Sanara MedTech
Evidence Based Healing

ANNUAL REPORT 2024

SANARA MEDTECH INC.

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, 2024

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

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

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 "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 28, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on the $28.22 closing price as of such date, was approximately $118,175,765.

As of March 18, 2025, 8,901,903 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 2025 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, 2024

Unless otherwise indicated, "Sanara MedTech," "Sanara," the "Company," "our," "us," or "we," 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, including topics such as our value-based wound and skincare services and Tissue Health Plus platforms. In some cases, you can identify forward-looking statements because they contain words such as "aims," "anticipates," "believes," "contemplates," "continue," "could," "estimates," "expects," "forecast," "guidance," "intends," "may," "plans," "possible," "potential," "predicts," "preliminary," "projects," "seeks," "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:

- shortfalls in forecasted revenue growth;
- our ability to implement our value-based wound and skincare 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 maintain compliance with our debt obligations;
- 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 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 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;
- the failure of third-party assessments to demonstrate desired outcomes in proposed endpoints;
- our ability to successfully expand into value-based wound, skincare 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 to the labeling, marketing and sale of our products, and our planned launch of value-based wound, skincare 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, chronic wound and skincare markets. Our products, services and technologies are designed to achieve our goal of providing better clinical outcomes at a lower overall cost for patients regardless of where they receive care. Through our two operating segments, Sanara Surgical and Tissue Health Plus ("THP"), we strive to be one of the most innovative and comprehensive providers of effective surgical, wound and skincare solutions and are continually seeking to expand our offerings for patients requiring treatments across the entire continuum of care in the United States.

Reportable Segments

Historically, we managed our business on the basis of one operating and reportable segment. During the second quarter of 2024, we changed our reportable segments to reflect a change in the manner in which the business is managed. Based on the growing importance of the value-based wound care program to our future outlook and how our chief operating decision maker, our Chief Executive Officer, reviews operating results and makes decisions about resource allocation, we now have two reportable segments: Sanara Surgical and THP.

Sanara Surgical

Our Sanara Surgical segment primarily markets and sells soft tissue repair and bone fusion products for use in the operating room or other sterile environments. Sanara Surgical's soft tissue repair products include, among other products, our lead product, CellerateRX Surgical Activated Collagen ("CellerateRX Surgical"), a hydrolyzed collagen that supports a local environment for surgical sites to aid in the natural wound healing process, and BIASURGE Advanced Surgical Solution ("BIASURGE"), a sterile no-rinse, advanced surgical solution used for wound irrigation. Sanara Surgical's bone fusion products include, among other products, BiFORM Bioactive Moldable Matrix ("BiFORM"), an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site, and ALLOCYTE Plus Advanced Viable Bone Matrix ("ALLOCYTE Plus"), a human allograft cellular bone matrix containing bone-derived progenitor cells and conformable bone fibers.

Our Sanara Surgical segment also includes an in-house research and development team (Rochal Technologies) with an extensive pipeline of innovative products under development.

Tissue Health Plus

Our THP segment is focused on value-based wound care services. Through THP, we plan to offer a first of its kind value-based wound care program to payers and risk-bearing entities, such as accountable care organizations and value-based primary care companies, with Medicare Advantage payers as the initial target market for this program.

THP's programs are expected to enable payers to divest wound care spend risk, reduce wound related hospitalizations and improve patient quality of life. THP plans to coordinate delivery of community and home-based wound care for its managed patients. Community based care spans a variety of settings including physician offices, skilled nursing facilities, assisted living facilities and senior living facilities. THP programs are intended to integrate science and evidence-based medicine protocols to standardize wound prevention and treatment. We are preparing to launch our first pilot program with a wound care provider group during the second quarter of 2025.

Summary of Our Product, Service and Technology Offerings and Development Programs

Sanara Surgical Products

Our Sanara Surgical segment markets and distributes surgical, wound and skincare products 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 believe we have the ability to drive our product pipeline from concept to preclinical and clinical development while meeting quality and regulatory requirements. We are constantly seeking long-term strategic partnerships with a focus on products that improve outcomes at a lower overall cost.

CellerateRX Surgical

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 with a proprietary process. CellerateRX Surgical powder is sterilized and packaged for use in the operating room or other sterile environment. CellerateRX Surgical products are primarily purchased by hospitals and ambulatory surgical centers for use by surgeons on surgical wounds. The majority of CellerateRX Surgical products are used for a variety of surgical wounds, including those associated with orthopedic, spine, trauma and oncologic procedures. Additional surgical wounds that may benefit from the use of CellerateRX Surgical include cardiovascular, gynecologic, urologic, vascular and plastic/reconstructive related procedures.

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 wounds. This is especially true in patients with certain comorbidities, including obesity, diabetes and hypertension. These complications can include surgical wound infections, dehiscence (where an incision opens after primary closure) and necrosis. Surgeons use CellerateRX Surgical to complement the body's normal healing process. By supporting the body to 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). Surgical wound complications have become increasingly problematic due to the high rates of surgical patient comorbidities and the financial strain on insurance payors as well as hospitals that suffer exorbitant costs for readmission of these patients within 90 days of surgery.

BIASURGE

BIASURGE is a 510(k) cleared sterile no-rinse, advanced surgical solution used for wound irrigation. It contains an antimicrobial preservative effective against a broad spectrum of pathogenic microorganisms in the solution. BIASURGE is indicated for use in the mechanical cleansing and removal of debris, including microorganisms, from surgical wounds. First sales of BIASURGE occurred in November 2023.

FORTIFY TRG

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

FORTIFY FLOWABLE

FORTIFY FLOWABLE Extracellular Matrix ("FORTIFY FLOWABLE") is an advanced wound care device that presents small intestine submucosa extracellular matrix technology in a way that can fill irregular wound shapes and depths. FORTIFY FLOWABLE is indicated for the management of wounds, including partial and full-thickness wounds, pressure ulcers, venous leg ulcers, diabetic foot ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence sites), traumatic wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. FORTIFY FLOWABLE is provided sterile and is intended for one-time use. It is a 510(k) cleared product. First sales of this product occurred in the first quarter of 2022.

Other Surgical Products

TEXAGEN Amniotic Membrane Allograft is a multi-layer amniotic membrane allograft used as an anatomical barrier with robust handling that can be sutured for securement if needed. BiFORM is an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site. It can be hydrated and used as a strip or molded into a putty to fill a bone defect. ACTIGEN Verified Inductive Bone Matrix is a naturally derived, differentiated allograft matrix with robust handling properties. ALLOCYTE Plus is a human allograft cellular bone matrices containing bone-derived progenitor cells and conformable bone fibers. These viable cellular allografts are ready to use upon thawing and have fibrous handling properties.

Tissue Health Plus Services and Technology

Through our subsidiary, Tissue Health Plus (formerly known as "WounDerm" and "United Wound and Skin Solutions, LLC"), we are seeking to simplify skin health, starting with wound care through a refined business plan. Through THP, we plan to offer a first of its kind value-based wound care program to payers and risk-bearing entities such as accountable care organizations and value-based primary care companies, with Medicare Advantage payers as the initial target segment for this program.

THP's programs are expected to enable payers to divest wound care spend risk, reduce wound related hospitalizations and improve patient quality of life. THP plans to coordinate delivery of community and home-based wound care for its managed patients. Community based care spans a variety of settings including physician offices, skilled nursing homes, assisted living facilities and senior living facilities. THP programs are intended to integrate science and evidence-based medicine protocols to standardize wound prevention and treatment. THP services are not expected to directly involve telemedicine or virtual consult services, and such services are no longer a primary focus of THP.

We anticipate that THP's customer contracts will have three-to-five-year terms. These contracts are expected to incorporate a mix of value-based pricing methodologies including episodic, "per member per month," and "fee for value" pricing. We believe this approach is aligned with the financial goals of the payers and will help deliver outstanding clinical outcomes for the patients.

Our vision for our comprehensive approach consists of three key sets of planned capabilities:

(a) *Care Hub* – This virtual patient monitoring, care coordination and navigation center is expected to help doctors and nurses support their patients throughout their wound care journey, from prevention to treatment. We expect to have Care Hub staffed by wound care certified nurse practitioners ("NPs") and registered nurses ("RNs"), incorporating care delivery best practices from partnerships with Direct Dermatology Inc. and certain physician-led multispecialty wound care groups. With NPs leading Care Hub, RNs are expected to be the wound specialists, providing patients with expert review and support of the overarching plan of care on each patient's journey through the process. In addition, care navigators are expected to serve as a primary point of contact for patients and their providers, coordinating care, managing appointments and ensuring seamless communication among all team members.

(b) *Managed Services Organization ("MSO") Network* – With respect to patient-side wound care, our plan is that THP's programs would be performed by a network of third-party providers who will be contracted through managed services agreements. These providers would include podiatrists, wound care provider groups, primary care physicians, and home health agencies. The providers in the THP network are expected to leverage THP's standard of care, patient education and tools to deliver optimal patient outcomes with high predictability and efficiency.

(c) *Technology Platform* – THP's technology platform will focus on scaling workflows of THP's Care Hub and MSO Network through automation and integration. We expect the THP technology platform to enable enhanced patient empowerment and self-healthcare. We anticipate that our platform will leverage our technology investments and partnerships with Precision Healing Inc. ("Precision Healing"), Pixalere Healthcare, Inc. and others, by leveraging modern technology including artificial intelligence and machine learning. Our platform technology is expected to manage program economics, standards of care, patient monitoring, wound assessments, network performance monitoring, and revenue cycle management. We expect that each of these components will work in concert with each other, constantly improving economics and care delivery.

We are seeking partners to facilitate commercialization of THP and share in the cost of development of the program.

SI Healthcare Technologies Joint Venture

In November 2022, we established a 50/50 joint venture, SI Healthcare Technologies, LLC ("SI Technologies") (formerly known as SI Wound Care, LLC), with InfuSystem Holdings, Inc. ("InfuSystem") focused on delivering a complete wound care solution targeted at improving patient outcomes, lowering the cost of care, and increasing patient and provider satisfaction. The partnership is expected to enable InfuSystem to offer innovative products, including our advanced wound care product line and Chemo Mouthpiece, a 510(k) cleared oral cryotherapy device that SI Technologies currently has the right to distribute and sell in the United States.

Tufts University License Agreement

In December 2023, we signed an exclusive license agreement with Tufts University ("Tufts") to develop and commercialize patented technology covering 18 unique collagen peptides. As part of this agreement, we formed a new subsidiary, Sanara Collagen Peptides, LLC ("SCP") and issued 10% of SCP's outstanding units to Tufts. SCP has exclusive rights to develop and commercialize new products based on the licensed patents and patents pending. SCP will pay royalties to Tufts based on net sales of licensed products and technologies. Pursuant to the exclusive license agreement, royalties will be calculated at a rate of 1.5% or 3%, depending on the type of product or technology developed. SCP will pay Tufts a minimum annual royalty of $50,000 on January 1 of the year following the first anniversary of the first commercial sale of the licensed products or technologies. SCP will pay Tufts a $100,000 minimum annual royalty on January 1 of each subsequent year during the royalty term specified in the exclusive license agreement.

Strategy

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

● *Launch new innovative products.* We are actively developing additional proprietary products for the surgical and chronic wound and skincare markets. We expect these products and services to deepen our portfolio of technologies to improve surgical site outcomes and treat chronic wounds. 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).

● *Seek and establish partnerships and product, services and/or technology 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.

● *Seek and establish partnerships for THP with Medicare Advantage, at-risk payors and other types of healthcare at-risk models*. We believe we have assembled the products, services and technologies to offer a comprehensive strategy to help improve outcomes and lower wound care costs across the continuum of care. Looking ahead, we plan to leverage these capabilities to partner with value-based care models to aid in the treatment of their wound care patients who currently are a significant cost for the healthcare system and challenging population to heal.

● *Aid in the treatment of patients throughout the entire continuum of care*. We intend to continue expanding our platform to aid in treating wound and skincare patients as they progress through the healing process in all care settings. We formed THP to hold certain investments in technologies and operations in value-based wound and skincare 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.

Competitive Strengths

● *Attractive markets for surgical and wound care*. We believe the surgical and wound care markets will continue to see accelerated growth given favorable global tailwinds that include an aging population, extended life expectancies, 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.

● *Comprehensive solution for improved wound care outcomes*. We are dedicated to offering a comprehensive portfolio of products, services and technologies to improve wound care treatment outcomes. We believe we are the only company that will be able to provide a comprehensive solution for wound care which includes a wound and skin specific electronic medical record, coordination of virtual consult services with expert wound care providers and dermatologists, propriety diagnostics and highly efficacious proprietary products allowing us to effectively treat wound care patients in any care setting.

● *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 long-term acute care hospitals) and post-acute (wound care clinics, physician offices, skilled nursing facilities ("SNFs"), home health, hospice, podiatrists and retail).

● *Innovative pipeline and proven clinical performance.* We have a robust pipeline of surgical, wound and skincare 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.

● *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 team has the vision and experience to implement our future growth strategy.

Market Opportunities for Our Products, Services and Technology-Based Offerings

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, senescent/aberrant cells or inappropriate treatment. Examples of chronic wounds include diabetic foot ulcers ("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 chronicity 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:

● *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 external forces causing tissue damage such as lacerations, puncture wounds or tissue loss. 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.

● *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. Diabetes is associated with pathological changes that contribute to poor wound healing. These changes may include peripheral vascular disease, neuropathy, excessive inflammation, and a disrupted cellular response to wound healing. 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 are the most common type of chronic wound in the lower extremity. 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. According to a 2023 report published by the *Journal of Vascular Surgery*, Venous and Lymphatic Disorders, chronic venous disorders are common, with varicose veins occurring in ~40% of the population. 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 presence of a VLU represents the sequela of progressive end-stage chronic venous disease, often related to a previous blood clot. The risk of VLUs 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 Injury/Ulcers*. Pressure injury/ulcers are injuries to the 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, more than 2.5 million people develop pressure ulcers in the United States according to a 2019 study published in the *National Library of Medicine*.

Recent Published Studies on CellerateRX Surgical

An animal study model by the Indiana University Center for Regenerative Medicine and Engineering and the McGowan Institute for Regenerative Medicine was published in Advances in Wound Care in September of 2023. The study, titled "Hydrolyzed Collagen Powder Dressing Improves Wound Inflammation, Perfusion, and Breaking Strength of Repaired Tissue," demonstrated the effects of CellerateRX Surgical powder on resolution of wound inflammation, perfusion, closure, and breaking strength of the repaired skin. Moreover, the study provided translational research validating published clinical case series and further highlighting mechanistic effects of hydrolyzed collagen. Future empirical and clinical research revealing the unique support hydrolyzed collagen provides the wound environment is currently ongoing.

Several research findings involving CellerateRX Surgical powder have been noted in scientific literature. For example, in November 2021, Dr. William Hotchkiss published a retrospective study of 154 patients in JSM Neurosurgery and Spine, in which patients underwent spinal surgery and CellerateRX Surgical was utilized in the surgical wound. The study found a lower wound dehiscence rate in a high-risk patient population when compared to previously published wound complication rates in the literature. Another retrospective case study regarding the use of CellerateRX Surgical was published by Dr. Alex Gitelman in November 2022. This study of 54 patients undergoing spinal surgery demonstrated no incidence of surgical wound complication.

In a retrospective study published in the *Journal of Surgery* in October 2023, the impact of CellerateRX Surgical collagen on surgical site infection rates in elective multispecialty surgical procedures was case matched 1:3 for a total of 5,335 patients and demonstrated an overall reduction of 59% in surgical site infection rates. This reduction was most pronounced in the clean cases with a 69% decrease in surgical site infection rates.

Intellectual Property

Since the acquisition of assets from Rochal Industries, LLC ("Rochal") in July 2021, the acquisition of Precision Healing in April 2022, and the acquisition of assets from The Hymed Group Corporation ("Hymed") and Applied Nutritionals, LLC ("Applied") in August 2023 (the "Applied Asset Purchase"), our research and development activities have included internally developing additional proprietary products, services and technologies for the surgical and chronic wound and skincare markets and actively working with third-party research and development partners. For our internally developed products, we seek patent protection for our inventions in order to protect and differentiate our products and technologies and establish a defense against third-party infringement claims. With the aim of optimizing commercial and regulatory success, our proprietary technology and innovative applications thereof are protected by product, system, process, and method-of-use patent claims. We believe that our granted patents and pending applications collectively protect our internally developed intellectual property, both in terms of our existing products, as well as our anticipated pipeline of new offerings.

In July 2021, we acquired certain assets from Rochal, including intellectual property. With respect to the assets we acquired from Rochal and products developed following the Rochal acquisition, our patent portfolio includes, among others, eight issued U.S. patents, including U.S. Patent No. 8,829,053 entitled "Biocidal Compositions and Methods of Using the Same" (expiring December 7, 2031) relating to BIASURGE Surgical Irrigation, BIAKŌS Antimicrobial Skin & Wound Cleanser and BIAKŌS Antimicrobial Wound Gel, as well as over 100 issued patents in foreign jurisdictions. Following our acquisition by merger of Precision Healing in April 2022, our patent portfolio now includes, among others, five pending U.S. patent applications as well as one pending international patent application. Following the Applied Asset Purchase in August 2023, our portfolio also now includes, among others, nine additional U.S. patent applications, five trademarks, four 510(k) clearances and various domain names.

In 2024, our research and development team submitted 11 provisional patent applications covering innovations in proprietary antimicrobial technologies and hydrolyzed collagen, including novel formulations, treatment applications and key component advancements.

Our pending patent applications and new filings are representative of our ongoing efforts to broaden our portfolio as we continue developing new products for the surgical and wound and skincare markets. We intend to further grow our patent portfolio by continuing to patent new products as they are developed, to defend intellectual property as we believe necessary by actively pursuing any infringements, to pursue the commercial opportunities our patents provide for our innovations, and to continue to develop our brands and trademarks.

Sales and Marketing

As of December 31, 2024, we employed 40 U.S. based field sales representatives. Our field sales representatives are recruited based on their previous industry experience and professional performance. We constantly evaluate new markets and sales opportunities to add to our sales teams as warranted.

Our surgical products are sold through a growing network of surgical specialty distributors and Company representatives who are credentialed to demonstrate the products in surgical settings. Field sales representatives 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 field sales representatives participate in field training with experienced field trainers to get insights into best practice as well as real world training. The initial training period lasts approximately eight weeks. Field sales representatives 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 approval process, allowing our products to be sold in those facilities. 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 our own manufacturing facilities. We rely on contract manufacturers to supply our products. Our contract manufacturing strategy is intended to drive cost leverage through scale and avoid 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.

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.

We anticipate that our THP strategy, once launched, will provide a significant amount 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 surgical 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, surgical wound irrigation products and other biopharmaceutical products. Manufacturers and distributors of competitive products include Medline Industries, Inc., ConvaTec Group plc, 3M Company, Integra LifeSciences Holdings Corporation and numerous others. Many of our competitors are significantly larger than we are and have greater financial and personnel resources.

With respect to our comprehensive value-based care strategy, THP plans to offer a comprehensive wound care and dermatology strategy to expand cost-effective, high-quality wound and skincare 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 THP plans to offer services and solutions. Any clinical wound care or dermatology physician provider group that has incorporated telemedicine into their practice could be considered competitive. However, most of these groups are not offering value-based care contracts to payers, integrating prevention into their programs, or enabling continuity across the different settings of care. Examples of large wound care specialty practices may include Vohra Physician Group, Healogics Specialty Physicians and WoundTech.

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 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. Most of 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 market certain products for use in surgical wound care regulated by the FDA under Section 361 of the Public Health Service Act ("PHSA") (42 U.S.C. § 264) and 21 C.F.R. Part 1271.

Device Premarket Regulatory Requirements

Before being introduced into the U.S. market, each medical device must obtain marketing clearance from the FDA through the 510(k) premarket notification process, the *de novo* classification process (summarized below), 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 or 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 ("preamendment 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. 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 preamendment 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.

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 the 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 Postmarket 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 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;

- 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
- postmarket surveillance regulations, which apply to Class II or Class III devices if the FDA has issued a postmarket 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.

We and our research and development partners and contract manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. If the FDA believes we or any of our research and development partners or contract manufacturers are not in compliance with the QSR, or other postmarket 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 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 premarket 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

Some of the products we currently market are regulated as biologics, more specifically as human cells, tissues, and cellular and tissue-based products ("HCT/Ps"). They include (i) TEXAGEN, (ii) ACTIGEN, and (iii) ALLOCYTE Plus. HCT/Ps are regulated by the 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 the 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 the FDA prior to commercialization, manufacturers of 361 products must register with the FDA, submit a list of HCT/Ps manufactured, and comply with current good tissue practices ("cGTP"), among other things.

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 (the "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 noncompliance 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.

The Health Insurance Portability Accountability Act ("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 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.

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.

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 protected health information ("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 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. 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 to HIPAA and 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, 2024, we had a staff of 141 full-time employees.

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 investor relations website (https://www.sanaramedtech.com/investor-relations/) 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 them.

