision Healing Inc.	$ 2,183,073	40.3%	$ -	
Cost Method Investments				
Direct Dermatology, Inc.	750,000		500,000	
Precision Healing Inc.	-		600,000	
Pixalere Healthcare, Inc.	2,084,278		-	
Total Cost Method Investments	2,834,278		1,100,000	
Total Investments	$ 5,017,351		$ 1,100,000	

The following summarizes the loss from the equity method investment reflected in the consolidated statements of operations:

	December 31,	
	2021	2020
Investment		
Precision Healing Inc.	$ (616,927)	$ -
Total	$ (616,927)	$ -

For the year ended December 31, 2021, Precision Healing recorded a total net loss of $2,363,215 and had total assets of $565,045 as of December 31, 2021.

The Company has reviewed the carrying value of its investments and has determined there was no impairment or observable price changes as of December 31, 2021.

NOTE 12 - RELATED PARTIES

Receivables

We had outstanding receivables to Rochal, a related party, totaling $79,787 at December 31, 2021, and $0 at December 31, 2020.

Payables

We had outstanding payables to related parties totaling $155,817 at December 31, 2021, and $223,589 at December 31, 2020.

Product License Agreements

On July 7, 2019, the Company executed a license agreement with Rochal, a related party, whereby the Company acquired an exclusive world-wide license to market, sell and further develop antimicrobial products for the prevention and treatment of microbes on the human body utilizing certain Rochal patents and pending patent applications (the "BIAKŌS License Agreement"). Currently, the products covered by the BIAKŌS License Agreement are BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser. Both products are 510(k) approved. The Company's Executive Chairman is a director of Rochal, and indirectly a significant shareholder of Rochal, and through the potential exercise of warrants, a majority shareholder of Rochal. Another one of the Company's directors is also a director and significant shareholder of Rochal.

On October 1, 2019, the Company executed a license agreement with Rochal whereby the Company acquired an exclusive world-wide license to market, sell and further develop certain antimicrobial barrier film and skin protectant products for use in the human health care market utilizing certain Rochal patents and pending patent applications (the "ABF License Agreement"). Currently, the products covered by the ABF License Agreement are CuraShield Antimicrobial Barrier Film and a no sting skin protectant product.

On May 4, 2020, The Company executed a product license agreement with Rochal, whereby the Company acquired an exclusive world-wide license to market, sell and further develop a debrider for human medical use to enhance skin condition or treat or relieve skin disorders, excluding uses primarily for beauty, cosmetic, or toiletry purposes

See **Note 6** for more information on these product license agreements.

Manufacturing and Technical Services Agreements

On September 9, 2020, we executed a manufacturing agreement with Rochal. Under the terms of the manufacturing agreement, Rochal agreed to manufacture, package, and label products we licensed from Rochal. The manufacturing agreement includes customary terms and conditions. The term of the agreement is for a period of five years unless extended by the mutual consent of the parties. For the year ended December 31, 2021, we incurred no inventory manufacturing costs with Rochal. The Company terminated this agreement on August 12, 2021.

On September 9, 2020, we executed a technical services agreement with Rochal. Under the terms of the technical services agreement, Rochal will provide its expertise and services on technical service projects identified by us for wound care, skin care and surgical site care applications. The technical services agreement includes customary terms and conditions for our industry. For the year ended December 31, 2021, we incurred $337,746 of costs for Rochal technical services. The Company terminated this agreement on August 12, 2021.

Ronald T. Nixon, our Executive Chairman, is also a director of Rochal, and indirectly a significant shareholder of Rochal, and through the potential exercise of warrants a majority shareholder of Rochal. Ann Beal Salamone, a director, is a significant shareholder, the former president and current Chairman of the Board of Rochal.

Rochal Asset Acquisition

As noted above, on July 14, 2021, we entered into an asset purchase agreement with Rochal, effective July 1, 2021, pursuant to which we purchased certain assets of Rochal, including, among others, certain of Rochal's intellectual property, furniture and equipment, supplies, rights and claims, other than certain excluded assets, and assumed certain liabilities upon the terms and subject to the conditions set forth in the asset purchase agreement. In exchange for the acquired assets, we paid Rochal (i) $496,100 in cash and (ii) 14,369 shares of common stock (See **Note 3** for more information).