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 investment in THP.
- Our revenue growth for a particular period is difficult to predict, and a shortfall in forecasted revenues may harm our operating results.
- Our current comprehensive, value-based wound and skincare strategy involves growth through technology development acquisitions and investments, which requires us to incur substantial costs and potential liabilities for which we may never realize the anticipated benefits.
- Failure to manage our growth strategy could harm our business.
- If we are unable to compete within our markets or our products, services and technologies do not gain market acceptance, our financial condition and operating results 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.
- Our indebtedness could adversely affect our financial condition and prevent us from fulfilling our obligations.
- Our outstanding indebtedness is subject to certain operating and financial covenants that restrict our business and financing activities and may adversely affect our cash flow and our ability to operate our business.
- We rely on our research and development partners to design, manufacture and supply certain products we have licensed for marketing. If we or one of our partners fails to perform adequately, fulfill our needs, or comply with regulations, we may be required to incur significant costs or even be subject to enforcement actions. We also may face significant delays in our product introductions and commercialization.
- Revenue generated from the sale of certain products is dependent on license agreements with certain manufacturers, and the termination of any of these license agreements could harm our business.
- Certain of our product candidates are still under development, and we may not be able to successfully commercialize 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.
- Disruption of, or changes in, our distribution model or customer base could harm our sales and margins.
- Interruptions in the supply of our products or inventory loss may adversely affect our business, financial condition and results of operations.
- Failure of any third-party assessments to demonstrate desired outcomes in proposed endpoints could have a negative impact on our business performance.
- Increased prices for, or unavailability of, raw materials used in our products could adversely affect our business, financial condition and results of operations.
- Our planned expansion into value-based wound, skincare and other services could have a material adverse effect on our business, financial condition and results of operations.

- Our planned expansion into value-based wound, skincare and other services will require entrance into certain markets, in which, in some cases, we have limited experience, which may not be successful and could be costly.
- If we are unable to adequately protect our intellectual property rights, we may not be able to compete effectively.
- CellerateRX Surgical is not currently protected by any pending patent application or any unexpired patent. CellerateRX Surgical may be subject to competition from the sale of substantially equivalent products that could adversely affect our business and operations.
- We may be found to infringe on or violate the 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.
- 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.
- 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.
- Disruptions in the FDA and other government agencies caused by leadership changes, funding shortages, or other legal or political pressures could hinder their ability to hire and retain key personnel, provide regulatory clarity, or otherwise prevent new products and services from being developed or commercialized in a timely manner or hinder our ability to continue marketing existing commercial products, which could negatively impact our business.
- Failure to obtain or maintain adequate reimbursement or insurance coverage for our products could limit our ability to market those products 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.
- We 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 research and development partners' use of PII, 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 have a material adverse effect on our client base, business, financial condition and results of operations.
- 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 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, product liability lawsuits and other litigation and negative publicity that could materially adversely affect our reputation, business, results of operations and financial condition.

Risks Related to How We Operate Our Business

We have had a history of losses, which may continue as we expand our investment in THP.

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 THP operating segment, which will substantially increase our operating expenses. Consequently, we will need to continue our revenue growth to become profitable in future periods. 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 forecasted revenues may harm our operating results.

Our revenue growth and results of operations are potentially 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, including increases in inflation, 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 pandemics or other potential outbreaks;
- 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 surgical 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, value-based wound and skincare strategy involves growth through technology development, 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 have acquired or will 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 value-based wound and skincare strategy, we may be unable to meet our financial targets, and our financial performance could be materially and adversely affected.

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 skincare products, services and technologies requires an effective plan for managing our future growth. 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.

If we are unable to compete within our markets or our products, services and technologies do not gain market acceptance, our financial condition and operating results 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. In addition, many specialized products companies have formed collaborations with large, established companies to support research, development and commercialization of surgical 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 surgical wound care products on their own or through joint ventures. 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 the anticipated full launch of our THP platform is successful, we will face competition from other value-based care 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 value-based care providers, our operating results and financial condition may suffer.

Several factors may limit the market acceptance of our products, services and technologies, including the timing of regulatory approvals and market entry relative to competitive products, services and technologies, the availability of alternative products, services and technologies, the price of our products, services and technologies relative to alternative products, services and technologies, the availability of third-party reimbursement and the extent of marketing efforts by third-party distributors or agents that we retain. Our products, services or technologies may not receive market acceptance in a commercially viable period of time, if at all. Furthermore, our competitors may develop products, services or technologies that are more effective or achieve greater market acceptance than those being developed by us, which would render our products, services 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 United States 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, services and technologies 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. If we fail to fully comply with the requirements of the Sarbanes-Oxley Act or our management concludes that our internal controls over financial reporting are not effective, our business may be harmed and our stock price may decline. In addition, because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements.

Risks Related to Our Indebtedness

Our indebtedness could adversely affect our financial condition and prevent us from fulfilling our obligations.

A significant portion of our future cash flow is required to pay interest and principal on our outstanding indebtedness, and we may be unable to generate sufficient cash flow from operations, or have future borrowings available, to enable us to repay our indebtedness or to fund other liquidity needs. Among other consequences, this indebtedness could:

- require us to use a significant percentage of our cash flow from operations for debt service and the satisfaction of repayment obligations, and not for other purposes, such as funding working capital and capital expenditures or making future acquisitions;
- cause our interest expense to increase if there is a general increase in interest rates, because our indebtedness bears interest at floating rates;
- limit our flexibility in planning for or reacting to changes in our business and limit our ability to exploit future business opportunities; and
- cause us to be more highly leveraged than some of our competitors, which may place us at a competitive disadvantage.

Our outstanding indebtedness is subject to certain operating and financial covenants that restrict our business and financing activities and may adversely affect our cash flow and our ability to operate our business.

On April 17, 2024 (the "Closing Date"), we, as borrower, entered into a term loan agreement with the subsidiary guarantors party thereto from time to time (collectively, the "Guarantors"), CRG Servicing LLC as administrative agent and collateral agent (the "Agent"), and the lenders party thereto from time to time (as amended from time to time, the "CRG Term Loan Agreement"), providing for a senior secured term loan of up to $55.0 million (the "CRG Term Loan"). The CRG Term Loan Agreement requires us and the Guarantors to maintain compliance with certain operating and financial covenants, which, among other things, limit our and the Guarantors' ability to incur additional debt, grant or permit additional liens, make investments and acquisitions above certain thresholds, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions.

In addition, the CRG Term Loan Agreement requires us to maintain:

- liquidity in an amount which shall exceed the greater of (i) $3.0 million and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of us by the creditors of such permitted debt; and
- annual minimum revenue of at least: (i) $60.0 million for the twelve-month period beginning on January 1, 2024 and ending on December 31, 2024, (ii) $75.0 million for the twelve-month period beginning on January 1, 2025 and ending on December 31, 2025, (iii) $85.0 million for the twelve-month period beginning on January 1, 2026 and ending on December 31, 2026, (iv) $95.0 million for the twelve-month period beginning on January 1, 2027 and ending on December 31, 2027 and (v) $105.0 million during each twelve-month period beginning on January 1 of a given year thereafter.

A breach of any of the covenants under the CRG Term Loan Agreement, subject to certain cure periods, will result in an event of default. Any event of default under the CRG Term Loan Agreement could cause all of our outstanding indebtedness to become immediately due and payable, and a default interest rate of up to an additional 4.0% per annum may be applied to the outstanding loan balance. If our indebtedness is accelerated, we cannot be certain that we will have sufficient funds available to pay the accelerated indebtedness or that we will have the ability to refinance the accelerated indebtedness on terms favorable to us or at all.

Risks Related to Our Products and Our Product Pipeline

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

While we expect to have the capability to develop certain of our pipeline in-house, we do not currently own any facility that may be used as a manufacturing and processing facility, and therefore rely on our research and development partners from whom we license most of the products we currently commercialize to design, manufacture and supply certain of our products.

We and our research and development partners responsible for manufacturing certain of 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 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.

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, cGTP, 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.

Revenue generated from the sale of certain products is dependent on license agreements with certain manufacturers, and the termination of any of these license agreements could harm our business.

We rely on license agreements with certain manufacturers in order to sell certain of our products. Many of these license agreements are nonexclusive, and our license agreements generally have a term between one and five years. The license agreements are subject to renewal; however, the manufacturers may determine not to renew the agreements or to terminate the contracts pursuant to their terms. We cannot be certain that these license agreements will continue to be available to us or will be available to us on reasonable terms. If any of these agreements are terminated, we may be unable to reacquire the necessary license on satisfactory terms or at all. The loss of, or inability to maintain, any of these license agreements could negatively impact our ability to sell our products, which could have a material adverse effect on our business, financial condition and results of operations.

Certain of our product candidates are still under development, and we may not be able to successfully commercialize 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 nonclinical 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 nonclinical 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 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 as healthcare practitioners may be hesitant to change their medical practices, and we may not be successful in these efforts. 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.

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, 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 result in disruption of or changes in our distribution model or customer base, which could harm our sales and margins. For instance, 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 with them. In addition, some of our resellers may have insufficient financial resources and may not be able to withstand changes in business conditions. If either of these situations were to occur, our reseller channels would weaken, which would result in a material adverse effect on our business.

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

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 noncompliance 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.

Failure of any third-party assessments to demonstrate desired outcomes in proposed endpoints 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.

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

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 THP Platform and Planned Expansion into Value-Based Wound, Skincare and Other Services

Our planned expansion into value-based wound, skincare and other services could have a material adverse effect on our business, financial condition and results of operations.

Our planned expansion into value-based wound, skincare 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 value-based wound, skincare and other services will require entrance into certain markets in which, in some cases, we have limited experience, which may not be successful and could be costly.

Our planned expansion into value-based wound, skincare and other services will require entrance into certain markets in which we have limited experience. While we intend to expand our staff with individuals with more experience in these markets and will closely scrutinize individuals we engage, we may not be able to retain or continue to hire well-qualified and experienced individuals or our assessment of individuals we retain may not 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.

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 sufficient or 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 and the damages or other remedies awarded if we were to prevail in upholding such patents may not be commercially meaningful. 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.

Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees.

Patent rights are territorial, and patent protection extends only to those countries where we have issued patents. Filing, prosecuting and defending patents on our products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less or more extensive than those in the United States, and their litigation processes differ. Competitors may successfully challenge or avoid our patents or manufacture products in countries where we have not applied for patent protection. Changes in the patent laws in the United States or other countries may diminish the value of our patent rights. As a result of these and other factors, the scope, validity, enforceability, and commercial value of our and our research development partners' patent rights are uncertain and unpredictable.

The patent positions of life sciences companies, including our and our research development partners' patent positions, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we and our research development partners may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. A third-party may submit prior patents, or we may become involved in

opposition, derivation, reexamination, inter partes review, post-grant review, supplemental examination, or interference proceedings challenging our patent rights or the patent rights of our licensors or development partners. The costs of defending or enforcing our proprietary rights in these proceedings can be substantial, and the outcome can be uncertain. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, or reduce our ability to manufacture or commercialize products. Furthermore, if the scope or strength of protection provided by our patents and patent applications is threatened, it could discourage companies from collaborating with us to license, develop or commercialize current or future products. The ownership of our proprietary rights could also be challenged.

Our and our research development partners' ability to enforce our respective patent rights depends on the ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product, particularly in litigation in countries other than the United States that do not provide an extensive discovery procedure.

CellerateRX Surgical is not currently protected by any pending patent application or any unexpired patent. CellerateRX Surgical may be subject to competition from the sale of substantially equivalent products that could adversely affect our business and operations.

Our CellerateRX Surgical products, from which we derive a substantial majority of our net revenue, have 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 nonpatent intellectual property, such as potential regulatory rights that would require various resources to separately obtain. 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. Trade secret protection is effective only against wrongful acquisition, use or disclosure of confidential information. A competitor can avoid a claim of trade secret misappropriation by showing independent development without use of a trade secret owner's information, however, this typically requires some time, effort and financial resources to develop independently. 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 may be found to infringe on or violate the intellectual property rights of others.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our products or R&D candidates, by preventing the patentability of one or more aspects of our products or R&D candidates to us or our licensors, or by covering the same or similar technologies that may affect our ability to market our products and R&D candidates. For example, we (or the licensor of a product or R&D candidate to us) may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products and candidates. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

Such 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, our operations and our products. 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 United States. 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 is completely free of infringement of the patent rights of others even when we take reasonably objective steps to determine that relevant patent rights might exist and, if so, to evaluate such patent rights relative to our proposed and actual products and methods with patent counsel. 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. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to cease developing, selling or otherwise commercializing one or more of our products; to pay substantial damages for past use of the asserted intellectual property; to obtain a license from the holder of the asserted intellectual property, which may not be available on reasonable terms, if at all; and redesign, or rename in the case of trademark claims, our product(s) to avoid such third party rights, which may not be possible or which could be costly and time-consuming. Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects. 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 noninfringing 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 and the resources required to engage in a full defense of such allegations, 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 noninfringing 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:

- appropriate establishment registration and product listing requirements;
- FDA's cGMP, cGTP and QSR regulations, which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices, drugs and/or biologics, as applicable;
- FDA labeling requirements, which mandate the inclusion of certain content in medical product labels and labeling, and which also prohibit the promotion of products for uncleared or unapproved, i.e., "off-label," indications;
- adverse event reporting regulations, which, generally, require applicable establishments (such as manufacturers and importers, among others) report to the FDA any adverse reactions, events, or experiences that meet the FDA's reporting thresholds for the given product type (e.g., under FDA's adverse-event reporting regulations under its device framework, adverse events must be reported if they 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 corrective actions and product removals (both of which are defined under applicable regulations) that meet the definition of a "recall" if undertaken to reduce a risk to health posed by the product 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.

In addition, private consumer and competitor litigation tends to follow FDA enforcement actions and publications, such that a company that is targeted by FDA or another regulatory body is also at an increased risk of facing civil litigation (often in the form of class actions).

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 FTC, 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 United States 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 FDCA 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.

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

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 United States 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.

Disruptions in the FDA and other government agencies caused by leadership changes, funding shortages, or other legal or political pressures could hinder their ability to hire and retain key personnel, provide regulatory clarity, or otherwise prevent new products and services from being developed or commercialized in a timely manner or hinder our ability to continue marketing existing commercial products, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Further, the recent presidential election and congressional seat turnover may result in increased regulatory and economic uncertainty, including the spending priorities of the new U.S. presidential administration and Congress and what challenges budget reductions will present for us and our industry generally. For example, on January 20, 2025, President Trump announced an executive order establishing the "Department of Government Efficiency" to reform federal government processes and reduce expenditures. Changes in federal policy by the executive branch and regulatory agencies may occur over time through the new presidential administration's and/or Congress's policy and personnel changes, which could lead to changes involving our industry. However, the nature and timing of such potential changes remain highly uncertain. At this time, it is unclear whether and how any future changes or uncertainty surrounding future changes will adversely affect our business, but material adverse effects are possible.

Failure to obtain or maintain adequate reimbursement or insurance coverage for our products could limit our ability to market those products 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 United States 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 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 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.

Certain 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 noncompliance 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 their own and, if they are successful, they 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 of PII, 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 have 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 each state's Attorney 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.

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.

Third party payors, governmental authorities, and other applicable stakeholders have developed, and are continuing to develop, increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been numerous legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Affordable Care Act was enacted in the United States in 2010, and various analogous or similarly intended state laws, as well as a number of executive, legislative, and judicial challenges have followed in the years since. There remains substantial uncertainty and continued evolution with regard to healthcare reform measures, and we cannot predict the effect that any current or future such measure will have on our business. Complying with any new or amended legislation, policies, rulings, or other relevant healthcare cost-containment and/or transparency requirements may be time-intensive and expensive, which could have a material adverse effect on our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for some or all of the products we currently market or may commercialize in the future, if any, including: our ability to receive or set a price that we believe is fair for our products; our ability to generate revenue and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital. We expect that existing healthcare reform legislation, and any similar measures implemented in the future, will result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the prices that we are able to charge or receive for our products and/or may create additional challenges in relation to reimbursement/coverage. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, product liability lawsuits and other 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 products are subject to extensive and rigorous regulation by numerous government agencies, including the FDA and similar foreign agencies. Compliance with these regulatory requirements 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.

Relatedly, although we have contractual indemnity from the manufacturers of our current products for certain liability claims related to their production, we could face product liability lawsuits or other similar proceedings relating to actual or alleged injuries, defects, deficiencies, failures, and/or representations relating to our products that could fall outside of the scope of the contractual indemnities. 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 or other applicable 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 any such 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.

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

It is possible that we will require additional capital to meet our financial obligations and support business growth, and this capital might not be available on acceptable terms or at all.

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;
- 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 and inflation;
- 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 or the perception that these sales might occur 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 in the near future, cash dividends on our securities. Because we have no 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 18, 2025, our directors beneficially owned, including through their affiliates, approximately 41% 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 Amended and Restated Certificate of Formation (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 for acts or omissions in the director's capacity as a director 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 owed 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. 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, our Certificate of Formation and our Amended and Restated 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 our Amended and Restated Bylaws ("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 twenty-five percent (25%) 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 our shareholders' ability to sell or purchase our common stock when our shareholders 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 noncompliance with Nasdaq's listing requirements.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

We recognize the critical importance of cybersecurity in safeguarding sensitive information and maintaining operational resilience. We have processes for assessing, identifying and managing cybersecurity risks, which are built into our information technology function and are designed to help protect our information assets and operations from internal and external cyber threats, protect employee and customer information from unauthorized access or attack, as well as secure our networks and systems.

The audit committee of the board of directors (the "Audit Committee") is responsible for overseeing cybersecurity risk and periodically updates our board of directors on such matters. The Audit Committee receives periodic updates from management regarding cybersecurity matters and is notified between such updates regarding any significant new cybersecurity threats or incidents.

As a company, we leverage the National Institute of Standards and Technology (NIST) Cybersecurity Framework to align with industry best practices and to develop policies and procedures, which include a Cybersecurity Response Plan focusing on detection, validation, mitigation, recovery, and refinement. In addition to the Cybersecurity Response Plan, we provide cybersecurity awareness training to our employees, including training on social engineering, phishing, password protection, confidential data protection, mobile security, and incident reporting, to help prevent and reduce the impact of potential cybersecurity events.

We have strategically invested resources and tools to combat the ever-changing cyber threat landscape. These investments include growing our internal technology team headcount and bolstering our partnerships with entities with external expertise, resulting in increased protection, monitoring, and response capabilities. We have also made investments to carry cybersecurity insurance that provides additional protection and resources to reduce a cybersecurity event's impact and potential losses.

Our technology and management teams meet regularly with key internal and external stakeholders to review cybersecurity concerns and areas for continued focus and improvement.

We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. To date, we have not experienced any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect our business strategy, financial condition, results of operations, or cash flows. See "Risk Factors – Risks Related to 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."

ITEM 2. PROPERTIES

We do not own any buildings or other real property. As of December 31, 2024, our leased office space in Fort Worth, Texas consisted of approximately 11,414 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. In March and September

of 2023, we amended our primary office lease to obtain additional space, as well as to extend the lease term. The lease had a remaining lease term of 72 months as of December 31, 2024. In March 2025, we increased our lease office space in Fort Worth, Texas by approximately 3,900 square feet.

Our leased office space in San Antonio, Texas consists of approximately 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 had a remaining lease term of eight months as of December 31, 2024. We are currently evaluating our renewal options for this lease.

Our leased office space in Orlando, Florida represents a lease we assumed in connection with our acquisition of Scendia Biologics, LLC. The lease consists of approximately 7,684 square feet in a 22,947 square foot office building. However, we are co-tenants in the lease with an unaffiliated company with our share of the lease being agreed to as 40% or approximately 3,074 square feet. The lease had a remaining term of two months as of December 31, 2024 and was not renewed.

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 Topic No. 842, such arrangements are included in our balance sheet.

See Note 7 to the consolidated 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 18, 2025, was $33.64.

Record Holders

As of March 18, 2025, there were 310 shareholders of record and there were 8,901,903 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, 2024 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, 2024.

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 to Consolidated Financial Statements 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, chronic wound and skincare markets. Our products, services and technologies are designed to achieve our goal of providing better clinical outcomes at a lower overall cost for patients regardless of where they receive care. Through our two operating segments, Sanara Surgical and Tissue Health Plus ("THP"), we strive to be one of the most innovative and comprehensive providers of effective surgical, wound and skincare solutions and are continually seeking to expand our offerings for patients requiring treatments across the entire continuum of care in the United States.

Change in Reportable Segments

Historically, we managed our business on the basis of one operating and reportable segment. During the second quarter of 2024, we changed our reportable segments to reflect a change in the manner in which the business is managed. Based on the growing importance of the value-based wound care program to our future outlook and how our chief operating decision maker ("CODM"), the Chief Executive Officer, reviews operating results and makes decisions about resource allocation, we now have two reportable segments: Sanara Surgical and THP.