Consulting Agreement

Concurrent with the Rochal asset purchase, on July 14, 2021, the Company entered into a consulting agreement with Ann Beal Salamone pursuant to which Ms. Salamone agreed to provide the Company with consulting services with respect to, among other things, writing new patents, conducting patent intelligence, and participating in certain grant and contract reporting. In consideration for the consulting services to be provided to the Company, Ms. Salamone is entitled to receive an annual consulting fee of $177,697, with payments to be paid once per month. The consulting agreement has an initial term of three years, unless earlier terminated by the Company, and is subject to renewal. Ms. Salamone is a director of the Company and is the current Chair of the board of directors of Rochal.

NOTE 13 – SUBSEQUENT EVENTS

On March 24, 2022, Sanara MedTech Inc. (the "Company") delivered notice to Cadence Bank, N.A. ("Cadence") of termination of its loan agreement, dated January 15, 2021, by and among Cadence, the Company, Cellerate, LLC, and United Wound and Skin Solutions, LLC (the "Loan Agreement"), as modified and amended by that certain modification agreement (the "Modification Agreement"), dated June 29, 2021, by and among Cadence, the Company, Cellerate, LLC and United Wound and Skin Solutions, LLC (the loan agreement, as amended by the Modification Agreement, the "Modified Loan Agreement"), effective as of March 25, 2022. The Modified Loan Agreement provided for a $2.5 million revolving line of credit that was secured by substantially all of the assets of the Company and was scheduled to mature on January 13, 2023. The Company determined to terminate the Loan Agreement because the Company has no present intention of drawing upon the revolving line of credit. Upon the termination of the Modified Loan Agreement, all security interests and pledges granted to Cadence thereunder were terminated and released. The Company did not have any borrowings outstanding under the Modified Loan Agreement and did not incur any early termination penalties in connection with the termination of the Modified Loan Agreement.

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

As previously disclosed, on September 8, 2021, the Audit Committee of the board of directors of the Company approved the dismissal of MaloneBailey, LLP ("MaloneBailey"), as the Company's independent registered public accounting firm, effective as of September 8, 2021, and informed MaloneBailey of such dismissal on the date thereof.

The reports of MaloneBailey on the Company's consolidated financial statements for the two most recent fiscal years, ended December 31, 2019 and 2020, did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles.

During the fiscal years ended December 31, 2019 and 2020, and the subsequent interim period through September 8, 2021, (i) there were no disagreements, as defined in Item 304(a)(1)(iv) of Regulation S-K, with MaloneBailey on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of MaloneBailey, would have caused MaloneBailey to make reference to the subject matter of the disagreements in connection with its reports on the Company's consolidated financial statements for such period, and (ii) there were no "reportable events," as defined in Item 304(a)(1)(v) of Regulation S-K, except that the Company identified a material weakness in its internal control over financial reporting related to the small size of the Company and limited segregation of duties, which was described in Item 9A of the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

On September 8, 2021, the Audit Committee of the board of directors approved the engagement of Weaver and Tidwell, L.L.P. ("Weaver") as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2021, effective as of such date.

During the fiscal years ended December 31, 2019 and 2020, and the subsequent interim period through September 8, 2021, neither the Company nor anyone acting on its behalf has consulted with Weaver regarding (i) the application of accounting principles to any specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements, and neither a written report nor oral advice was provided to the Company that Weaver concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue, or (ii) any matter that was either the subject of a "disagreement," as defined in Item 304(a)(1)(iv) of Regulation S-K, or a "reportable event," as defined in Item 304(a)(1)(v) of Regulation S-K.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the SEC under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms, and that information is accumulated and communicated to our management, including our principal executive and principal financial officers (whom we refer to in this periodic report as our "Certifying Officers"), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of December 31, 2021, pursuant to Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of December 31, 2021, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate over time.

Management believes that our policies and procedures provide reasonable assurance that our operations are conducted with a high standard of business ethics. In management's opinion, our financial statements present fairly, in all material respects, our financial position, results of operations, and cash flows. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Management applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

The Company's management, specifically its Certifying Officers, has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2021 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013) and SEC guidance on conducting such assessments. Based on this assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We will continue to evaluate the effectiveness of internal controls and procedures on an on-going basis.