Sanara Surgical

Our Sanara Surgical segment primarily markets and sells soft tissue repair and bone fusion products for use in the operating room or other sterile environments. Sanara Surgical's soft tissue repair products include, among other products, our lead product, CellerateRX Surgical Activated Collagen ("CellerateRX Surgical"), a hydrolyzed collagen that supports a local environment for surgical sites to aid in the natural wound healing process, and BIASURGE Advanced Surgical Solution ("BIASURGE"), a sterile no-rinse, advanced surgical solution used for wound irrigation. Sanara Surgical's bone fusion products include, among other products, BiFORM Bioactive Moldable Matrix ("BiFORM"), an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site, and ALLOCYTE Plus Advanced Viable Bone Matrix ("ALLOCYTE Plus"), a human allograft cellular bone matrix containing bone-derived progenitor cells and conformable bone fibers.

Our Sanara Surgical segment also includes an in-house research and development team, Rochal Technologies, with an extensive pipeline of innovative products under development.

Tissue Health Plus

Our value-based care segment, THP, is focused on value-based wound care services. Through THP, we plan to offer a first of its kind value-based wound care program to payers and risk-bearing entities such as accountable care organizations and value-based primary care companies, with Medicare Advantage payers as the initial target market for this program.

THP's programs are expected to enable payers to divest wound care spend risk, reduce wound related hospitalizations and improve patient quality of life. THP plans to coordinate delivery of community and home-based wound care for its managed patients. Community based care spans a variety of settings, including physician offices, skilled nursing facilities, assisted living facilities and senior living facilities. THP programs are intended to integrate science and evidence-based medicine protocols to standardize wound prevention and treatment.

Summary of Our Product, Service and Technology Offerings and Development Programs

Sanara Surgical Products

Our Sanara Surgical segment markets and distributes surgical, wound and skincare products 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 believe we have the ability to drive our product pipeline from concept to preclinical and clinical development while meeting quality and regulatory requirements. We are constantly seeking long-term strategic partnerships with a focus on products that improve outcomes at a lower overall cost.

CellerateRX Surgical

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 with a proprietary process. CellerateRX Surgical powder is sterilized, packaged and designed specifically for use in the operating room or other sterile environment. CellerateRX Surgical products are primarily purchased by hospitals and ambulatory surgical centers for use by surgeons on surgical wounds. The majority of CellerateRX Surgical products are used for a variety of surgical wounds, including those associated with orthopedic, spine, trauma and oncologic procedures. Additional surgical wounds that may benefit from the use of CellerateRX Surgical include cardiovascular, gynecologic, urologic, vascular and plastic/reconstructive related procedures.

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 wounds. This is especially true in patients with certain comorbidities, including obesity, diabetes and hypertension. These complications can include surgical wound infections, dehiscence (where an incision opens after primary closure) and necrosis. Surgeons use CellerateRX Surgical to complement the body's normal healing process. By supporting the body to 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). Surgical wound complications have become increasingly problematic due to the high rates of surgical patient comorbidities and the financial strain on insurance payors as well as hospitals who suffer exorbitant costs for readmission of these patients within 90 days of surgery.

BIASURGE

BIASURGE is a 510(k) cleared sterile no-rinse, advanced surgical solution used for wound irrigation. It contains an antimicrobial preservative effective against a broad spectrum of pathogenic microorganisms in the solution. BIASURGE is indicated for use in the mechanical cleansing and removal of debris, including microorganisms, from surgical wounds. First sales of BIASURGE occurred in November 2023.

FORTIFY TRG

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

FORTIFY FLOWABLE

FORTIFY FLOWABLE Extracellular Matrix ("FORTIFY FLOWABLE") is an advanced wound care device that presents small intestine submucosa extracellular matrix technology in a way that can fill irregular wound shapes and depths. FORTIFY FLOWABLE is indicated for the management of wounds, including partial and full-thickness wounds, pressure ulcers, venous leg ulcers, diabetic foot ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence sites), traumatic wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. FORTIFY FLOWABLE is provided sterile and is intended for one-time use. It is a 510(k) cleared product. First sales of this product occurred in the first quarter of 2022.

Other Surgical Products

TEXAGEN Amniotic Membrane Allograft is a multi-layer amniotic membrane allograft used as an anatomical barrier with robust handling that can be sutured for securement if needed. BiFORM is an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site. It can be hydrated and used as a strip or molded into a putty to fill a bone defect. ACTIGEN Verified Inductive Bone Matrix is a naturally derived, differentiated allograft matrix with robust handling properties. ALLOCYTE Plus is a human allograft cellular bone matrices containing bone-derived progenitor cells and conformable bone fibers. These viable cellular allografts are ready to use upon thawing and have fibrous handling properties.

Tissue Health Plus Services and Technology

In June 2020, we formed a subsidiary, United Wound and Skin Solutions, LLC (formerly known as "WounDerm"), to hold certain investments and operations in wound and skincare virtual consult services. In 2024, United Wound and Skin Solutions, LLC was renamed to Tissue Health Plus, LLC. THP is continuing its current mission to simplify skin health, starting with value-based wound care through a refined business plan. Through THP, we plan to offer a first of its kind value-based wound care program to payers and risk-bearing entities such as accountable care organizations and value-based primary care companies, with Medicare Advantage payers as the initial target segment for this program. THP services are not expected to directly involve telemedicine or virtual consult services, and such services are no longer a primary focus of THP.

We anticipate that THP's customer contracts will have three-to-five-year terms. These contracts are expected to incorporate a mix of value-based pricing methodologies including episodic, "per member per month," and "fee for value" pricing. We believe this approach is aligned with the financial goals of the payers and will help deliver outstanding clinical outcomes for the patients.

Our vision for our comprehensive approach consists of three key sets of planned capabilities:

(a) *Care Hub* – This virtual patient monitoring, care coordination and navigation center is expected to help doctors and nurses support their patients throughout their wound care journey, from prevention to treatment. We expect to have Care Hub staffed by wound care certified nurse practitioners ("NPs") and registered nurses ("RNs"), incorporating care delivery best practices from partnerships with Direct Dermatology Inc. and certain physician-led multispecialty wound care groups. With NPs leading Care Hub, RNs are expected to be the wound specialists, providing patients with expert review and support of the overarching plan of care on each patient's journey through the process. In addition, care navigators are expected to serve as a primary point of contact for patients and their providers, coordinating care, managing appointments and ensuring seamless communication among all team members.

(b) *Managed Services Organization ("MSO") Network* – With respect to patient-side wound care, our plan is that THP's programs would be performed by a network of third-party providers who will be contracted through managed services agreements. These providers would include podiatrists, wound care provider groups, primary care physicians, and home health agencies. The providers in the THP network are expected to leverage THP's standard of care, patient education and tools to deliver optimal patient outcomes with high predictability and efficiency.

(c) *Technology Platform* – THP's technology platform will focus on scaling workflows of THP's Care Hub and MSO Network through automation and integration. We expect the THP technology platform to enable enhanced patient empowerment and self-healthcare. We anticipate that our platform will leverage our technology investments and partnerships with Precision Healing Inc. ("Precision Healing"), Pixalere Healthcare, Inc. ("Pixalere") and others, by leveraging modern technology including artificial intelligence and machine learning. Our platform technology is expected to manage program economics, standards of care, patient monitoring, wound assessments, network performance monitoring, and revenue cycle management. We expect that each of these components will work in concert with each other, constantly improving economics and care delivery.

We are seeking partners to facilitate commercialization of THP and share in the cost of development of the program.

SI Healthcare Technologies Joint Venture

In November 2022, we established a 50/50 joint venture, SI Healthcare Technologies, LLC ("SI Technologies") (formerly known as SI Wound Care, LLC), with InfuSystem Holdings, Inc. ("InfuSystem") focused on delivering a complete wound care solution targeted at improving patient outcomes, lowering the cost of care, and increasing patient and provider satisfaction. The partnership is expected to enable InfuSystem to offer innovative products, including our advanced wound care product line and Chemo Mouthpiece, a 510(k) cleared oral cryotherapy device that SI Technologies currently has the right to distribute and sell in the United States.

Tufts University License Agreement

In December 2023, we signed an exclusive license agreement with Tufts University ("Tufts") to develop and commercialize patented technology covering 18 unique collagen peptides. As part of this agreement, we formed a new subsidiary, Sanara Collagen Peptides, LLC ("SCP") and issued 10% of SCP's outstanding units to Tufts. SCP has exclusive rights to develop and commercialize new products based on the licensed patents and patents pending. SCP will pay royalties to Tufts based on net sales of licensed products and technologies. Pursuant to the exclusive license agreement, royalties will be calculated at a rate of 1.5% or 3%, depending on the type of product or technology developed. SCP will pay Tufts a minimum annual royalty of $50,000 on January 1 of the year following the first anniversary of the first commercial sale of the licensed products or technologies. SCP will pay Tufts a $100,000 minimum annual royalty on January 1 of each subsequent year during the royalty term specified in the exclusive license agreement.

RECENT DEVELOPMENTS

CRG Term Loan

On April 17, 2024 (the "Closing Date"), we, as borrower, entered into a Term Loan Agreement (the "CRG Term Loan Agreement") with the subsidiary guarantors party thereto from time to time (collectively, the "Guarantors"), CRG Servicing LLC as administrative agent and collateral agent (the "Agent"), and the lenders party thereto from time to time, providing for a senior secured term loan of up to $55.0 million (the "CRG Term Loan"). In April 2024, our first borrowing (the "First Borrowing") under the CRG Term Loan of $15.0 million was used to repay the Cadence Term Loan and to pay fees and

expenses related to the CRG Term Loan Agreement. In September 2024, we borrowed an additional $15.5 million under the CRG Term Loan (the "Second Borrowing"), a portion of the proceeds of which were used for the investment in ChemoMouthpiece, LLC ("CMp") described below. On March 19, 2025, we and the Guarantors entered into the First Amendment to the Term Loan Agreement with the Agent and the lenders party thereto from time to time (the "CRG Amendment") to provide for up to two additional borrowings following the Second Borrowing under the CRG Term Loan, which must occur on or prior to December 31, 2025, if at all.

ChemoMouthpiece Investment

On September 10, 2024, Sanara CMP LLC, a wholly owned subsidiary of the Company ("Sanara CMP"), entered into a Unit Purchase Agreement (the "Unit Purchase Agreement") with CMp, pursuant to which Sanara CMP purchased 100,674.72 common units in CMp for an aggregate purchase price of $5.0 million, which represented approximately 6.64% of the issued and outstanding membership interests of CMp immediately following such purchase. Subsequent to our initial investment in CMp, units of CMp were sold to other investors, thereby decreasing our ownership of CMp to 6.59% as of December 31, 2024. CMp is a privately held medical device company that develops and commercializes propriety oral cryotherapy products for cancer patients, including, among other things, CMp's Chemo Mouthpiece oral cryotherapy device, which is a 510(k) cleared cryotherapy device designed to reduce the incidence and severity of chemotherapy induced oral mucositis.

In connection with the Unit Purchase Agreement, we, CMp, certain subsidiaries of CMp, InfuSystem and SI Technologies, entered into an Exclusive Distribution Agreement (the "Distribution Agreement") pursuant to which SI Technologies was appointed as the sole and exclusive U.S. distributor of CMp's Standard Chemo Regiment Kits, each kit consisting of the Chemo Mouthpiece oral cryotherapy device and associated materials used in the treatment of oral mucositis (the "CMp Product"), for a term of five years, subject to meeting certain minimum order requirements.

The parties to the Distribution Agreement also entered into an Intellectual Property Rights Agreement, pursuant to which SI Technologies was granted the exclusive right to use CMp's intellectual property rights to permit resale and use of the CMp Product in the United States.

BMI Investment

On January 16, 2025 (the "Execution Date"), we entered into a Licensing and Distribution Agreement (the "BMI License Agreement") with Biomimetic Innovation Limited, a privately-held medical device company headquartered in Shannon, Co. Clare Ireland ("BMI"), pursuant to which we acquired the exclusive U.S. marketing, sales and distribution rights to OsStic Synthetic Injectable Structural Bio-Adhesive Bone Void Filler ("OsStic"), as well as an adjunctive internal fixation technology featuring novel delivery to promote targeted application of OsStic ("ARC" and together with OsStic, the "BMI Products"), for use in the treatment of a wound or injury caused by a traumatic incident. Pursuant to the BMI License Agreement, we were appointed by BMI as the exclusive distributor to promote, market, offer to sell, transfer, distribute and sell the BMI Products for trauma indications inside the United States and its territories for an initial five-year term, which term may be automatically renewed for successive two-year periods at our discretion, provided that we are in compliance with our obligations thereunder (the "BMI Term").

In connection with the BMI License Agreement, on the Execution Date, we entered into a Share Subscription and Shareholders' Agreement (the "BMI Subscription Agreement") with The Russell Revocable Living Trust, BMI and the existing shareholders of BMI, pursuant to which we agreed to contribute up to approximately €8.0 million to BMI through a series of capital contributions in exchange for an aggregate of 16,460 ordinary shares of BMI, constituting approximately 12.5% of the outstanding equity of BMI as of the Execution Date. We made an initial cash investment totaling approximately €3.0 million on the Execution Date, and our previously announced convertible loan to BMI was converted into €1.0 million of equity in BMI. Pursuant to the BMI Subscription Agreement, the remaining €4.0 million contribution is due upon the achievement of certain development, clinical and regulatory milestones (the "Milestones"), which are expected to occur at various points during 2025. For more information regarding the BMI License Agreement and BMI Subscription Agreement, see the *"Liquidity and Capital Resources*" section below.

COMPONENTS OF RESULTS OF OPERATIONS

Sources of Revenue

Our revenue is derived primarily from sales of our soft tissue repair and bone fusion products to hospitals and other acute care facilities. In particular, the substantial majority of our product sales revenue is derived from sales of CellerateRX Surgical. 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 a purchase order is received from the customer and our product is received by the customer. Prior to 2024, we recognized royalty revenue from a development and licensing agreement with BioStructures, LLC. Under the terms of the development and license agreement, royalties of 2% were recognized on sales of products containing our patented resorbable bone hemostasis. The minimum annual royalty due to us was $201,000 per year throughout the life of the patent, which expired in 2023.

Revenue streams from product sales and royalties are summarized below for the years ended December 31, 2024 and 2023.

	For the Year Ended December 31,	
	2024	**2023**
Soft tissue repair products	$76,125,012	$54,836,410
Bone fusion products	10,547,413	9,952,432
Royalty revenue	—	201,000
Total Net Revenue	$86,672,425	$64,989,842

Cost of Goods Sold

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

Operating Expenses

Selling, general and administrative ("SG&A") consists primarily of salaries, sales commissions, benefits, bonuses and share-based compensation. SG&A also includes outside legal counsel fees, audit fees, insurance premiums, rent and other corporate expenses. We expense all SG&A as incurred.

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

Depreciation and amortization includes depreciation of fixed assets and amortization of intangible assets that have a finite life, such as product licenses, patents and intellectual property, customer relationships and assembled workforces.

Change in fair value of earnout liabilities represents our measurement of the change in fair value at the balance sheet date of our earnout liabilities that were established at the time of our Precision Healing merger and acquisition of Scendia Biologics, LLC ("Scendia").

Other Income (Expense)

Other income (expense) is primarily comprised of interest expense and other nonoperating activities.

RESULTS OF OPERATIONS

The following table presents certain information about the results and Segment Adjusted EBITDA (as described below) of our reportable business segments. See Note 14, Segment Reporting, in Part II, Item 8 of this report for more information on our reportable business segments:

	Year Ended December 31,					
	2024			2023		
	Sanara Surgical	THP	Total	Sanara Surgical	THP	Total
Net revenue	$86,672,425	$ -	$86,672,425	$64,987,112	$ 2,730	$64,989,842
Cost of goods sold	8,139,901	-	8,139,901	7,843,721	8,965	7,852,686
Selling, general and administrative	71,673,642	4,886,221	76,559,863	54,826,852	2,167,901	56,994,753
Research and development	2,828,663	2,874,699	5,703,362	902,782	3,229,643	4,132,425
Depreciation and amortization	2,785,829	2,137,395	4,923,224	2,046,859	1,628,167	3,675,026
Change in fair value of earnout liabilities	(14,451)	(1,924,000)	(1,938,451)	(1,298,336)	(2,151,559)	(3,449,895)
Other expense	3,196,424	-	3,196,424	224,749	-	224,749
Net income (loss)	$ (1,937,583)	$(7,974,315)	$ (9,911,898)	$ 440,485	$(4,880,387)	$ (4,439,902)
Segment Adjusted EBITDA	$ 9,148,722	$(6,457,415)	$ 2,691,307	$ 5,289,634	$(5,162,387)	$ 127,247

Net Revenue. For the year ended December 31, 2024, we generated net revenue of $86.7 million compared to net revenue of $65.0 million for the year ended December 31, 2023, a 33% increase over the prior year. The higher net revenue in 2024 was primarily due to increased sales of soft tissue repair products, including CellerateRX Surgical and BIASURGE, and certain bone fusion products as a result of our increased market penetration, geographic expansion and our continuing strategy to expand our independent distribution network in both new and existing U.S. markets. In addition, during the fourth quarter of 2024, we experienced a growth in sales of BIASURGE as a result of supply chain issues and shortages of intravenous ("IV") fluids and saline solutions due to Hurricane Helene. BIASURGE revenues returned to normal levels in the first quarter of 2025 as access to IV fluids and saline solutions used for the treatment of wound irrigation was restored.

Cost of Goods Sold. Cost of goods sold for the year ended December 31, 2024 was $8.1 million compared to cost of goods sold of $7.9 million for the year ended December 31, 2023. The higher gross margins realized in 2024 were due to increased sales of soft tissue repair products, particularly CellerateRX Surgical, and the elimination of royalties paid on the sales of CellerateRX Surgical as a result of the Applied Asset Purchase (as described in further detail in the "Liquidity and Capital Resources" section below.

Gross Profit. On a consolidated basis, we generated gross profit of $78.5 million for the year ended December 31, 2024 compared to gross profit of $57.1 million for the year ended December 31, 2023, a 37.4% increase over the prior year period. The higher gross profit in 2024 was primarily due to increased sales of soft tissue repair products, particularly CellerateRX Surgical and BIASURGE, as a result of our increased market penetration and geographic expansion, and our continuing strategy to expand our independent distribution network in both new and existing U.S. markets.

Selling, general and administrative. SG&A for the year ended December 31, 2024 was $76.6 million compared to SG&A of $57.0 million for the year ended December 31, 2023. The higher SG&A expenses in 2024 were primarily due to increased direct sales and marketing expenses, which accounted for approximately $13.0 million of the increase compared to the prior year period. Our 2024 SG&A also included $4.9 million of costs related to the buildout of our THP platform and infrastructure, $1.0 million of executive separation costs and $1.4 million of acquisition costs related to prospective investments.

Research and development. R&D for the year ended December 31, 2024 was $5.7 million compared to R&D of $4.1 million for the year ended December 31, 2023. The higher R&D in 2024 was primarily due to development projects associated with surgical product candidates.

Depreciation and amortization. Depreciation and amortization for the year ended December 31, 2024 was $4.9 million compared to depreciation and amortization of $3.7 million for the year ended December 31, 2023. The increase in depreciation and amortization in 2024 was primarily due to amortization of intangible assets acquired as part of the Applied Asset Purchase, which closed in August 2023, and a $0.5 million non-cash charge during the fourth quarter of 2024 to write-off the remaining net book value of certain THP internal use software assets.

Change in fair value of earnout liabilities. Change in fair value of earnout liabilities was a benefit of $1.9 million for the year ended December 31, 2024 compared to a benefit of $3.4 million for the year ended December 31, 2023. The benefit recognized in 2024 was due to a decrease in the estimated fair value of earnout liabilities associated with the Precision Healing merger, as well as adjustments to the projected timing of payments related to the Applied Asset Purchase earnout.

Other expense. Other expense for the year ended December 31, 2024 was $3.2 million compared to $0.2 million for the year ended December 31, 2023. Other expense for the year ended December 31, 2024 primarily included higher interest expense and fees related to the CRG Term Loan.

Net loss. For the year ended December 31, 2024, we had a net loss of $9.9 million, compared to a net loss of $4.4 million for the year ended December 31, 2023. Our net loss included $8.0 million and $4.9 million related to our THP segment for the year ended December 31, 2024 and 2023, respectively. The higher net loss in 2024 was primarily due to higher costs related to the buildout of our THP platform and infrastructure, increased interest expense related to the CRG Term Loan, lower benefits realized in connection with changes in fair value of earnout liabilities, and higher amortization of our acquired intangible assets, partially offset by higher gross profit.

Segment Adjusted EBITDA. Segment Adjusted EBITDA is the primary profitability measure used by the CODM for purposes of assessing financial performance and resource allocation. We define Segment Adjusted EBITDA for the reportable segments as net income (loss) excluding interest expense/income, provision/benefit for income taxes, depreciation and amortization, non-cash share-based compensation expense, change in fair value of earnout liabilities, share of losses from equity method investments, executive separation costs, legal and diligence expenses related to acquisitions, and gains/losses on the disposal of property and equipment, as each are applicable to the periods presented. We have historically presented this profitability measure as Segment EBITDA and, starting with the fourth quarter ended December 31, 2024, are presenting it as Segment Adjusted EBITDA. The definition and methodology for calculating this measure has remained unchanged. Segment Adjusted EBITDA is a non-GAAP measure and should be considered in addition to, not as a substitute for, net income (loss), cash flow and other measures of financial performance reported in accordance with GAAP.

We believe Segment Adjusted EBITDA is useful to investors because it facilitates comparisons of our core business operations across periods on a consistent basis. Accordingly, we adjust for certain items, such as change in fair value of earnout liabilities, when calculating Segment Adjusted EBITDA because we believe that such items are not related to our core business operations. We do not, nor do we suggest that investors should, consider these non-GAAP financial measures in isolation from, or as a substitute for, financial information prepared in accordance with GAAP. Material limitations associated with the use of such measures include that they do not reflect all costs included in operating expenses and may not be comparable with similarly named financial measures of other companies. Furthermore, these non-GAAP financial measures are based on subjective determinations of management regarding the nature and classification of events and circumstances. We present these non-GAAP financial measures to provide investors with information to evaluate our operating results in a manner similar to how management evaluates business performance. To compensate for any limitations in such non-GAAP financial measures, management believes that it is useful in understanding and analyzing the results of the business to review both GAAP information and the related non-GAAP financial measures.

The following table provides a reconciliation of net income (loss) to Segment Adjusted EBITDA for our business segments for the periods indicated below:

	Year Ended December 31,					
	2024			2023		
	Sanara Surgical	THP	Total	Sanara Surgical	THP	Total
Net Income (Loss)	$ (1,937,583)	$ (7,974,315)	$ (9,911,898)	$ 440,485	$ (4,880,387)	$ (4,439,902)
Adjustments:						
Interest expense	3,128,395	-	3,128,395	475,783	-	475,783
Interest income	(21,978)	-	(21,978)	-	-	-
Depreciation and amortization [1]	2,785,829	2,137,395	4,923,224	2,046,859	1,628,167	3,675,026
Noncash share-based compensation	3,969,008	138,245	4,107,253	3,201,330	241,392	3,442,722
Change in fair value of earnout liabilities	(14,451)	(1,924,000)	(1,938,451)	(1,298,336)	(2,151,559)	(3,449,895)
Share of losses from equity method investments	90,007	-	90,007	-	-	-
Executive separation costs [2]	964,466	-	964,466	-	-	-
Acquisition costs [3]	185,029	1,165,260	1,350,289	423,513	-	423,513
Segment Adjusted EBITDA	$ 9,148,722	$ (6,457,415)	$ 2,691,307	$ 5,289,634	$ (5,162,387)	$ 127,247

(1) Includes a $506,836 non-cash charge during the fourth quarter of 2024 to write-off the remaining net book value of certain THP internal use software assets.

(2) Includes $328,795 of share-based compensation related to executive separation costs for the year ended December 31, 2024.

(3) Acquisition costs include legal, tax and accounting services related to prospective acquisitions.

For the year ended December 31, 2024, our Segment Adjusted EBITDA was $2.7 million compared to $0.1 million for the year ended December 31, 2023. Our Segment Adjusted EBITDA included $(6.5) million and $(5.2) million related to our THP segment for the year ended December 31, 2024 and 2023, respectively. The higher Segment Adjusted EBITDA in 2024 was primarily due to higher net revenue and gross profit as discussed above.

LIQUIDITY AND CAPITAL RESOURCES

Cash on hand at December 31, 2024 was $15.9 million, compared to $5.1 million at December 31, 2023. Historically, we have financed our operations primarily from borrowings under our credit facilities and the sale of equity securities. We expect to continue to investment in the THP strategy in preparation for launch of our first pilot program with a wound care provider group during the second quarter of 2025. We expect our continued investment over the first half of 2025 is currently estimated at $7.5 million to $10.0 million. We are pursuing financial partners to invest in the execution of this strategy.

We expect our future needs for cash to include the funding of our additional investment in THP, potential acquisitions, further development of our products, services and technologies pipeline, clinical studies, repayment of debt as it becomes due and for general corporate purposes. If we seek to consummate acquisitions in the future, we expect to finance such acquisitions with the proceeds from equity or debt issuances. Based on our current plan of operations, we believe our cash on hand, when combined with expected cash flows from operations and available proceeds from the CRG Term Loan discussed herein, will be sufficient to fund our growth strategy and to meet our anticipated operating expenses and capital expenditures for at least the next 12 months. As of December 31, 2024, there was $24.5 million available for future borrowing under the CRG Term Loan.

At-the-Market Offering

In February 2023, we entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which we could offer and sell from time to time, to or through Cantor, shares of our common stock having an aggregate offering price of up to $75.0 million.

Sales of the shares, pursuant to the Sales Agreement, were made in sales deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Cantor agreed to use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market to sell the shares from time to time based upon our instructions, including any price, time period or size limits specified by us. We had no obligation to sell any of the shares under the Sales Agreement and could suspend or terminate the offering of our common stock pursuant to the Sales Agreement upon notice to Cantor and subject to other conditions. Pursuant to the Sales Agreement, we paid Cantor a commission of 3.0% of the aggregate gross proceeds from each sale of the shares.

In 2023, we sold an aggregate of 26,143 shares of common stock for gross proceeds of approximately $1.1 million and net proceeds of approximately $0.9 million pursuant to the Sales Agreement. We paused the offering at the end of the first quarter of 2023 and did not reactivate it during the remainder of 2023. The Registration Statement on Form S-3 relating to this offering expired in January 2024.

Applied Asset Purchase

On August 1, 2023, we entered into an asset purchase agreement (the "Applied Purchase Agreement") by and among the Company, Sanara MedTech Applied Technologies, LLC ("SMAT"), The Hymed Group Corporation, Applied and Dr. George D. Petito (the "Owner"), pursuant to which SMAT acquired certain assets of the Sellers and the Owner, including, among others, the Sellers' and Owner's inventory, intellectual property, manufacturing and related equipment, goodwill, rights and claims, other than certain excluded assets (the "Applied Purchased Assets") and assumed certain Assumed Liabilities (as defined in the Applied Purchase Agreement) upon the terms and subject to the conditions set forth in the Applied Purchase Agreement. The transaction closed on August 1, 2023. The Applied Purchased Assets were purchased for an initial aggregate purchase price of $15.25 million, consisting of (i) $9.75 million in cash (the "Cash Closing Consideration"), (ii) 73,809 shares of our common stock, with an agreed upon value of $3.0 million (the "Stock Closing Consideration") and (iii) $2.5 million in cash, to be paid in four equal installments on each of the next four anniversaries of the Closing (the "Installment Payments"). The first Installment Payment of $625,000 was made in August 2024.

In addition to the Cash Closing Consideration, Stock Closing Consideration and Installment Payments, the Applied Purchase Agreement provides that the Sellers are entitled to receive up to an additional $10.0 million (the "Applied Earnout"), which is payable to the Sellers in cash, upon the achievement of certain performance thresholds relating to SMAT's collections from net sales of a collagen-based product currently under development. Upon expiration of the seventh anniversary of the Closing, to the extent the Sellers have not earned the entirety of the Applied Earnout, SMAT shall pay the Sellers a pro-rata amount of the Applied Earnout based on collections from net sales of the product, with such amount to be due credited against any Applied Earnout payments already made by SMAT (the "True-Up Payment"). The Applied Earnout, minus the True-Up Payment and any Applied Earnout payments already made by SMAT, may be earned at any point in the future, including after the True-Up Payment is made.

Cadence Loan Agreement

On August 1, 2023, we, as guarantor, and our wholly owned subsidiary SMAT, as borrower, entered into a loan agreement (the "Cadence Loan Agreement") with Cadence Bank ("Cadence") that provided for, among other things, a term loan in the aggregate principal amount of up to $12.0 million, which was evidenced by an advancing promissory note. Pursuant to the Cadence Loan Agreement, Cadence agreed to make, at any time and from time to time prior to February 1, 2024, one or more advances to SMAT. On August 1, 2023, Cadence made an advance under the Cadence Term Loan for $9.75 million, the proceeds of which were used to fund the Cash Closing Consideration for the Applied Asset Purchase. The Cadence Term Loan Agreement was terminated and all outstanding amounts under the Cadence Term Loan were repaid in full and all security interest and other liens granted to or held by Cadence were terminated and released in April 2024.

CRG Term Loan Agreement

On April 17, 2024, we entered into the CRG Term Loan Agreement by and among us, as borrower, the Guarantors, the Agent and the lenders party thereto from time to time, providing for a senior secured term loan of up to $55.0 million. On the Closing Date, the First Borrowing of $15.0 million was made to repay the Cadence Term Loan and to pay certain fees and expenses related to the CRG Loan Agreement. The remaining proceeds of $4.5 million were distributed to us. As a result, the Cadence Term Loan Agreement was terminated and all outstanding amounts under the Cadence Term Loan were repaid in full and all security interest and other liens granted to or held by Cadence were terminated and released.

On September 4, 2024, pursuant to our option under the CRG Term Loan Agreement, we borrowed an additional $15.5 million under the CRG Term Loan Agreement (the "Second Borrowing"). We used $5.0 million of the proceeds of the Second Borrowing for the investment in CMp (discussed in more detail below). Prior to the CRG Amendment, pursuant to the CRG Term Loan Agreement, we were entitled to one additional borrowing, which was required to occur on or prior to June 30, 2025 and be at least $5.0 million or a multiple of $5.0 million. On March 19, 2025, we entered into the CRG Amendment, which amended the CRG Term Loan Agreement to, among other things, (i) entitle us to two additional borrowings following the Second Borrowing, which borrowings must occur on or prior to December 31, 2025, if at all, and (ii) remove the requirement that any borrowing be in whole multiples of $5.0 million. Any additional borrowings under the CRG Term Loan will be subject to the satisfaction of certain conditions, including the Agent having received certain fees.

The First Borrowing, Second Borrowing and any additional borrowings under the CRG Term Loan are due and payable on March 30, 2029 (the "Maturity Date"), absent any acceleration.

The CRG Term Loan bears interest at a per annum rate equal to 13.25% (subject to a 4.0% increase during an event of default), of which 8.00% must be paid in cash and 5.25% may, at our election, be deferred through the 19th quarterly Payment Date (defined below) by adding such amount to the aggregate principal loan amount, so long as no default or event of default under the CRG Term Loan Agreement has occurred and is continuing. We are required to make quarterly interest payments on the final business day of each calendar quarter following the Closing Date, commencing on the first such date to occur at least 30 days after the Closing Date (each, a "Payment Date"). Interest is payable on each Payment Date in arrears with respect to the time between each Payment Date and upon the payment or prepayment of the CRG Term Loan, ending on the Maturity Date. In addition, we are required to pay an upfront fee of 1.50% of the principal amount of the CRG Term Loan, which is payable as amounts are advanced under the CRG Term Loan on a pro rata basis. We are also required to pay a back-end fee equal to 7.00% of the aggregate principal amount advanced under the CRG Term Loan Agreement. We paid upfront fees of $225,000 on the Closing Date related to the First Borrowing and $232,500 of upfront fees on September 4, 2024 related to the Second Borrowing. As of December 31, 2024, there was $30.5 million of principal outstanding and $24.5 million available for future borrowing under the CRG Term Loan.

Subject to certain exceptions, we are required to make mandatory prepayments of the CRG Term Loan with the proceeds of certain assets sales and in the event of a change of control of the Company. In addition, we may make a voluntary prepayment of the CRG Term Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Term Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs on or prior to the date that is one year following the applicable borrowing (the "Borrowing Date"), an amount equal to 10.0% of the aggregate outstanding principal amount of the Loan being prepaid and (ii) if prepayment occurs one year after the applicable Borrowing Date and on or prior to two years following the applicable Borrowing Date, an amount equal to 5.0% of the aggregate outstanding principal amount of the CRG Term Loan being prepaid. No prepayment premium is due on any principal prepaid if prepayment occurs two years or more after the applicable Borrowing Date.

Certain of our current and future subsidiaries, including the Guarantors, are guaranteeing our obligations under the CRG Term Loan Agreement. As security for our obligations under the CRG Term Loan Agreement, on the Closing Date, we and the Guarantors entered into a security agreement with the Agent pursuant to which we and the Guarantors granted to the Agent, as collateral agent for the lenders, a lien on substantially all of our and the Guarantors' assets, including intellectual property (subject to certain exceptions).

The CRG Term Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and the Guarantors' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions above certain thresholds, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Term Loan Agreement contains the following financial covenants requiring us and the Guarantors in the aggregate to maintain:

- liquidity in an amount which shall exceed the greater of (i) $3.0 million and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of us by the creditors of such permitted debt; and
- annual minimum revenue of at least (i) $60.0 million for the twelve-month period beginning on January 1, 2024 and ending on December 31, 2024, (ii) $75.0 million for the twelve-month period beginning on January 1, 2025 and ending on December 31, 2025, (iii) $85.0 million for the twelve-month period beginning on January 1, 2026 and ending on December 31, 2026, (iv) $95.0 million for the twelve-month period beginning on January 1, 2027 and ending on December 31, 2027 and (v) $105.0 million during each twelve-month period beginning on January 1 of a given year thereafter.

As of December 31, 2024, we were in compliance with all debt covenants.

ChemoMouthpiece Investment

On September 10, 2024, Sanara CMP entered into the Unit Purchase Agreement with CMp, pursuant to which Sanara CMP purchased 100,674.72 common units in CMp for an aggregate purchase price of $5.0 million, or $49.6649 per unit, which represented approximately 6.64% of the issued and outstanding membership interests of CMp immediately following such purchase. Subsequent to our initial investment in CMp, additional units of CMp were sold to other investors, thereby decreasing our ownership of CMp to 6.59% as of December 31, 2024.

In connection with the Unit Purchase Agreement, we, CMp, certain subsidiaries of CMp, InfuSystem and SI Technologies, entered into the Distribution Agreement pursuant to which SI Technologies was appointed as the sole and exclusive U.S. distributor of the CMp Product for a term of five years, subject to meeting certain minimum order requirements.

The parties to the Distribution Agreement also entered into an Intellectual Property Rights Agreement, pursuant to which SI Technologies was granted the exclusive right to use CMp's intellectual property rights to permit resale and use of the CMp Product in the United States.

BMI Investment

On January 16, 2025, we entered into the BMI License Agreement with BMI, pursuant to which we acquired the exclusive U.S. marketing, sales and distribution rights to OsStic, as well as ARC, for use in the treatment of a wound or injury caused by a traumatic incident.

Pursuant to the License Agreement, we were appointed by BMI as the exclusive distributor to promote, market, offer to sell, transfer, distribute and sell the BMI Products for trauma indications inside the United States and its territories for the BMI Term, provided that we are in compliance with its obligations thereunder. From the Execution Date until October 13, 2025, we have an exclusive option to negotiate exclusive distribution rights for the BMI Products in additional fields and/or additional territories on substantially the same terms as those set forth in the BMI License Agreement.

The BMI License Agreement requires that we pay BMI Quarterly Royalties based on a percentage of the Net Sales Value (as defined in the License Agreement) of the Products during the BMI Term, with the applicable percentage of the Net Sales Value for OsStic being in the mid-single digit range. Pursuant to the BMI License Agreement, we and BMI agreed to negotiate the applicable percentage of the Net Sales Value for ARC at a future date. The BMI License Agreement also requires that we pay BMI minimum royalty payments being in the low to mid six figure range for the first, second and third years, respectively, following the receipt of first regulatory approval for the marketing and sale of a Product.

In connection with the BMI License Agreement, on the Execution Date, we entered into the Subscription Agreement, pursuant to which we agreed to contribute up to approximately €8.0 million to BMI through a series of capital contributions in exchange for an aggregate of 16,460 ordinary shares of BMI, constituting approximately 12.5% of the outstanding equity of BMI as of the Execution Date. We made an initial cash investment totaling approximately €3.0 million on the Execution Date, and the Company's previously announced convertible loan to BMI was converted into €1.0 million of equity in BMI. Pursuant to the Subscription Agreement, the remaining €4.0 million contribution is due upon the achievement of the Milestones, which are expected to occur at various points during 2025.

Cash Flow Analysis

For the year ended December 31, 2024, net cash used in operating activities was $23,784 compared to $3.2 million used in operating activities for the year ended December 31, 2023. The lower use of cash in operating activities in 2024 was largely due to our net revenue growth outpacing the growth of our cash operating expenses and partly due to the timing of cash expenditures for certain accrued payables.

For the year ended December 31, 2024, net cash used in investing activities was $6.6 million compared to $10.2 million used in investing activities during the year ended December 31, 2023. Cash used in investing activities during 2024 primarily included $5.3 million for our investment in CMp and $1.1 million for the funding of a convertible loan related to our minority investment in BMI. Cash used in investing activities during 2023 primarily included $9.9 million used for the Applied Asset Purchase.

For the year ended December 31, 2024, net cash provided by financing activities was $17.4 million compared to $9.6 million provided by financing activities for the year ended December 31, 2023. The increase in cash provided by financing activities during the year ended December 31, 2024 was due to the receipt of proceeds from the CRG Term Loan, which were partially offset by the payoff of the Cadence Term Loan and the final earnout payment of approximately $1.1 million related to the Scendia earnout.

MATERIAL TRANSACTIONS WITH RELATED PARTIES

CellerateRX Surgical Sublicense Agreement

On August 1, 2023, we acquired, among other things, the underlying intellectual property of, as well as the rights to manufacture and sell, CellerateRX Surgical from Applied for human wound care use. Prior to such time, we had licensed the rights to these products through a sublicense agreement (the "Sublicense Agreement") with CGI Cellerate RX, LLC ("CGI Cellerate RX"), an affiliate of The Catalyst Group, Inc. ("Catalyst"), both of which are related parties. Prior to the Applied Asset Purchase, we paid royalties based on the annual Net Sales of licensed products (as defined in the Sublicense Agreement) consisting of 3% of all collected Net Sales each year up to $12.0 million, 4% of all collected Net Sales each year that exceed $12.0 million up to $20.0 million, and 5% of all collected Net Sales each year that exceed $20.0 million. Ronald T. Nixon, our Chief Executive Officer and Executive Chairman, is the founder and managing partner of Catalyst.

In connection with the Applied Asset Purchase, Applied assigned its license agreement with CGI Cellerate RX to SMAT (the "License Agreement"), and on October 10, 2024, the License Agreement and the Sublicense Agreement were terminated for no additional consideration.

Consulting Agreement

In July 2021, we entered into an asset purchase agreement with Rochal, a related party. Concurrent with the Rochal asset purchase, we entered into a consulting agreement with Ann Beal Salamone pursuant to which Ms. Salamone agreed to provide us 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 us, Ms. Salamone is entitled to receive an annual consulting fee of $177,697, with payments to be paid once per month. The consulting

agreement had an initial term of three years, unless earlier terminated by us, and is subject to renewal. Effective July 13, 2024, the consulting agreement with Ms. Salamone was amended to provide that the initial term shall be automatically renewed for successive one-year terms for up to three successive years unless earlier terminated by either party without cause at any time, provided that the terminating party provides 90 days advance written notice of termination. Ms. Salamone is a director of the Company, is a significant shareholder and the current chair of the board of directors of Rochal.

Catalyst Transaction Advisory Services Agreement

In March 2023, we entered into a Transaction Advisory Services Agreement (the "Catalyst Services Agreement") effective March 1, 2023 with Catalyst, a related party. Pursuant to the Catalyst Services Agreement, Catalyst, by and through its directors, officers, employees and affiliates that are not simultaneously serving as directors, officers or employees of the Company (collectively, the "Covered Persons"), agreed to perform certain transaction advisory, business and organizational strategy, finance, marketing, operational and strategic planning, relationship access and corporate development services for us in connection with any merger, acquisition, recapitalization, divestiture, financing, refinancing, or other similar transaction in which we may be, or may consider becoming, involved, and any such additional services as mutually agreed upon in writing by and between Catalyst and us (the "Catalyst Services").

Pursuant to the Catalyst Services Agreement, we agreed to reimburse Catalyst for (i) compensation actually paid by Catalyst to any of the Covered Persons at a rate no more than a rate consistent with industry practice for the performance of services similar to the Catalyst Services, as documented in reasonably sufficient detail, and (ii) all reasonable out-of-pocket costs and expenses payable to unaffiliated third parties, as documented in customary expense reports, as each of (i) and (ii) is incurred in connection with the Catalyst Services rendered under the Catalyst Services Agreement, with all reimbursements being contingent upon the prior approval of the Audit Committee of our Board of Directors. We incurred costs relating to the Catalyst Services Agreement of $288,594 and $174,486 during year ended December 31, 2024 and 2023, respectively.

Receivables and Payables

We had outstanding related party receivables totaling $40,566 at December 31, 2024 and $8,400 at December 31, 2023. We had outstanding related party payables totaling $30,913 at December 31, 2024 and $77,805 at December 31, 2023.