No Attestation Report of Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required in response to this Item 10 is incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A to be filed with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required in response to this Item 11 is incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A to be filed with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required in response to this Item 12 is incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A to be filed with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required in response to this Item 13 is incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A to be filed with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A to be filed with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements

Refer to Index to Financial Statements appearing on page F-1.

(b) Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown in the financial statements or the notes thereto.

(c) Exhibits

The exhibits listed below are filed or incorporated by reference as a part of this report.

Exhibit No.	Description
2.1#	Asset Purchase Agreement, dated July 14, 2021, by and between Sanara MedTech Inc., as Purchaser, and Rochal Industries, LLC, as Seller (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 19, 2021).
3.1	Articles of Incorporation of Sanara MedTech Inc. (as amended through December 30, 2020) (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed on March 30, 2021).
3.2	Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed April 11, 2008).
4.1	Description of Securities.
10.1.1 †	Sanara MedTech Inc. Restated 2014 Omnibus Long-Term Incentive Plan dated February 10, 2020 effective upon shareholder approval on July 9, 2020(incorporated by reference to Exhibit A to the Company's Definitive Proxy Statement on Schedule 14A filed on June 25, 2020).
10.1.2 †	Form of Restricted Stock Award Agreement under the Sanara MedTech Inc. Restated 2014 Omnibus Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1.2 to the Company's Annual Report on Form 10-K filed on March 30, 2021).
10.2 †	Employment Agreement dated June 1, 2019 between Sanara MedTech Inc. and Shawn M. Bowman (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K filed on March 26, 2020).
10.3 †	Employment Agreement dated June 1, 2019 between Sanara MedTech Inc. and Zachary B. Fleming (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K filed on March 26, 2020).
10.4	Contribution Agreement dated August 27, 2018 between Wound Care Innovations, LLC and Catalyst Cellerate RX, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed November 14, 2018).
10.5	Operating Agreement dated August 27, 2018 between Wound Care Innovations, LLC and Catalyst Cellerate RX, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 14, 2018).
10.6.1	Sublicense Agreement dated August 27, 2018 between Catalyst Cellerate RX, LLC and Cellerate, LLC (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed November 14, 2018).
10.6.2	First Amendment of Sublicense Agreement dated May 31, 2019, between Cellerate, LLC, as Sublicensee, and CGI Cellerate RX, LLC, as Sublicensor (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 26, 2021).
10.6.3	Second Amendment of Sublicense Agreement dated January 26, 2021, between Cellerate, LLC, as Sublicensee, and CGI Cellerate RX, LLC, as Sublicensor (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 26, 2021).
10.7.1	Exclusive License Agreement dated July 8, 2019 between Sanara MedTech Inc. and Rochal Industries, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2019).
10.7.2	Amendment No. 1 to Exclusive License Agreement dated May 4, 2020 between Sanara MedTech Inc. and Rochal Industries, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 13, 2020).

10.8	Exclusive License Agreement dated October 1, 2019 between Sanara MedTech Inc. and Rochal Industries, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2019).
10.9	Exclusive License Agreement dated May 4, 2020 between Sanara MedTech Inc. and Rochal Industries, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2020).
10.10	Promissory Note, dated April 22, 2020, between Sanara MedTech Inc., as Borrower, and Cadence Bank, N.A., as Lender (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 29, 2020).
10.11	Consulting Agreement, dated July 14, 2021, by and between Sanara MedTech Inc. and Ann Beal Salamone (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company filed on July 19, 2021 by the Company with the SEC).
10.12	Retirement Agreement, dated December 22, 2021, between Sanara MedTech Inc. and J. Michael Carmena (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on December 12, 2021 by the Company with the SEC).
21.1	List of Subsidiaries.
23.1*	Consent of Weaver and Tidwell, L.L.P.
23.2*	Consent of MaloneBailey, LLP.
31.1*	Certification of Principal Executive Officer in accordance with 18 U.S.C. Section 1350, as adopted by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer in accordance with 18 U.S.C. Section 1350, as adopted by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer in accordance with 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer in accordance with 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith
# Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Sanara MedTech Inc. hereby undertakes to furnish supplementally copies of any of the omitted schedules upon request by the Securities and Exchange Commission or its staff.