IMPACT OF INFLATION AND CHANGING PRICES

Inflation and changing prices have not had a material impact on our historical results of operations. We do not currently anticipate that inflation and changing prices will have a material impact on our future results of operations.

CRITICAL ACCOUNTING 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 United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported revenue and expenses during the reporting period. 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 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.

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 primarily of finished goods, and also include an immaterial amount of raw materials and related packaging components. We recorded inventory obsolescence expense of $521,757 for the year ended December 31, 2024 and $406,812 for the year ended December 31, 2023. The allowance for obsolete and slow-moving inventory had a balance of $534,549 at December 31, 2024 and $446,917 at December 31, 2023.

Goodwill

The excess of purchase price over the fair value of identifiable net assets acquired in business combinations is recorded as goodwill. As of December 31, 2024 and 2023, all of our goodwill relates to the acquisition of Scendia. Goodwill has an indefinite useful life and is not amortized. Goodwill is tested annually as of December 31 for impairment, or more frequently if circumstances indicate impairment may have occurred. We may first perform a qualitative assessment to determine if it is more likely than not that the fair value of the reporting unit is less than the respective carrying value. If it is determined that it is more likely than not that a reporting unit's fair value is less than its carrying value, then we will determine the fair value of the reporting unit and record an impairment charge for the difference between fair value and carrying value (not to exceed the carrying amount of goodwill). No impairment was recorded during the years ended December 31, 2024 or 2023.

Impairment of Long-Lived Assets

Long-lived assets, including certain identifiable intangibles held and to be used by us, are reviewed for impairment whenever events or changes in circumstances 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 fair value less cost to sell. A $0.5 million non-cash charge to write-off the remaining net book value of certain THP internal use software assets was recorded during the year ended December 31, 2024. No impairment was recorded during the year ended December 31, 2023.

Investments in Equity Securities

Our equity investments consist of nonmarketable 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 for investments when we have 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. As discussed further in Note 6, as of December 31, 2024, we had two investments that are recorded applying the equity method of accounting. 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 investments" 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 our equity method investments using the cumulative earnings approach in our Consolidated Statements of Cash Flows.

We reviewed the carrying value of our investments and determined there was no impairment or observable price changes as of and for the years ended December 31, 2024 and 2023.

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. A valuation allowance is provided if it is more likely than not that some or all of a net deferred tax asset will not be realized.

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 sheets of Sanara MedTech Inc. and subsidiaries (collectively, the Company) as of December 31, 2024 and 2023, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for each of the two years in the period ended December 31, 2024, 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 Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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 these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matters

The critical audit matter communicated below is a matter 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. The communication of critical audit matters 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.

Evaluation of Impairment Triggering Events for Tissue Health Plus Segment Intangible Assets (Note 5 and Note 14)

Critical Audit Matter Description

As discussed in Note 14, as of December 31, 2024, the Company determined that it has two reportable segments. As of December 31, 2024, the Tissue Health Plus segment was primarily comprised of research and development activities related to the intangible assets acquired in the 2022 acquisition of Precision Healing, Inc. as the Company pursues its value-based wound care strategy.

The Company performs an evaluation of whether triggering events have occurred which may indicate that the carrying amount of an asset may not be recoverable. During the year-ended December 31, 2024, management concluded that there were no triggering events which indicated that the carrying amount of the intellectual property intangible assets acquired from Precision Healing, Inc. is not recoverable. Management did, however, determine that the historic WounDerm software assets were no longer expected to be used in the Company's strategic plans and, accordingly, concluded that the carrying amount was not recoverable and recorded an impairment charge to reduce the carrying amount of those assets to $0.

We identified the evaluation of triggering events as a critical audit matter because such analysis required the application of greater auditor judgment. Potential triggering events, such as the changes to the Company's segments, required a higher degree of auditor judgment to evaluate. These possible triggering events could have a significant effect on the Company's assessment to determine whether further quantitative analysis of recoverability was required.

How the Critical Audit Matter Was Addressed in the Audit

Our primary audit procedures related to the Company's analysis included the following, among others:

- We obtained an understanding of the design and implementation of management's controls over the triggering event analysis.
- We obtained and evaluated the related triggering event analysis prepared by management, evaluated responses as to factors considered, and evaluated whether the Company omitted any significant internal or external factors in their evaluation.
- Inquired of management and the board of directors to gain an understating of the Company's strategic plans and considered such responses in relation to the matters evaluated and management's assessment contained in the triggering event analysis.
- Evaluated the appropriateness of the evaluation framework utilized by management and the matters considered. This testing included inquiries with management as well as consideration of positive and negative evidence impacting management's considerations.

We have served as the Company's auditor since 2021.

/s/ Weaver and Tidwell, L.L.P.
Austin, Texas
March 25, 2025

SANARA MEDTECH INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash	$ 15,878,295	$ 5,147,216
Accounts receivable, net	12,408,819	8,474,965
Accounts receivable – related parties	40,566	8,400
Royalty receivable	-	49,344
Inventory, net	2,753,032	4,717,533
Convertible loan receivable	1,101,478	-
Prepaid and other assets	1,123,798	608,411
Total current assets	**33,305,988**	**19,005,869**
Long-term assets		
Intangible assets, net	41,006,776	44,926,061
Goodwill	3,601,781	3,601,781
Investment in equity securities	8,297,223	3,084,278
Right of use assets – operating leases	1,447,907	1,995,204
Property and equipment, net	432,317	1,257,956
Total long-term assets	**54,786,004**	**54,865,280**
Total assets	**$ 88,091,992**	**$ 73,871,149**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 1,499,764	$ 1,924,082
Accounts payable – related parties	30,913	77,805
Accrued bonuses and commissions	10,778,840	7,676,770
Accrued royalties and expenses	2,621,867	2,047,678
Earnout liabilities – current	-	1,100,000
Current portion of debt	-	580,357
Operating lease liabilities – current	358,687	361,185
Total current liabilities	**15,290,071**	**13,767,877**
Long-term liabilities		
Long-term debt, net of current portion	30,689,290	9,113,123
Earnout liabilities – long-term	748,001	2,723,001
Operating lease liabilities – long-term	1,237,051	1,737,445
Other long-term liabilities	1,215,617	1,941,686
Total long-term liabilities	**33,889,959**	**15,515,255**
Total liabilities	**49,180,030**	**29,283,132**
Commitments and contingencies (Note 9)		
Shareholders' equity		
Common Stock: $0.001 par value, 20,000,000 shares authorized; 8,753,773 issued and outstanding as of December 31, 2024 and 8,535,239 issued and outstanding as of December 31, 2023	8,754	8,535
Additional paid-in capital	77,179,211	72,860,556
Accumulated deficit	(37,784,392)	(28,036,814)
Total Sanara MedTech shareholders' equity	**39,403,573**	**44,832,277**
Equity attributable to noncontrolling interest	(491,611)	(244,260)
Total shareholders' equity	**38,911,962**	**44,588,017**
Total liabilities and shareholders' equity	**$ 88,091,992**	**$ 73,871,149**

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,	
	2024	**2023**
Net Revenue	**$ 86,672,425**	**$ 64,989,842**
Cost of goods sold	**8,139,901**	**7,852,686**
Gross profit	**78,532,524**	**57,137,156**
Operating expenses		
Selling, general and administrative	76,559,863	56,994,753
Research and development	5,703,362	4,132,425
Depreciation and amortization	4,923,224	3,675,026
Change in fair value of earnout liabilities	(1,938,451)	(3,449,895)
Total operating expenses	**85,247,998**	**61,352,309**
Operating loss	**(6,715,474)**	**(4,215,153)**
Other income (expense)		
Interest expense	(3,128,395)	(475,783)
Share of losses from equity method investments	(90,007)	-
Interest income	21,978	-
Gain on disposal of investment	-	251,034
Total other income (expense)	**(3,196,424)**	**(224,749)**
Net loss	**(9,911,898)**	**(4,439,902)**
Less: Net loss attributable to noncontrolling interest	(247,351)	(136,705)
Net loss attributable to Sanara MedTech shareholders	**$ (9,664,547)**	**$ (4,303,197)**
Net loss per share of common stock, basic and diluted	$ (1.14)	$ (0.52)
Weighted average number of common shares outstanding, basic and diluted	8,484,224	8,278,949

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

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

	Common Stock $0.001 par value		Additional Paid-In	Accumulated	Noncontrolling	Total Shareholders'
	Shares	Amount	Capital	Deficit	Interest	Equity
Balance at December 31, 2022	8,299,957	$ 8,300	$65,213,987	$ (23,394,757)	$ (107,555)	$ 41,719,975
Share-based compensation	100,829	100	3,442,622	-	-	3,442,722
Net settlement and retirement of equity-based awards	34,501	35	203,031	(338,860)	-	(135,794)
Issuance of common stock for acquisitions	73,809	74	3,089,571	-	-	3,089,645
Issuance of common stock in equity offering	26,143	26	911,345	-	-	911,371
Net loss	-	-	-	(4,303,197)	(136,705)	(4,439,902)
Balance at December 31, 2023	8,535,239	$ 8,535	$72,860,556	$ (28,036,814)	$ (244,260)	$ 44,588,017
Share-based compensation	164,451	165	4,435,883	-	-	4,436,048
Net settlement and retirement of equity-based awards	54,083	54	(42,228)	(83,031)	-	(125,205)
Issuance of common stock in equity offering	-	-	(75,000)	-	-	(75,000)
Net loss	-	-	-	(9,664,547)	(247,351)	(9,911,898)
Balance at December 31, 2024	8,753,773	$ 8,754	$77,179,211	$ (37,784,392)	$ (491,611)	$ 38,911,962

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (9,911,898)	$ (4,439,902)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,923,224	3,675,026
Credit loss expense	624,448	202,941
Inventory obsolescence	521,757	406,812
Share-based compensation	4,436,048	3,442,722
Noncash lease expense	547,297	342,972
Share of losses from equity method investments	90,007	-
Gain on disposal of investment	-	(251,034)
Back-end fee	358,086	-
Paid-in-kind interest	838,965	-
Accretion of finance liabilities	210,931	98,926
Amortization and write-off of debt issuance costs	209,499	5,138
Change in fair value of earnout liabilities	(1,938,451)	(3,449,895)
Accrued interest income	(21,978)	-
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,508,958)	(1,821,895)
Accounts receivable – related parties	(32,166)	90,148
Inventory, net	1,442,744	(1,545,339)
Prepaid and other assets	(515,496)	496,200
Accounts payable	(424,318)	531,380
Accounts payable – related parties	(46,891)	43,768
Accrued royalties and expenses	574,189	(739,645)
Accrued bonuses and commissions	3,102,069	(81,513)
Operating lease liabilities	(502,892)	(252,366)
Net cash used in operating activities	(23,784)	(3,245,556)
Cash flows from investing activities:		
Purchases of property and equipment	(205,848)	(265,246)
Purchases of intangible assets	(23,452)	-
Proceeds from disposal of property and equipment	-	650
Investment in equity securities	(5,302,952)	-
Convertible loan receivable	(1,079,391)	-
Acquisitions, net of cash acquired	-	(9,942,750)
Net cash used in investing activities	(6,611,643)	(10,207,346)
Cash flows from financing activities:		
Loan proceeds, net of debt issuance costs of $1,160,740 in 2024 and $61,658 in 2023	29,339,260	9,688,341
Pay off line of credit	(9,750,000)	-
Equity offering net proceeds (expenses)	(75,000)	911,371
Net settlement of equity-based awards	(125,205)	(135,794)
Cash payment of finance and earnout liabilities	(2,022,549)	(822,795)
Net cash provided by financing activities	17,366,506	9,641,123
Net increase (decrease) in cash	10,731,079	(3,811,779)
Cash, beginning of period	5,147,216	8,958,995
Cash, end of period	$ 15,878,295	$ 5,147,216
Cash paid during the period for:		
Interest	$ 1,580,984	$ 283,948
Supplemental noncash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	-	1,531,773
Equity issued for acquisitions	-	3,089,645
Earnout and other liabilities generated by acquisitions	-	3,759,642

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

NOTE 1 – NATURE OF BUSINESS AND BACKGROUND

Sanara MedTech Inc. (together with its wholly owned and majority owned subsidiaries on a consolidated basis, 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, chronic wound and skincare markets. Each of the Company's products, services and technologies are designed to achieve the Company's goal of providing better clinical outcomes at a lower overall cost for patients, regardless of where they receive care. Through its two operating segments, Sanara Surgical and Tissue Health Plus ("THP"), the Company strives to be one of the most innovative and comprehensive providers of effective surgical, wound and skincare solutions and is continually seeking to expand its offerings for patients requiring treatments across the entire continuum of care in the United States.

As further discussed in Note 14, the Company historically managed its business on the basis of one operating and reportable segment. During the second quarter of 2024, the Company changed its reportable segments to reflect a change in the manner in which the business is managed. Based on the growing importance of the value-based wound care program to the Company's future outlook and how the Company's chief operating decision maker, the Chief Executive Officer, reviews operating results and makes decisions about resource allocation, the Company now has two reportable segments: Sanara Surgical and THP.

Sanara Surgical

The Sanara Surgical segment primarily markets and sells soft tissue repair and bone fusion products for use in the operating room or other sterile environments. Sanara Surgical's soft tissue repair products include, among other products, the Company's lead product, CellerateRX Surgical Activated Collagen ("CellerateRX Surgical"), a hydrolyzed collagen that provides a moist environment for surgical sites to aid in the natural wound healing process, and BIASURGE Advanced Surgical Solution, a sterile no-rinse, advanced surgical solution used for wound irrigation. Sanara Surgical's bone fusion products include, among other products, BiFORM, an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site, and ALLOCYTE Plus, a human allograft cellular bone matrix containing bone-derived progenitor cells and conformable bone fibers.

Sanara Surgical also includes an in-house research and development team, Rochal Technologies, with an extensive pipeline of innovative products under development.

Tissue Health Plus

Through the Company's subsidiary, Tissue Health Plus (formerly known as "WounDerm" and "United Wound and Skin Solutions, LLC"), the Company is seeking to simplify skin health, starting with wound care through a refined business plan. Through THP, the Company plans to offer a first of its kind value-based wound care program to payers and risk-bearing entities such as accountable care organizations and value-based primary care companies, with Medicare Advantage payers as the initial target market for this program. The THP segment is focused on value-based wound care services. Through THP, the Company plans to offer a first of its kind value-based wound care program to payers and risk-bearing entities such as accountable care organizations and value-based primary care companies, with Medicare Advantage payers as the initial target market for this program.

THP's programs are expected to enable payers to divest wound care spend risk, reduce wound related hospitalizations and improve patient quality of life. THP plans to coordinate delivery of community and home-based wound care for its managed patients. Community-based care spans a variety of settings including physician offices, skilled nursing facilities, assisted living facilities and senior living facilities. THP's programs are intended to integrate science and evidence-based medicine protocols to standardize wound prevention and treatment.

As a result of the change in reportable segments, certain prior period amounts have been recast to conform to the current period presentation. Throughout this Annual Report on Form 10-K, unless otherwise indicated, amounts and activity reflect reclassifications related to the Company's change in reportable segments. The change in reportable segments had no impact on the Company's previously reported Consolidated Balance Sheets, Consolidated Statements of Operations, Consolidated Statements of Cash Flows or Consolidated Statements of Shareholders' Equity.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of Sanara MedTech Inc. and 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. Certain prior year amounts have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported revenue and expenses during the reporting period. 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/loss per share in accordance with Accounting Standards Codification ("ASC") Topic 260, Earnings per Share, which requires the Company to present basic and diluted income per share when the effect is dilutive. Basic income/loss per share is computed by dividing income/loss attributable to common shareholders by the weighted average number of shares of common stock outstanding. Diluted income/loss per share is computed similarly to basic income/loss 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 common stock equivalents were excluded from the calculations for the periods presented as their inclusion would have been anti-dilutive during the years ended December 31, 2024 and 2023 due to the Company's net loss.

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, 2024 and 2023 as such shares would have had an anti-dilutive effect:

	As of December 31,	
	2024	**2023**
Stock options[(a)]	31,013	93,892
Warrants[(b)]	—	16,725
Unvested restricted stock	202,787	144,211

(a) Shares underlying stock options assumed pursuant to the merger agreement with Precision Healing, Inc. ("Precision Healing") in April 2022.

(b) Shares underlying warrants assumed pursuant to the merger agreement with Precision Healing in April 2022.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Revenues are recognized when a purchase order is received from the customer and 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 the 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 2024 or 2023.

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 only one performance obligation exists. For certain sales transactions, we incur group purchasing organization fees that are based on a contractual percentage of applicable sales and are recorded as a reduction of the revenue for those transactions.

Recognition of revenue as performance obligations are satisfied

Product revenues are recognized when a purchase order is received from the customer, 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, 2024 and 2023.

	For the Year Ended December 31,	
	2024	**2023**
Soft tissue repair products	$76,125,012	$54,836,410
Bone fusion products	10,547,413	9,952,432
Royalty revenue	—	201,000
Total Net Revenue	**$86,672,425**	**$64,989,842**

For the years ended December 31, 2024 and 2023, all of the Company's net revenue was generated from Sanara Surgical. The Company is preparing to launch the first THP pilot program with a wound care provider group during the second quarter of 2025.

Accounts Receivable Allowances

Accounts receivable are typically due within 30 days of invoicing. The Company establishes an allowance for credit losses to provide for an estimate of accounts receivable which are not expected to be collectible. The Company bases the allowance on an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and other information as applicable and will record its allowance based on the estimated credit losses. The Company's accounts receivable balance, net was $12,408,819, $8,474,965, and $6,805,761 as of December 31, 2024, December 31, 2023, and December 31, 2022, respectively. The Company recorded credit loss expense of $624,448 and $202,941 during the years ended December 31, 2024 and 2023, respectively. The allowance for credit losses was $1,173,441 at December 31, 2024 and $528,030 at December 31, 2023. Credit loss 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 provide for estimated customer rebates and other expected customer deductions. These allowances totaled $4,897 at December 31, 2024 and $3,820 at December 31, 2023. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted.

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 primarily of finished goods, and also include an immaterial amount of raw materials and related packaging components. The Company recorded inventory obsolescence expense of $521,757 and $406,812 during the years ended December 31, 2024 and 2023, respectively. The allowance for obsolete and slow-moving inventory had a balance of $534,549 at December 31, 2024 and $446,917 at December 31, 2023.

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 two to ten years. Below is a summary of property and equipment for the periods presented:

	Useful Life	December 31, 2024	December 31, 2023
Computers	3-5 years	$ 295,963	$ 194,788
Office equipment	3-7 years	216,491	201,785
Furniture and fixtures	5-10 years	346,508	304,338
Leasehold improvements	2-5 years	181,968	134,170
Internal use software	5 years	—	1,618,999
		1,040,930	2,454,080
Less accumulated depreciation		(608,613)	(1,196,124)
Property and equipment, net		**$ 432,317**	**$ 1,257,956**

Depreciation expense related to property and equipment was $1,031,487 and $456,138 during the year ended December 31, 2024 and 2023, respectively. Depreciation expense for the year ended December 31, 2024 included a non-cash charge of $506,836 to write-off the remaining net book value of certain internal use software assets.

Internal Use Software

The Company accounted for costs incurred to develop or acquire computer software for internal use in accordance with ASC Topic 350-40, Intangibles – Goodwill and Other. The Company capitalized the costs incurred during the application development stage, which generally included third-party developer fees to design the software configuration and interfaces, coding, installation and testing.

The Company began capitalization of qualifying costs when both the preliminary project stage was completed and management 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 was expensed as incurred. The Company also capitalized costs related to specific upgrades and enhancements when it was probable the expenditures would result in additional functionality. Capitalized development costs were classified as “Property and equipment, net” in the Consolidated Balance Sheets and were depreciated over the estimated useful life of the software, which was generally five years.

Goodwill

The excess of purchase price over the fair value of identifiable net assets acquired in business combinations is recorded as goodwill. As of December 31, 2024 and December 31, 2023, all of the Company’s goodwill relates to the acquisition of Scendia Biologics, LLC (“Scendia”), which is included in the Sanara Surgical segment. Goodwill has an indefinite useful life and is not amortized. Goodwill is tested annually as of December 31 for impairment, or more frequently if circumstances indicate impairment may have occurred. The Company may first perform a qualitative assessment to determine if it is more likely than not that the fair value of the reporting unit is less than the respective carrying value. If it is determined that it is more likely than not that a reporting unit’s fair value is less than its carrying value, then the Company will determine the fair value of the reporting unit and record an impairment charge for the difference between fair value and carrying value (not to exceed the carrying amount of goodwill). No impairment was recorded during the year ended December 31, 2024 or 2023.

Intangible Assets

Intangible assets are stated at cost of acquisition less accumulated amortization and impairment loss, if any. Cost of acquisition includes the purchase price and any cost directly attributable to bringing the asset to its working condition for the intended use. The Company amortizes its finite-lived intangible assets on a straight-line basis over the estimated useful life of the respective assets which is generally the life of the related patents or licenses, seven years for customer relationships and five years for assembled workforces. See Note 5 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 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 fair value less cost to sell. A $0.5 million non-cash charge to write-off the remaining net book value of certain THP internal use software assets was recorded during the year ended December 31, 2024. No impairment was recorded during the year ended December 31, 2023.

Investments in Equity Securities

The Company's equity investments consist of nonmarketable 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 in 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. As discussed further in Note 6 as of December 31, 2024, the Company had two investments that are recorded applying the equity method of accounting. 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 investments" in the Company's Consolidated Statements of Operations. The Company's equity method investments are adjusted each period for the Company's share of the investee's income or loss and dividend paid, if any. The Company classifies distributions received from its equity method investments using the cumulative earnings approach in the Company's 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 or for the year ended December 31, 2024 and 2023.

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 the 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 nonexchange-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, other than acquisition-related expenses, approximate fair value because of the short-term nature of these instruments. The fair value of acquisition-related accrued expenses is categorized as Level 2 of the fair value hierarchy. The value of these instruments has been estimated using discounted cash flow analysis based on the Company's incremental borrowing rate. The carrying value of the Company's CRG Term Loan (defined below), which has a fixed interest rate approximates fair value based on instruments with similar terms (Level 2 inputs). The fair value of the contingent earnout consideration and the acquisition date fair value of goodwill and intangibles related to the acquisitions discussed in Notes 3 and 5 are based on Level 3 inputs.

Liabilities for contingent consideration for the Precision Healing merger, acquisition of Scendia and Applied Asset Purchase (defined below) (see Note 3 for more information) are measured at fair value each reporting period, with the acquisition-date fair value included as part of the consideration transferred. The contingent consideration for the Scendia acquisition was settled as of September 30, 2024, and the final earnout payment of approximately $1.1 million was paid in cash in October 2024. The Precision Healing contingent consideration is classified as a liability at its fair value at each reporting period due to the fact that the monetary value of the shares to be issued is predominantly dependent on the exercise contingency (i.e., revenue targets). Subsequent changes in fair value of contingent consideration related to the Precision Healing merger are reported under the line item captioned "Change in fair value of earnout liabilities" in the Company's Consolidated Statements of Operations. The Company reviewed the thresholds necessary to trigger a payment on the Precision Healing earnout as of December 31, 2024 and deemed the thresholds to be unachievable by the sellers, therefore, the remaining fair value on the earnout was reduced to zero. Due to the Applied Asset Purchase being accounted for as an asset acquisition and given that the transaction did not include contingent shares, subsequent revaluations of contingent consideration for the Applied Asset Purchase results in an adjustment to the contingent consideration liability and the intellectual property intangible asset with a cumulative catch-up amortization adjustment. The current year change in fair value of earnout liability below is as a result of a net decrease in the estimated fair value of the earnout liability established at the time of the Company's Precision Healing merger. The current year revaluation of earnout liability below is a result of a decrease in the estimated value of the earnout liability established at the time of the Applied Asset Purchase. The following table sets forth a summary of the changes in fair value for the Level 3 contingent earnout considerations.

Balance at December 31, 2023	$ 3,823,001
Change in fair value of earnout liabilities	(1,938,451)
Revaluation of earnout liability	(51,000)
Settlements	(1,085,549)
Balance at December 31, 2024	$ 748,001

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 the deferred tax asset will not be realized.

Share-based Compensation

The Company accounts for share-based compensation to employees and nonemployees in accordance with ASC Topic 718, Compensation – Stock Compensation. Share-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 share-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 grants of common stock, including restricted stock awards.

Research and Development Costs

Research and development ("R&D") expenses consist of personnel-related expenses, including salaries, share-based compensation and benefits for all personnel directly engaged in R&D activities, contracted services, materials, prototype expenses and allocated overhead, which is comprised of compensation and benefits, 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

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments - Credit Losses (Topic 326). This update amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The Company adopted the new guidance effective January 1, 2023. The adoption did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In November 2023, FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which requires disclosure of incremental segment information on an annual and interim basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The Company adopted the new guidance effective December 31, 2024. The adoption did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

Recently Issued Accounting Pronouncements

In December 2023, FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"), which expands the disclosure required for income taxes. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect of this pronouncement on its disclosures.

In November 2024, FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires new disclosures providing further detail of a company's income statement expense line items. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the effect of this pronouncement on its disclosures.

NOTE 3 – APPLIED ASSET PURCHASE

On August 1, 2023, the Company entered into an Asset Purchase Agreement (the "Applied Purchase Agreement") by and among the Company, as guarantor, Sanara MedTech Applied Technologies, LLC, a Texas limited liability company and wholly owned subsidiary of the Company ("SMAT"), The Hymed Group Corporation, a Delaware corporation ("Hymed"), Applied Nutritionals, LLC, a Delaware limited liability company ("Applied", and together with Hymed, the "Sellers"), and Dr. George D. Petito (the "Owner"), pursuant to which SMAT acquired certain assets of the Sellers and the Owner, including, among others, the Sellers' and Owner's inventory, intellectual property, manufacturing and related equipment, goodwill, rights and claims, other than certain excluded assets, all as more specifically set forth in the Applied Purchase Agreement (collectively, the "Applied Purchased Assets"), and assumed certain Assumed Liabilities (as defined in the Applied Purchase Agreement), upon the terms and subject to the conditions set forth in the Applied Purchase Agreement (such transaction, the "Applied Asset Purchase"). The Applied Purchased Assets include the underlying intellectual property of, as well as the rights to manufacture and sell, certain hydrolyzed collagen products, including CellerateRX Surgical, for human wound care use.

The Applied Purchased Assets were purchased for an initial aggregate purchase price of $15.25 million, consisting of (i) $9.75 million in cash (the "Cash Closing Consideration"), (ii) 73,809 shares of the Company's common stock (the "Stock Closing Consideration") with an agreed upon value of $3.0 million and (iii) $2.5 million in cash (the "Installment Payments"), to be paid in four equal installments on each of the next four anniversaries of the closing of the Applied Asset Purchase (the "Closing"). The first Installment Payment of $625,000 was made in August 2024.

Prior to the Closing, the Company licensed certain of its products from Applied through a sublicense agreement (the "Sublicense Agreement") with CGI Cellerate RX, LLC ("CGI Cellerate RX"), a related party (see Note 13 for additional information regarding transactions with related parties). Pursuant to the Sublicense Agreement, the Company had an exclusive,

world-wide sublicense to distribute certain hydrolyzed collagen products, including CellerateRX Surgical, into the surgical and wound care markets. In connection with the Applied Asset Purchase, Applied assigned its license agreement with CGI Cellerate RX to SMAT (the "License Agreement"), and on October 10, 2024, the License Agreement and the Sublicense Agreement were terminated for no additional consideration.

In addition to the Cash Closing Consideration, Stock Closing Consideration and Installment Payments, the Applied Purchase Agreement provides that the Sellers are entitled to receive up to an additional $10.0 million (the "Applied Earnout"), which is payable to the Sellers in cash, upon the achievement of certain performance thresholds relating to SMAT's collections from net sales of a collagen-based product currently under development. Upon expiration of the seventh anniversary of the Closing, to the extent the Sellers have not earned the entirety of the Applied Earnout, SMAT shall pay the Sellers a pro-rata amount of the Applied Earnout based on collections from net sales of the product, with such amount to be due credited against any Applied Earnout payments already made by SMAT (the "True-Up Payment"). The Applied Earnout, minus the True-Up Payment and any Applied Earnout payments already made by SMAT, may be earned at any point in the future, including after the True-Up Payment is made.

In connection with the Applied Asset Purchase and pursuant to the Applied Purchase Agreement, effective August 1, 2023, the Company entered into a professional services agreement (the "Petito Services Agreement") with the Owner, pursuant to which the Owner, as an independent contractor, agreed to provide certain services to the Company, including, among other things, assisting with the development of products already in development and assisting with research, development, formulation, invention and manufacturing of any future products (the "Petito Services"). As consideration for the Petito Services, the Owner is entitled to receive: (i) a base salary of $12,000 per month during the term of the Petito Services Agreement, (ii) a royalty payment equal to three percent (3%) of the actual collections from net sales of certain products the Owner develops or co-develops that reach commercialization, (iii) a royalty payment equal to five percent (5%) for the first $50.0 million in aggregate collections from net sales of certain future products and a royalty payment of two and one-half percent (2.5%) on aggregate collections from net sales of certain future products on any amounts exceeding $50.0 million but up to $100.0 million, (iv) $500,000 in cash in the event that 510(k) clearance is issued for any future product accepted by the Company and (v) $1.0 million in cash in the event that a U.S. patent is issued for a certain product; provided that with respect to the incentive payments described in (iv) and (v) of the foregoing, the Owner shall not earn more than $2.5 million.

The Petito Services Agreement has an initial term of three years and is subject to automatic successive one-month renewals unless earlier terminated in accordance with its terms. The Petito Services Agreement may be terminated upon the Owner's death or disability or by the Company or the Owner "For Cause" (as defined in the Petito Services Agreement); provided, however, that the base salary described in (i) of the foregoing paragraph shall survive termination through the three-year initial term and the royalty payments and incentive payments described in (ii)-(v) of the foregoing paragraph shall survive termination of the Petito Services Agreement.

As the contingent consideration was negotiated as part of the transfer of assets, the contingent obligation was measured at fair value and included in the total purchase consideration transferred. Accordingly, since the Applied Asset Purchase was accounted for as an asset acquisition and did not include contingent shares, the contingent consideration is classified as a liability at its estimated fair value at each reporting period with subsequent revaluations recognized as an adjustment to the intellectual property intangible asset and the earnout liability with a cumulative catch-up amortization adjustment.

The total purchase consideration for the Applied Asset Purchase as determined by the Company was as follows:

Consideration	Equity Shares	Dollar Value
Cash Closing Consideration		$ 9,750,000
Fair value of Stock Closing Consideration	73,809	3,089,645
Fair value of Installment Payments		2,040,808
Cash paid for inventory		30,007
Fair value of Petito Services Agreement defined payments		825,834
Fair value of Petito Services Agreement contingent consideration		893,000
Direct transaction costs		162,743
Total purchase consideration		**$ 16,792,037**

Based on guidance provided by ASC 805, Business Combinations ("ASC 805"), the Company recorded the Applied Asset Purchase as an asset acquisition due to the determination that substantially all 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 being the only significant asset acquired. Accordingly, the Company accounted for the transaction 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 estimated fair value of the gross assets acquired, the total fair value of the net assets acquired was primarily attributable to, and classified as, finite-lived intellectual property in the fourth quarter of 2023. The total purchase consideration was allocated based on the relative estimated fair value of such assets as follows:

Description	Amount
Inventory	$ 30,007
Equipment	33,062
Intellectual property	16,728,968
Net assets acquired	**$16,792,037**

NOTE 4 – CONVERTIBLE LOAN RECEIVABLE

In connection with a potential equity investment in an unaffiliated entity engaged in the development of certain surgical technologies, the Company entered into a convertible loan agreement in July 2024 pursuant to which the Company loaned $1,079,391 to the unaffiliated entity. The loan was initially set to be repaid on October 1, 2024. However, the Company extended the repayment date to January 15, 2025. On October 1, 2024, the Company began accruing interest at 8% per annum. Pursuant to the convertible loan agreement, the Company had the option to convert the outstanding balance of the loan into noncontrolling equity interests of the unaffiliated entity upon satisfactory completion of certain due diligence activities. As of December 31, 2024, the loan balance was $1,101,478 including accrued interest and is recorded under the caption "Convertible loan receivable" in the Company's Consolidated Balance Sheets. As of January 16, 2025, the loan was converted into equity of the unaffiliated entity (see Note 15 for additional information).

NOTE 5 – GOODWILL AND INTANGIBLES, NET

The changes in the carrying amount of the Company's goodwill were as follows:

	Total
Balance as of December 31, 2022	$ 3,601,781
Acquisitions	-
Balance as of December 31, 2023	3,601,781
Acquisitions	-
Balance as of December 31, 2024	$ 3,601,781

In connection with the change in reportable operating segments, the Company reassessed goodwill with respect to the change in reportable operating segments as they are presented in this report. Goodwill was recorded in connection with the acquisition of Scendia and is included entirely within the Sanara Surgical segment. The Company's assessment determined that these changes, or any other matters noted, did not alter the Company's conclusion that goodwill is not impaired as of December 31, 2024 or 2023.

The carrying values of the Company's intangible assets were as follows for the periods presented:

	December 31, 2024			December 31, 2023		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Amortizable Intangible Assets:						
Patents and Other IP	$ 38,009,240	$ (5,008,856)	$ 33,000,384	$ 38,570,549	$ (3,181,186)	$ 35,389,363
Customer relationships and other	7,948,299	(3,007,118)	4,941,181	7,947,332	(1,861,887)	6,085,445
Product Licenses	4,793,879	(1,728,668)	3,065,211	4,793,879	(1,342,626)	3,451,253
Total	**$ 50,751,418**	**$ (9,744,642)**	**$ 41,006,776**	**$ 51,311,760**	**$ (6,385,699)**	**$ 44,926,061**

As of December 31, 2024, the weighted-average amortization period for finite-lived intangible assets was 14.6 years. Amortization expense related to intangible assets was $3,891,737 and $3,218,888 for the year ended December 31, 2024 and 2023, respectively. The estimated remaining amortization expense as of December 31, 2024 for finite-lived intangible assets is as follows:

2025	$ 3,894,221
2026	3,876,965
2027	3,763,113
2028	3,722,054
2029	3,722,054
Thereafter	22,028,369
Total	$41,006,776

The Company has reviewed the carrying value of intangible assets and has determined there was no impairment during the year ended December 31, 2024 or 2023.

NOTE 6 – INVESTMENTS IN EQUITY SECURITIES

The Company's equity investments consist of nonmarketable 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.

DirectDerm

In July 2020, the Company made a $500,000 long-term investment to purchase certain nonmarketable securities consisting of 7,142,857 Series B-2 Preferred Shares of Direct Dermatology Inc. ("DirectDerm"), representing approximately 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. In 2021, the Company purchased an additional 3,571,430 shares of DirectDerm's Series B-2 Preferred for $250,000. In March 2022, the Company purchased an additional 3,571,429 shares of DirectDerm's Series B-2 Preferred for $250,000. The Company's ownership of DirectDerm was approximately 8.1% as of December 31, 2024. The Company does not have the ability to exercise significant influence over DirectDerm's operating and financial activities. In accordance with ASC Topic 321, Investments - Equity Securities ("ASC 321"), this investment was reported at cost as of December 31, 2024.

Pixalere

In June 2021, the Company invested $2,084,278 to purchase 278,587 Class A Preferred Shares (the "Pixalere Shares") of Canada based Pixalere Healthcare Inc. ("Pixalere"). The Pixalere Shares are convertible into approximately 27.3% 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 Pixalere 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 reviewed the characteristics of the Pixalere Shares in accordance with ASC Topic 323, Investments – Equity Method and Joint Ventures ("ASC 323"). Due to the substantive liquidation preferences of the Pixalere Shares over Pixalere's common stock, the Pixalere Shares are not "in-substance" common stock, and therefore, the Company does not utilize the equity method of accounting for this investment. In accordance with ASC 321, this investment was reported at cost as of December 31, 2024.

ChemoMouthpiece

In September 2024, the Company, through its wholly owned subsidiary, Sanara CMP LLC ("Sanara CMP"), entered into a Unit Purchase Agreement (the "Unit Purchase Agreement") with ChemoMouthpiece, LLC ("CMp"), pursuant to which Sanara CMP purchased 100,674.72 common units in CMp for an aggregate purchase price of $5.0 million, or $49.6649 per unit, which represented approximately 6.64% of the issued and outstanding membership interest of CMp immediately following such purchase. Subsequent to the Company's initial investment in CMp, units of CMp were sold to other investors, thereby decreasing the Company's ownership of CMp to 6.59% as of December 31, 2024. CMp is a privately held medical device

company that develops and commercializes propriety oral cryotherapy products for cancer patients, including, among other things, CMp's Chemo Mouthpiece oral cryotherapy device, which is a 510(k) cleared cryotherapy device designed to reduce the incidence and severity of chemotherapy induced oral mucositis.

The Company has reviewed the characteristics of Sanara CMP's investment in CMp in accordance with ASC 323 and determined that Sanara CMP made a non-controlling investment in a limited liability company. According to the guidance provided in ASC 323-30-S99-1, investments in limited liability companies whereby an investor holds more than a 3% to 5% ownership interest would generally be accounted for under the equity method of accounting. Therefore, the Company utilized the equity method of accounting for this investment and recorded its initial investment at cost plus transaction costs. Sanara CMP's share of the earnings or losses of CMp is recorded in the Company's Consolidated Statements of Operations.

SI Technologies

In November 2022, the Company established a 50/50 joint venture, SI Healthcare Technologies, LLC ("SI Technologies") (formerly known as SI Wound Care, LLC), with InfuSystem Holdings, Inc. ("InfuSystem").

In connection with the Unit Purchase Agreement with CMp, the Company, CMp, certain subsidiaries of CMp, InfuSystem and SI Technologies, entered into an Exclusive Distribution Agreement (the "Distribution Agreement") pursuant to which SI Technologies was appointed as the sole and exclusive U.S. distributor of CMp's Standard Chemo Regiment Kits.

The parties to the Distribution Agreement also entered into an Intellectual Property Rights Agreement, pursuant to which SI Technologies was granted the exclusive right to use CMp's intellectual property rights to permit resale and use of the CMp Product in the United States.

The Company has reviewed the characteristics the Company's investment in SI Technologies in accordance with ASC 323 and determined that the Company made a non-controlling investment in a limited liability company. According to the guidance provided in ASC 323-30-S99-1, investments in limited liability companies whereby an investor holds more than a 3% to 5% ownership interest would generally be accounted for under the equity method of accounting. Therefore, the Company utilized the equity method of accounting for this investment and recorded its initial investment at cost. The Company's share of the earnings or losses of SI Technologies is recorded in the Company's Consolidated Statements of Operations.

The following table summarizes the Company's investments for the periods presented:

	December 31, 2024		December 31, 2023	
	Carrying Amount	Economic Interest	Carrying Amount	Economic Interest
Equity Method Investments				
ChemoMouthpiece, LLC	$ 5,172,242	6.59%	$ -	-%
SI Healthcare Technologies, LLC	40,703	50.00%	-	-%
Total Equity Method Investments	$ 5,212,945		$ -	
Cost Method Investments				
Direct Dermatology, Inc.	$ 1,000,000		$ 1,000,000	
Pixalere Healthcare Inc.	2,084,278		2,084,278	
Total Cost Method Investments	$ 3,084,278		$ 3,084,278	
Total Investments	**$ 8,297,223**		**$ 3,084,278**	

The following table summarizes the Company's share of losses from equity method investments reflected in the Company's Consolidated Statements of Operations for the periods presented:

	Year Ended December 31,	
	2024	2023
Investments		
ChemoMouthpiece, LLC	$ (105,710)	$ -
SI Healthcare Technologies, LLC	15,703	-
Total	**$ (90,007)**	**$ -**

NOTE 7 – OPERATING LEASES

The Company periodically enters 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 ("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.

As of December 31, 2024, the Company had two material operating leases for office space. In March and September of 2023, the Company amended its primary office lease to obtain additional space, as well as extend the term. The leases had remaining lease terms of 72 and eight months as of December 31, 2024. The Company is evaluating its renewal options for the lease expiring in eight months. For practical expediency, the Company has elected to not recognize ROU assets and lease liabilities related to short-term leases.

In accordance with ASC Topic 842, Leases, the Company has recorded ROU assets of $1,447,907 and a related lease liability of $1,595,738 as of December 31, 2024. The Company recorded lease expense of $555,192 and $434,066 for the year ended December 31, 2024 and 2023, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $505,017 and $380,576 for the year ended December 31, 2024 and 2023, respectively.

The present value of the Company's operating lease liabilities as of December 31, 2024 is shown below:

Maturity of Operating Lease Liabilities

	December 31, 2024
2025	$ 466,800
2026	300,369
2027	291,220
2028	295,689
2029	300,158
Thereafter	303,891
Total lease payments	1,958,127
Less imputed interest	(362,389)
Present Value of Lease Liabilities	$ 1,595,738
Operating lease liabilities – current	$ 358,687
Operating lease liabilities – long-term	$ 1,237,051

As of December 31, 2024, the Company's operating leases had a weighted average remaining lease term of 5.5 years and a weighted average discount rate of 7.8%.