** The certifications attached as Exhibit 32.1 and Exhibit 32.2 are not deemed "filed" with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Sanara MedTech Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.
† Identifies a management contract or compensatory plan

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SANARA MEDTECH INC.

March 30, 2022

By: */s/ Michael McNeil*
Michael McNeil
Chief Financial Officer
(Principal Financial Officer and duly authorized officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Zachary B. Fleming Zachary B. Fleming	Chief Executive Officer (Principal Executive Officer)	March 30, 2022
/s/ Michael McNeil Michael McNeil	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2022
/s/ Ronald T. Nixon Mr. Ronald T. Nixon	Chairman	March 30, 2022
/s/ Robert DeSutter Robert DeSutter	Director	March 30, 2022
/s/ Roszell Mack III Roszell Mack III	Director	March 30, 2022
/s/ Sara N. Ortwein Sara N. Ortwein	Director	March 30, 2022
/s/ Ann Beal Salamone Ann Beal Salamone	Director	March 30, 2022
/s/ James W. Stuckert James W. Stuckert	Director	March 30, 2022
/s/ Eric D. Tanzberger Eric D. Tanzberger	Director	March 30, 2022
/s/ Kenneth E. Thorpe Kenneth E. Thorpe	Director	March 30, 2022

Exhibit 21.1

Subsidiaries of Sanara MedTech Inc.

Following is a list of subsidiaries of Sanara MedTech Inc., a Texas corporation, as of December 31, 2021, and the states in which they are organized. The indentation reflects the principal parenting of each subsidiary. The names of particular subsidiaries may be omitted if the unnamed subsidiaries, considered in the aggregate as a single subsidiary, would not constitute a significant subsidiary as of the end of the year covered by this report. (See the definition of "significant subsidiary" in Rule 1-02(w) (17 CFR 210.1-02(w)) of Regulation S-X.)

1. Cellerate, LLC, a Texas a limited liability company
2. Wound Care Innovations, LLC, a Nevada limited liability company
3. Sanara Pulsar, LLC, a Texas limited liability company
4. Sanara Biologics, LLC, a Texas limited liability company
5. Rochal Technologies, LLC, a Texas limited liability company
6. United Wound and Skin Solutions, LLC, a Delaware limited liability company
7. WounDerm, LLC, a Delaware limited liability company
8. Pixalere Healthcare USA, LLC, a Delaware limited liability company

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-236558) and Form S-3 (File No. 333-251652) of Sanara MedTech Inc. of our report dated March 30, 2022 with respect to the consolidated financial statements of Sanara MedTech Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Weaver and Tidwell, L.L.P.
Austin, Texas
March 30, 2022

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-236558) and Form S-3 (File No. 333-251652) of our report dated March 30, 2021 with respect to the consolidated financial statements of Sanara MedTech Inc. and its subsidiaries (the "Company") as of and for the year ended December 31, 2020, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2021.

/s/ MaloneBailey, LLP
www.malonebailey.com
Houston, Texas
March 30, 2022

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
IN ACCORDANCE WITH 18 U.S.C. SECTION 1350,
AS ADOPTED BY SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Zachary B. Fleming, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sanara MedTech Inc. for the fiscal year ended December 31, 2021;

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries is made known to me by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2022

/s/ Zachary B. Fleming

Zachary B. Fleming, Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
IN ACCORDANCE WITH 18 U.S.C. SECTION 1350,
AS ADOPTED BY SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael McNeil, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sanara MedTech Inc. for the fiscal year ended December 31, 2021;

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries is made known to me by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2022

/s/ Michael McNeil

Michael McNeil, Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
IN ACCORDANCE WITH 18 U.S.C. SECTION 1350,
AS ADOPTED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Sanara MedTech Inc. (the "Company") for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof, I, Zachary B. Fleming, in my capacity as principal executive officer of the Company and not in my individual capacity, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

March 30, 2022

/s/ Zachary B. Fleming

Zachary B. Fleming, Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
IN ACCORDANCE WITH 18 U.S.C. SECTION 1350,
AS ADOPTED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Sanara MedTech Inc. (the "Company") for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof, I, Michael McNeil, in my capacity as principal financial officer of the Company and not in my individual capacity, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

March 30, 2022

/s/ Michael McNeil

Michael McNeil, Chief Financial Officer