NOTE 8 – DEBT AND CREDIT FACILITIES

CRG Term Loan Agreement

On April 17, 2024 (the "Closing Date"), the Company entered into a term loan agreement, by and among the Company, as borrower, the subsidiary guarantors party thereto from time to time (collectively, the "Guarantors"), CRG Servicing LLC as administrative agent and collateral agent (the "Agent"), and the lenders party thereto from time to time (the "CRG Term Loan Agreement"), providing for a senior secured term loan of up to $55.0 million (the "CRG Term Loan"). As of December 31, 2024, the CRG Term Loan Agreement provided for (i) $15.0 million of the CRG Term Loan that was borrowed on the Closing Date (the "First Borrowing") and (ii) up to an aggregate of $40.0 million available for borrowing in two subsequent borrowings, provided that each such borrowing was required to be at least $5.0 million and occur between the Closing Date and June 30, 2025, subject to the satisfaction of certain conditions, including the Agent having received certain fees. The Company used a portion of the initial proceeds of the First Borrowing under the CRG Term Loan to extinguish the Cadence Term Loan described further below.

On September 4, 2024, the Company, pursuant to its option under the CRG Term Loan Agreement, borrowed an additional $15.5 million under the CRG Term Loan Agreement (the "Second Borrowing"). The Company used $5.0 million of the proceeds of the Second Borrowing for its investment in CMp.

The First Borrowing, Second Borrowing and any additional borrowings under the CRG Term Loan are due and payable on March 30, 2029 (the "Maturity Date"), absent any acceleration.

The CRG Term Loan bears interest at a per annum rate equal to 13.25% (subject to a 4.0% increase during an event of default), of which 8.00% must be paid in cash and 5.25% may, at the election of the Company, be deferred through the 19th quarterly Payment Date (defined below) by adding such amount to the aggregate principal loan amount, so long as no default or event of default under the CRG Term Loan Agreement has occurred and is continuing. The Company is required to make quarterly interest payments on the final business day of each calendar quarter following the Closing Date, commencing on the first such date to occur at least 30 days after the Closing Date (each, a "Payment Date"). Interest is payable on each Payment Date in arrears with respect to the time between each Payment Date and upon the payment or prepayment of the CRG Term Loan, ending on the Maturity Date. In addition, the Company is required to pay an upfront fee of 1.50% of the principal amount of the CRG Term Loan, which is payable as amounts are advanced under the CRG Term Loan on a pro rata basis. The Company is also required to pay a back-end fee equal to 7.00% of the aggregate principal amount advanced under the CRG Term Loan Agreement.

For the year ended December 31, 2024, the Company paid $1,278,424 of interest in cash and recorded $838,965 of interest paid-in-kind related to the CRG Term Loan. The paid-in-kind interest was applied to the principal balance of the CRG Term Loan. The Company recorded $358,086 for the year ended December 31, 2024 to interest expense related to the back-end fee. The back-end fee is accreted and amortized to interest expense over the term of the CRG Term Loan. Paid-in-kind interest and the accreted back-end fee are included in "Long-term debt, net of current portion" in the Consolidated Balance Sheets.

Subject to certain exceptions, the Company is required to make mandatory prepayments of the CRG Term Loan with the proceeds of certain assets sales and in the event of a change of control of the Company. In addition, the Company may make a voluntary prepayment of the CRG Term Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Term Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs on or prior to the date that is one year following the applicable borrowing (the "Borrowing Date"), an amount equal to 10.0% of the aggregate outstanding principal amount of the CRG Term Loan being prepaid and (ii) if prepayment occurs one year after the applicable Borrowing Date and on or prior to two years following the applicable Borrowing Date, an amount equal to 5.0% of the aggregate outstanding principal amount of the CRG Term Loan being prepaid. No prepayment premium is due on any principal prepaid if prepayment occurs two years or more after the applicable Borrowing Date.

Certain of the Company's current and future subsidiaries, including the Guarantors, are guaranteeing the obligations of the Company under the CRG Term Loan Agreement. As security for their obligations under the CRG Term Loan Agreement, on the Closing Date, the Company and the Guarantors entered into a security agreement with the Agent pursuant to which the Company and the Guarantors granted to the Agent, as collateral agent for the lenders, a lien on substantially all of the Company's and the Guarantors' assets, including intellectual property (subject to certain exceptions).

The CRG Term Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on the Company's and the Guarantors' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions above certain thresholds, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Term Loan Agreement contains the following financial covenants requiring the Company and the Guarantors in the aggregate to maintain:

- liquidity in an amount which shall exceed the greater of: (i) $3.0 million and (ii) to the extent the Company has incurred certain permitted debt, the minimum cash balance, if any, required of the Company by the creditors of such permitted debt; and
- annual minimum revenue of at least: (i) $60.0 million for the twelve-month period beginning on January 1, 2024 and ending on December 31, 2024, (ii) $75.0 million for the twelve-month period beginning on January 1, 2025 and ending on December 31, 2025, (iii) $85.0 million for the twelve-month period beginning on January 1, 2026 and ending on December 31, 2026, (iv) $95.0 million for the twelve-month period beginning on January 1, 2027 and ending on December 31, 2027, and (v) $105.0 million during each twelve-month period beginning on January 1 of a given year thereafter.

The CRG Term Loan Agreement contains representations and warranties of the Company and the Guarantors customary for financings of this type, and also includes events of default customary for financings of this type, including, among other things, non-payment, inaccuracy of representations and warranties, covenant breaches, a material adverse change, bankruptcy and insolvency, material judgments and a change of control, in certain cases subject to customary periods to cure. The occurrence and continuance of an event of default could result in the acceleration of the obligations under the CRG Term Loan Agreement. As of December 31, 2024, the Company was in compliance with all debt covenants.

Cadence Term Loan

In connection with the entry into the Applied Purchase Agreement, on August 1, 2023, SMAT, as borrower, and the Company, as guarantor, entered into a loan agreement (the "Cadence Loan Agreement") with Cadence Bank (the "Bank") providing for, among other things, an advancing term loan in the aggregate principal amount of $12.0 million (the "Cadence Term Loan"), which was evidenced by an advancing promissory note. Pursuant to the Cadence Loan Agreement, the Bank agreed to make, at any time and from time to time prior to February 1, 2024, one or more advances to SMAT.

The proceeds of the advances under the Cadence Loan Agreement were used for working capital and for purposes of financing up to one hundred percent (100%) of the Cash Closing Consideration and Installment Payments for the Applied Asset Purchase and related fees and expenses, including any subsequent payments that were due to the Sellers after the Closing. On August 1, 2023, the Bank, at the request of SMAT, made an advance for $9.75 million. The proceeds from the advance were used to fund the Cash Closing Consideration for the Applied Asset Purchase.

The unpaid principal balance of outstanding advances bore interest, subject to certain conditions, at the lesser of the Maximum Rate (as defined in the Cadence Loan Agreement) or the Base Rate, which was for any day, a rate per annum equal to the term secured overnight financing rate (Term SOFR) (as administered by the Federal Reserve Bank of New York) for a one-month tenor in effect on such day plus three percent (3.0%). As of December 31, 2023, the interest rate on the advance under the Cadence Term Loan was 8.3%.

On the Closing Date of the CRG Term Loan Agreement, the Cadence Loan Agreement was terminated and all outstanding amounts under the Cadence Term Loan were repaid in full and all security interest and other liens granted to or held by Cadence were terminated and released. In addition, unamortized debt issuance costs as of the termination date of $53,438 were included in "Interest expense" in the Consolidated Statements of Operations.

The table below presents the components of the Company's outstanding debt for the periods presented:

	December 31, 2024	December 31, 2023
CRG Term Loan	$ 30,500,000	$ -
Paid-in-kind interest	838,965	-
Back-end fee	358,086	-
Cadence Term Loan	-	9,750,000
Debt	31,697,051	9,750,000
Less: unamortized debt issuance costs	(1,007,761)	(56,520)
Debt, net of debt issuance costs	30,689,290	9,693,480
Less: Current portion of debt	-	580,357
Long-term debt, net of current portion	$ 30,689,290	$ 9,113,123

The table below presents the aggregate maturities of the Company's outstanding debt as of December 31, 2024:

Year	Total
2025	$ -
2026	-
2027	-
2028	-
2029	31,697,051
Thereafter	-
Total debt	**$ 31,697,051**

In connection with the CRG Term Loan, the Company incurred $1,160,740 in debt issuance costs during the year ended December 31, 2024. Debt issuance costs are amortized to "Interest expense" in the Consolidated Statements of Operations over the life of the debt to which they pertain. The total unamortized debt issuance costs were $1,007,761 and $56,520 as of December 31, 2024 and December 31, 2023, respectively. Debt issuance costs are included in "Long-term debt, net of current portion" in the Consolidated Balance Sheets. Amortization expense related to debt issuance costs was $209,499 and $5,138 for the year ended December 31, 2024 and 2023, respectively. Amortization for the year ended December 31, 2024 includes the write-off of debt issuance costs of $56,520 related to the termination of Cadence Term Loan. The fair value of the Company's long-term debt approximated its carrying value as December 31, 2024.

NOTE 9 - COMMITMENTS AND CONTINGENCIES

License Agreements and Royalties

CellerateRX Surgical

In August 2018, the Company entered an exclusive, world-wide sublicense agreement with CGI Cellerate RX to distribute certain hydrolyzed collagen products, including CellerateRX Surgical, into the surgical and wound care markets. Pursuant to the Sublicense Agreement, the Company paid royalties of 3-5% of annual collected net sales of these products.

As discussed further in Note 3, on August 1, 2023, the Company purchased certain assets from Applied, including the rights to manufacture and sell certain hydrolyzed collagen products, including CellerateRX Surgical, for use in the human wound care market. In connection with the Applied Asset Purchase, Applied assigned the License Agreement with CGI Cellerate RX to SMAT, and on October 10, 2024, the License Agreement and Sublicense Agreement were terminated for no additional consideration.

Under the Sublicense Agreement, royalty expense, which was recorded in "Cost of goods sold" in the accompanying Consolidated Statements of Operations, totaled zero and $991,099, respectively, for the year ended December 31, 2024 and 2023.

BIASURGE Advanced Surgical Solution, BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser

In July 2019, the Company executed a license agreement with Rochal Industries, LLC ("Rochal"), a related party, pursuant to which 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 BIASURGE Advanced Surgical Solution, BIAKŌS Antimicrobial Wound Gel, BIAKŌS Antimicrobial Skin and Wound Cleanser. All three products are 510(k) cleared.

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

- The Company pays Rochal a royalty of 2-4% of net sales. The minimum annual royalty due to Rochal will increase to a maximum amount of $150,000 in 2025.
- The Company may pay additional royalties 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 expires with the related patents in December 2031.

Under this agreement, royalty expense, which is recorded in "Cost of goods sold" in the accompanying Consolidated Statements of Operations, was $177,005 and $130,000 for the year ended December 31, 2024 and 2023, respectively. The Company's Executive Chairman and Chief Executive Officer 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.

CuraShield Antimicrobial Barrier Film and No Sting Skin Protectant

In October 2019, the Company executed a license agreement with Rochal pursuant to which 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, 2024.

Debrider License Agreement

In May 2020, the Company executed a product license agreement with Rochal, pursuant to which 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:

- Upon FDA clearance of the licensed products, the Company will pay Rochal $500,000 in cash and an additional $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, 2024.

Acquisitions

Rochal Asset Acquisition

The Company entered into an asset purchase agreement with Rochal effective July 1, 2021, pursuant to which the Company purchased certain assets of Rochal. Pursuant to the asset purchase agreement, for the three-year period after the effective date, Rochal was 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 was also entitled to receive an amount in cash equal to twenty-five percent of the proceeds 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.

Precision Healing Merger Agreement

In April 2022, the Company closed a merger transaction with Precision Healing pursuant to which Precision Healing became a wholly owned subsidiary of the Company. Pursuant to the terms of the merger agreement, holders of Precision Healing common stock and preferred stock, other than the Company, were entitled to receive closing consideration, consisting of $125,966 in cash consideration, which was paid to stockholders who were not accredited investors, 165,738 shares of the Company's common stock, which was paid only to accredited investors, and the payment in cash of approximately $0.6 million of transaction expenses of Precision Healing. The Company recorded the issuance of the 165,738 shares to accredited investors and cash payments to nonaccredited investors based on the closing price per share of the Company's common stock on April 4, 2022, which was $30.75.

Upon the closing of the merger, the Precision Healing outstanding options previously granted under the Precision Healing Plan converted, pursuant to their terms, into options to acquire an aggregate of 144,191 shares of Company common stock with a weighted average exercise price of $10.71 per share. These options expire between August 2030 and April 2031. In addition, outstanding and unexercised Precision Healing warrants converted into rights to receive warrants to purchase (i) 4,424 shares of the Company's common stock with an initial exercise price of $7.32 per share and an expiration date of April 22, 2031, and (ii) 12,301 shares of the Company's common stock with an initial exercise price of $12.05 per share and an expiration date of August 10, 2030. Concurrent with the assumption of the Precision Healing Plan, the Company terminated the ability to offer future awards under the Precision Healing Plan. As of December 31, 2024, all warrants to purchase shares of the Company's common stock pursuant to the transaction with Precision Healing were exercised and there were 31,013 share options remaining to be exercised.

Pursuant to the merger agreement, upon the achievement of certain performance thresholds, the securityholders of Precision Healing, including the holders of options and warrants to purchase Precision Healing common stock and certain persons promised options to purchase Precision Healing common stock, was also entitled to receive payments of up to $10.0 million, which was accounted for as contingent consideration pursuant to ASC 805. The earnout consideration was payable in cash or, at the Company's election, was payable to accredited investors in shares of Company common stock at a price per share equal to the greater of (i) $27.13 or (ii) the average closing price of Company common stock for the 20 trading days prior to the date such earnout consideration was due and payable. Pursuant to the merger agreement, a minimum percentage of the earnout consideration may be required to be issued to accredited investors in shares of Company common stock for tax purposes. The amount and composition of the portion of earnout consideration payable was subject to adjustment and offsets as set forth in the merger agreement. The Company reviewed the performance thresholds necessary to trigger an earnout payment as of December 31, 2024 and deemed the performance thresholds to be unachievable. Therefore, the remaining fair value of the earnout consideration was reduced to zero.

Scendia Purchase Agreement

In July 2022, the Company closed the Scendia acquisition pursuant to which Scendia became a wholly owned subsidiary of the Company. Pursuant to the purchase agreement, the aggregate consideration for the acquisition at closing was approximately $7.6 million, subject to customary post-closing adjustments. The consideration consisted of (i) approximately $1.6 million of cash, subject to certain adjustments, and (ii) 291,686 shares of common stock of the Company. Pursuant to the purchase agreement, at closing, the Company withheld 94,798 Indemnity Holdback Shares, which such Indemnity Holdback Shares were withheld to the extent provided in the purchase agreement to satisfy Ryan Phillips' ("Phillips") indemnification obligations and subsequently issued and released to Phillips in July 2023.

In addition to the cash consideration and the stock consideration, the purchase agreement provides that Phillips was entitled to receive two potential earnout payments, payable on an annual basis, not to exceed $10.0 million in the aggregate, which was accounted for as contingent consideration pursuant to ASC 805. The earnout consideration was payable to Phillips in cash or, at the Company's election, in up to 486,145 shares of the Company's common stock upon the achievement of certain performance thresholds relating to net revenue attributable to sales of Scendia products during the two-year period following the closing. The Company made the first earnout payment of approximately $693,000 in cash in August 2023 and the second and final earnout payment of approximately $1.1 million in cash in October 2024.

Applied Asset Purchase

On August 1, 2023, the Company closed the Applied Asset Purchase. The Applied Purchased Assets were purchased for an initial aggregate purchase price of $15.25 million, consisting of (i) the Cash Closing Consideration, (ii) the Stock Closing Consideration and (iii) the Installment Payments.

In addition to the Cash Closing Consideration, Stock Closing Consideration and Installment Payments, the Applied Purchase Agreement provides that the Sellers are entitled to receive the Applied Earnout, which is payable to the Sellers in cash, upon the achievement of certain performance thresholds relating to SMAT's collections from net sales of a collagen-based product currently under development. Upon expiration of the seventh anniversary of the Closing, to the extent the Sellers have not earned the entirety of the Applied Earnout, SMAT shall pay the Sellers the True-Up Payment. The Applied Earnout, minus the True-Up Payment and any Applied Earnout payments already made by SMAT, may be earned at any point in the future, including after the True-Up Payment is made. The first Installment Payment of $625,000 was made in August 2024.

In connection with the Applied Asset Purchase and pursuant to the Applied Purchase Agreement, effective August 1, 2023, the Company entered into the Petito Services Agreement with the Owner, pursuant to which the Owner, as an independent contractor, agreed to provide the Petito Services. As consideration for the Petito Services, the Owner is entitled to receive: (i) a base salary of $12,000 per month during the term of the Petito Services Agreement, (ii) a royalty payment equal to three percent (3%) of the actual collections from net sales of certain products the Owner develops or codevelops that reach commercialization, (iii) a royalty payment equal to five percent (5%) for the first $50.0 million in aggregate collections from net sales of certain future products and a royalty payment of two and one-half percent (2.5%) on aggregate collections from net sales of certain future products on any amounts exceeding $50.0 million but up to $100.0 million, (iv) $500,000 in cash in the event that 510(k) clearance is issued for any future product accepted by the Company and (v) $1.0 million in cash in the event that a U.S. patent is issued for a certain product; provided that with respect to the incentive payments described in (iv) and (v) of the foregoing, the Owner shall not earn more than $2.5 million.

The Petito Services Agreement has an initial term of three years and is subject to automatic successive one-month renewals unless earlier terminated in accordance with its terms. The Petito Services Agreement may be terminated upon the Owner's death or disability or by the Company or the Owner "For Cause" (as defined in the Petito Services Agreement); provided, however, that the base salary described in (i) of the foregoing paragraph shall survive termination through the three-year initial term and the royalty payments and incentive payments described in (ii)-(v) of the foregoing paragraph shall survive termination of the Petito Services Agreement.

Other Commitments

On December 20, 2023, the Company signed an exclusive license agreement with Tufts University ("Tufts") to develop and commercialize patented technology covering 18 unique collagen peptides. As part of this agreement, the Company formed a new subsidiary, Sanara Collagen Peptides, LLC ("SCP") and issued 10% of SCP's outstanding units to Tufts. SCP has exclusive rights to develop and commercialize new products based on the licensed patents and patents pending. SCP will pay royalties to Tufts based on net sales of licensed products and technologies. Under the exclusive license agreement, royalties will be calculated at a rate of 1.5% or 3%, depending on the type of product or technology developed. SCP will pay Tufts a minimum annual royalty of $50,000 on January 1 of the year following the first anniversary of the first commercial sale of the licensed products or technologies. SCP will pay Tufts a $100,000 minimum annual royalty on January 1 of each subsequent year during the royalty term specified in the exclusive license agreement. There have been no material accounting impacts related to this arrangement as of December 31, 2024.

NOTE 10 – SHAREHOLDERS' EQUITY

Common Stock

At the Company's Annual Meeting of Shareholders held in July 2020, the Company approved the Restated 2014 Omnibus Long Term Incentive Plan (the "2014 LTIP") in which the Company's directors, officers, employees and consultants are eligible to participate. The 2014 LTIP terminated on September 3, 2024, and no future awards may be granted pursuant to the 2014 LTIP. Previously granted awards under the 2014 LTIP will remain outstanding until they expire by their terms or under the terms of the 2014 LTIP.

On June 12, 2024, the Company's shareholders approved the 2024 Omnibus Long-Term Incentive Plan (the "2024 LTIP"), which went into effect upon shareholder approval. The maximum number of shares of the Company's common stock that may be delivered pursuant to awards granted under the 2024 LTIP is 1,000,000, subject to increase by any awards under the 2014 LTIP (i) that were outstanding on or after June 12, 2024, and that, on or after such date, are forfeited, expire or are canceled, and (ii) any shares subject to awards relating to common stock under the 2014 LTIP that are settled in cash on or after June 12, 2024 (the "Prior LTIP Awards"). The 2024 LTIP also provides that, to the extent an award under the 2024 LTIP or a Prior LTIP Award is forfeited, expires or is canceled, in whole or in part, the shares subject to such forfeited, expired or canceled award may again be awarded under the 2024 LTIP. As of December 31, 2024, a total of 742,405 shares had been issued under the 2014 LTIP, 2,543 shares had been issued under the 2024 LTIP and 1,000,137 were available for issuance under the 2024 LTIP.

On August 1, 2023, the Company closed the Applied Asset Purchase. Included in the purchase price was 73,809 shares of the Company's common stock. See Note 3 for more information regarding the acquisition of Applied.

In February 2023, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which the Company could offer and sell from time to time, to or through Cantor, shares of the Company's common stock having an aggregate offering price of up to $75,000,000.

Sales of the shares were made in sales deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Cantor agreed to use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market to sell the shares from time to time based upon the Company's instructions, including any price, time period or size limits specified by the Company. The Company had no obligation to sell any of the shares under the Sales Agreement and could suspend or terminate the offering of its common stock pursuant to the Sales Agreement upon notice to Cantor and subject to other conditions. Cantor's obligations to sell the shares under the Sales Agreement were subject to satisfaction of certain conditions, including customary closing conditions. Pursuant to the Sales Agreement, the Company paid Cantor a commission of 3.0% of the aggregate gross proceeds from each sale of the shares.

In 2023, the Company sold an aggregate of 26,143 shares of common stock for gross proceeds of approximately $1.1 million and net proceeds of approximately $0.9 million pursuant to the Sales Agreement. The Company paused the offering at the end of the first quarter of 2023 and did not reactivate it during the remainder of 2023. The Form S-3 registration statement for this offering expired at the beginning of 2024.

In April 2022, the Company closed a merger transaction with Precision Healing pursuant to which Precision Healing became a wholly owned subsidiary of the Company. Pursuant to the terms of the merger agreement, holders of Precision Healing common stock and preferred stock, other than the Company, were entitled to receive closing consideration, consisting of $125,966 in cash consideration, which was paid to stockholders who were not accredited investors, 165,738 shares of the Company's common stock, which was paid only to accredited investors, and the payment in cash of approximately $0.6 million of transaction expenses of Precision Healing. The Company recorded the issuance of the 165,738 shares to accredited investors and cash payments to nonaccredited investors based on the closing price per share of the Company's common stock on April 4, 2022, which was $30.75.

Upon the closing of the merger, the Precision Healing outstanding options previously granted under the Precision Healing Plan converted, pursuant to their terms, into options to acquire an aggregate of 144,191 shares of Company common stock with a weighted average exercise price of $10.71 per share. These options expire between August 2030 and April 2031. In addition, outstanding and unexercised Precision Healing warrants converted into rights to receive warrants to purchase (i) 4,424 shares of the Company's common stock with an initial exercise price of $7.32 per share and an expiration date of April 22, 2031, and (ii) 12,301 shares of the Company's common stock with an initial exercise price of $12.05 per share and an expiration date of August 10, 2030. Concurrent with the assumption of the Precision Healing Plan, the Company terminated the ability to offer future awards under the Precision Healing Plan.

Pursuant to the merger agreement, upon the achievement of certain performance thresholds, the securityholders of Precision Healing, including the holders of options and warrants to purchase Precision Healing common stock and certain persons promised options to purchase Precision Healing common stock, were entitled to receive payments of up to $10.0 million, which was accounted for as contingent consideration pursuant to ASC 805. The earnout consideration was payable in cash or, at the Company's election, payable to accredited investors in shares of Company common stock at a price per share equal to the greater of (i) $27.13 or (ii) the average closing price of Company common stock for the 20 trading days prior to the date such earnout consideration is due and payable. The Company reviewed the performance thresholds necessary to trigger an earnout payment as of December 31, 2024 and deemed the performance thresholds to be unachievable. Therefore, no earnout consideration is expected to be paid to the securityholders of Precision Healing.

Restricted Stock Awards

During the year ended December 31, 2024, the Company issued restricted stock awards under the 2014 LTIP which are subject to certain vesting provisions and other terms and conditions set forth in each recipient's respective restricted stock agreement. The Company issued 161,908 shares, net of forfeitures, under the 2014 LTIP and 2,543 shares under the 2024 LTIP, of restricted common stock to employees, directors, and certain advisors of the Company during the year ended December 31, 2024. The fair value of these awards was $5,747,656 based on the closing price of the Company's common stock on the respective grant dates, which will be recognized as compensation expense on a straight-line basis over the vesting period of the awards.

Share-based compensation expense of $4,436,048 and $3,442,722 was recognized in "Operating expenses" in the accompanying Consolidated Statements of Operations during the year ended December 31, 2024 and 2023, respectively.

At December 31, 2024, there was $4,189,272 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 1.5 years.

Below is a summary of restricted stock activity for the year ended December 31, 2024:

	For the Year Ended December 31, 2024	
	Shares	Weighted Average Grant Date Fair Value
Nonvested at beginning of period	144,211	$ 34.07
Granted	192,783	35.00
Vested	(105,875)	34.19
Forfeited	(28,332)	35.31
Nonvested at December 31, 2024	202,787	$ 34.72

Stock Options

A summary of the status of outstanding stock options at December 31, 2024 and changes during the year then ended is presented below:

	For the Year Ended December 31, 2024			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contract Life	Aggregate Intrinsic Value
Outstanding at beginning of period	93,892	$ 10.22		
Granted or assumed	-	-		
Exercised	(62,879)	10.05		
Forfeited	-	-		
Expired	-	-		
Outstanding at December 31, 2024	31,013	$ 10.57	5.8	$ 701,975.3
Exercisable at December 31, 2024	31,013	$ 10.57	5.8	$ 701,975.3

Warrants

A summary of the status of outstanding warrants to purchase common stock at December 31, 2024 and changes during the year then ended is presented below:

	For the Year Ended December 31, 2024		
	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Outstanding at beginning of period	16,725	$ 10.80	
Granted or assumed	-	-	
Exercised	(16,725)	-	
Forfeited	-	-	
Expired	-	-	
Outstanding at December 31, 2024	-	$ -	-
Exercisable at December 31, 2024	-	$ -	-

NOTE 11 – CUSTOMERS AND SUPPLIERS

The Company had no customers in 2024 that accounted for at least 10% of the Company's annual sales or whose accounts receivable balance exceeded 10% of the year-end balance. The Company had no customers in 2023 that accounted for at least 10% of Company's annual sales and 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 12 – 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") carryforward at December 31, 2024 was approximately $57.5 million, of which, approximately $26.5 million, generated in 2017 and prior, will expire between 2024 and 2037. Under the Tax Cuts and Jobs Act, the NOL generated from 2018 through 2024, of approximately $30.9 million, will have an indefinite carryforward period but can generally only be used to offset 80% of taxable income in any particular year. The Company may be subject to certain limitations in its 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:

	As of December 31,	
	2024	2023
Deferred tax assets		
Net operating loss carry forwards	$ 12,907,965	$ 12,467,570
Research and development costs	3,006,029	2,119,193
Stock compensation expense	789,373	711,598
Accrued expenses	7,330	528,148
Lease liability	389,882	512,668
Contingent liability	221,065	221,028
Acquisition liability	112,722	176,629
Bad debt and other reserves	287,900	129,924
Inventory reserves	130,605	109,176
Other temporary differences	1,049,365	203,340
Total deferred tax assets	18,902,236	17,179,274
Deferred tax liabilities		
Depreciation and amortization	(5,683,259)	(6,180,688)
Right of Use assets	(353,763)	(487,402)
Accrued expenses	-	(424,423)
Contingent liability	(38,308)	(130,802)
Other temporary differences	(294,608)	(166,712)
Valuation allowance	(12,532,298)	(9,789,247)
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 expense (benefit) based on the statutory income tax rate of 21% to the actual benefit for the years ended December 31, 2024 and 2023 are listed below.

	For the Year Ended December 31,	
	2024	2023
Expected federal income tax benefit	$ (2,019,060)	$ (903,220)
State and local taxes, net of federal benefit	(338,138)	(226,714)
Fair value adjustments	(497,373)	(819,270)
Share-based compensation	(237,838)	(557,168)
Other permanent differences	199,857	118,765
NOL carryover adjustments	97,806	(5,148,128)
Intangibles	-	(720,407)
Other true ups	90,343	(230,474)
Changes in tax rates	9,732	673,449
Change in valuation allowance	2,743,051	7,813,167
Income tax expense	$ 48,380	$ -

All tax years starting with 2021 are open for examination. The Company's 2022 federal tax return was under audit as of March 24, 2025.

NOTE 13 – RELATED PARTIES

CellerateRX Sublicense Agreement

The Company had an exclusive, world-wide sublicense to distribute certain hydrolyzed collagen products, including CellerateRX Surgical into the surgical and wound care markets from an affiliate of The Catalyst Group, Inc. ("Catalyst"), CGI Cellerate RX, which licensed the rights to these products from Applied.

As discussed further in Note 3, on August 1, 2023, the Company purchased certain assets from Applied, including the underlying intellectual property of, as well as the rights to manufacture and sell certain hydrolyzed collagen products, including CellerateRX Surgical. In connection with the Applied Asset Purchase, Applied assigned the License Agreement with CGI Cellerate RX to SMAT, and on October 10, 2024, the License Agreement and Sublicense Agreement were terminated for no additional consideration. Ronald T. Nixon, the Company's Chief Executive Officer and Executive Chairman, is the founder and managing partner of Catalyst.

Product License Agreements

In July 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. Currently, the products covered by the BIAKŌS License Agreement are BIASURGE Advanced Surgical Solution, BIAKŌS Antimicrobial Wound Gel and BIAKŌS Antimicrobial Skin and Wound Cleanser. Each of these products are 510(k) cleared. Mr. Nixon 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.

In October 2019, the Company executed the ABF 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. Currently, the products covered by the ABF License Agreement are CuraShield Antimicrobial Barrier Film and a no sting skin protectant product.

In May 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 9 for more information on these product license agreements.

Consulting Agreement

Concurrent with the Rochal asset purchase, in July 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 had an initial term of three years, unless earlier terminated by the Company, and was subject to renewal. Effective July 13, 2024, the consulting agreement with Ms. Salamone was amended to provide that the initial term shall be automatically renewed for successive one-year terms for up to three successive years unless earlier terminated by either party without cause at any time, provided that the terminating party provides 90 days advance written notice of termination. Ms. Salamone is a director of the Company and is a significant shareholder and the current Chair of the board of directors of Rochal.

Catalyst Transaction Advisory Services Agreement

In March 2023, the Company entered into a Transaction Advisory Services Agreement (the "Catalyst Services Agreement") effective March 1, 2023 with Catalyst, a related party. Pursuant to the Catalyst Services Agreement, Catalyst, by and through its directors, officers, employees and affiliates that are not simultaneously serving as directors, officers or employees of the Company (collectively, the "Covered Persons"), agreed to perform certain transaction advisory, business and organizational strategy, finance, marketing, operational and strategic planning, relationship access and corporate development services for the Company in connection with any merger, acquisition, recapitalization, divestiture, financing, refinancing, or other similar transaction in which the Company may be, or may consider becoming, involved, and any such additional services as mutually agreed upon in writing by and between Catalyst and the Company (the "Catalyst Services").

Pursuant to the Catalyst Services Agreement, the Company agreed to reimburse Catalyst for (i) compensation actually paid by Catalyst to any of the Covered Persons at a rate no more than a rate consistent with industry practice for the performance of services similar to the Catalyst Services, as documented in reasonably sufficient detail, and (ii) all reasonable out-of-pocket costs and expenses payable to unaffiliated third parties, as documented in customary expense reports, as each of (i) and (ii) is incurred in connection with the Catalyst Services rendered under the Catalyst Services Agreement, with all reimbursements being contingent upon the prior approval of the Audit Committee of the Company's Board of Directors. The Company incurred costs pursuant to the Catalyst Services Agreement of $288,594 and $174,486 in the year ended December 31, 2024 and 2023, respectively, and is recorded in "Selling, general and administrative" in the accompanying Consolidated Statements of Operations.

NOTE 14 – SEGMENT REPORTING

As discussed in Note 1, the Company historically managed its business as one operating and reportable segment. During the second quarter of 2024, the Company changed its reportable segments to reflect a change in the manner in which the business is managed. Based on the growing importance of the value-based wound care program to the Company's future outlook and how the Company's chief operating decision maker ("CODM"), the Chief Executive Officer, reviews operating results and makes decisions about resource allocation, the Company has two reportable segments: Sanara Surgical and THP.

Segment Adjusted EBITDA is the primary profitability measure used by the CODM for purposes of assessing financial performance and resource allocation. The Company defines Segment Adjusted EBITDA for the reportable segments as net income (loss) excluding interest expense/income, provision/benefit for income taxes, depreciation and amortization, non-cash share-based compensation expense, change in fair value of earnout liabilities, share of losses from equity method investments, executive separation costs, legal and diligence expenses related to acquisitions, and gains/losses on disposal of property and equipment, as each are applicable to the periods presented. The Company has historically presented this profitability measure as Segment EBITDA and, starting with the fourth quarter ended December 31, 2024, is presenting it as Segment Adjusted EBITDA. The definition and methodology for calculating this measure has remained unchanged. Segment Adjusted EBITDA, as it relates to the Company's reportable segments, is presented in conformity with ASC 280, Segment Reporting, and is excluded from the definition of non-GAAP financial measures under the Securities and Exchange Commission's Regulation G and Item 10(e) of Regulation S-K. Segment Adjusted EBITDA may not be comparable to similarly titled measures reported by other companies. The CODM also reviews budget-to-actual variances for expenses on a monthly basis when making decisions about allocating resources to the segments. The Company has not included any disclosure regarding total segment assets, as no segment level asset information is regularly provided to the CODM.

Sanara Surgical

The Sanara Surgical segment primarily markets and sells soft tissue repair and bone fusion products for use in the operating room or other sterile environments. Sanara Surgical's soft tissue repair products include, among other products, the Company's lead product, CellerateRX Surgical, and BIASURGE Advanced Surgical Solution, which is a sterile no-rinse, advanced surgical solution used for wound irrigation. Sanara Surgical's bone fusion products include, among other products, BiFORM, which is an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site, and ALLOCYTE Plus, which is a human allograft cellular bone matrix containing bone-derived progenitor cells and conformable bone fibers.

Sanara Surgical also includes an in-house research and development team (Rochal Technologies) with an extensive pipeline of innovative products under development.

Tissue Health Plus

The THP segment is focused on value-based wound care services. Through THP, the Company plans to offer a first of its kind value-based wound care program to payers and risk-bearing entities such as accountable care organizations and value-based primary care companies, with Medicare Advantage payers as the initial target market for this program.

THP's programs are expected to enable payers to divest wound care spend risk, reduce wound related hospitalizations and improve patient quality of life. THP plans to coordinate delivery of community and home-based wound care for its managed patients. Community based care spans a variety of settings including physician offices, skilled nursing facilities, assisted living facilities and senior living facilities. THP programs are intended to integrate science and evidence-based medicine protocols to standardize wound prevention and treatment.

Currently, there are no allocated costs included in the THP segment. All corporate and overhead expenses are included in the Sanara Surgical segment, as substantially all of those costs relate to supporting the operations and activities of the Sanara Surgical segment.

As a result of the change in reportable segments, certain prior period amounts have been recast to conform to the current period presentation. Throughout this Annual Report on Form 10-K, unless otherwise indicated, amounts and activity reflect reclassifications related to the Company's change in reportable segments. The change in reportable segments had no impact on the Company's previously reported Consolidated Balance Sheets, Consolidated Statements of Operations, Consolidated Statements of Cash Flows or Consolidated Statements of Shareholders' Equity.

The following table reflects results of operations including significant segment expenses that are regularly provided to the CODM for the Company's reportable segments and Segment Adjusted EBITDA for the periods indicated below:

	Year Ended December 31,					
	2024			2023		
	Sanara Surgical	THP	Total	Sanara Surgical	THP	Total
Net revenue	$ 86,672,425	$ -	$ 86,672,425	$ 64,987,112	$ 2,730	$ 64,989,842
Gross profit (loss)	78,532,524	-	78,532,524	57,143,391	(6,235)	57,137,156
Selling, general and administrative	71,673,642	4,886,221	76,559,863	54,826,852	2,167,901	56,994,753
Research and development	2,828,663	2,874,699	5,703,362	902,782	3,229,643	4,132,425
Depreciation and amortization	2,785,829	2,137,395	4,923,224	2,046,859	1,628,167	3,675,026
Change in fair value of earnout liabilities	(14,451)	(1,924,000)	(1,938,451)	(1,298,336)	(2,151,559)	(3,449,895)
Other expense	3,196,424	-	3,196,424	224,749	-	224,749
Net income (loss)	$ (1,937,583)	$ (7,974,315)	$ (9,911,898)	$ 440,485	$ (4,880,387)	$ (4,439,902)
Segment Adjusted EBITDA	$ 9,148,722	$ (6,457,415)	$ 2,691,307	$ 5,289,634	$ (5,162,387)	$ 127,247

The following table provides a reconciliation of net income (loss) to Segment Adjusted EBITDA for the Company's reportable segments for the periods indicated below:

	Year Ended December 31,					
	2024			2023		
	Sanara Surgical	THP	Total	Sanara Surgical	THP	Total
Net Income (Loss)	$(1,937,583)	$(7,974,315)	$(9,911,898)	$ 440,485	$(4,880,387)	$(4,439,902)
Adjustments:						
Interest expense	3,128,395	-	3,128,395	475,783	-	475,783
Interest income	(21,978)	-	(21,978)	-	-	-
Depreciation and amortization [1]	2,785,829	2,137,395	4,923,224	2,046,859	1,628,167	3,675,026
Noncash share-based compensation	3,969,008	138,245	4,107,253	3,201,330	241,392	3,442,722
Change in fair value of earnout liabilities	(14,451)	(1,924,000)	(1,938,451)	(1,298,336)	(2,151,559)	(3,449,895)
Share of losses from equity method investments	90,007	-	90,007	-	-	-
Executive separation costs [2]	964,466	-	964,466	-	-	-
Acquisition costs [3]	185,029	1,165,260	1,350,289	423,513	-	423,513
Segment Adjusted EBITDA	$ 9,148,722	$(6,457,415)	$ 2,691,307	$ 5,289,634	$(5,162,387)	$ 127,247

[1] Includes a $506,836 non-cash charge during the fourth quarter of 2024 to write-off the remaining net book value of certain THP internal use software assets.

[2] Includes $328,795 of share-based compensation related to executive separation costs for the twelve months ended December 31, 2024.

[3] Acquisition costs include legal, tax and accounting services related to prospective acquisitions.

NOTE 15 – SUBSEQUENT EVENTS

Exclusive License and Distribution Agreement With, and Minority Investment in, Biomimetic Innovations Ltd

Licensing and Distribution Agreement

On January 16, 2025 (the "Execution Date"), the Company entered into a Licensing and Distribution Agreement (the "License Agreement"), by and between the Company and Biomimetic Innovation Limited, a privately-held medical device company headquartered in Shannon, Co. Clare Ireland ("BMI"), pursuant to which the Company acquired the exclusive U.S. marketing, sales and distribution rights to OsStic® Synthetic Injectable Structural Bio-Adhesive Bone Void Filler ("OsStic"), as well as an adjunctive internal fixation technology featuring novel delivery to promote targeted application of OsStic ("ARC" and together with OsStic, the "Products"), for use in the treatment of a wound or injury caused by a traumatic incident.

Pursuant to the License Agreement, the Company was appointed by BMI as the exclusive distributor to promote, market, offer to sell, transfer, distribute and sell the Products for trauma indications inside the United States and its territories for an initial five-year term, which term may be automatically renewed for successive two-year periods at the Company's discretion, provided that the Company is in compliance with its obligations thereunder (the "Term"). From the Execution Date until October 13, 2025, the Company has an exclusive option to negotiate exclusive distribution rights for the Products in additional fields and/or additional territories on substantially the same terms as those set forth in the License Agreement.

The License Agreement requires that the Company pay BMI quarterly royalties (the "Quarterly Royalties") based on a percentage of the Net Sales Value (as defined in the License Agreement) of the Products during the Term, with the applicable percentage of the Net Sales Value for OsStic being in the mid-single digit range. Pursuant to the License Agreement, the Company and BMI agreed to negotiate the applicable percentage of the Net Sales Value for ARC at a future date. The License Agreement also requires that the Company pay BMI minimum royalty payments being in the low to mid six figure range for the first, second and third years, respectively, following the receipt of first regulatory approval for the marketing and sale of a Product.

Subscription and Shareholders' Agreement

In connection with the License Agreement, on the Execution Date, the Company entered into a Share Subscription and Shareholders' Agreement (the "Subscription Agreement"), by and among the Company, The Russell Revocable Living Trust, BMI and the existing shareholders of BMI, pursuant to which the Company agreed to contribute up to approximately €8.0 million to BMI through a series of capital contributions in exchange for an aggregate of 16,460 ordinary shares of BMI, constituting approximately 12.5% of the outstanding equity of BMI as of the Execution Date. The Company made an initial

cash investment totaling approximately €3.0 million on the Execution Date, and the Company's previously announced convertible loan to BMI was converted into €1.0 million of equity in BMI. Pursuant to the Subscription Agreement, the remaining €4.0 million contribution is due upon the achievement of certain development, clinical and regulatory milestones (the "Milestones").

Pursuant to the Subscription Agreement, so long as the Company holds a five percent ownership interest or greater in BMI, the Company is entitled to have one person appointed to BMI's board of directors. The Company's initial investment of approximately €4.0 million caused the Company to exceed the five percent ownership interest threshold in BMI, and as a result the Company's Chief Corporate Development & Strategy Officer, Tyler Palmer, has been nominated and appointed to BMI's board of directors. In addition, the Company has the right to send one non-voting observer to attend meetings of the BMI board of directors, regardless of the Company's ownership interest level. The Company's capital contributions must be used to fund the development and commercialization of the Products, and the Company has certain veto and consent rights to further protect the Company's investment in BMI and to support its ability to successfully market and sell the Products.

CRG Term Loan Amendment

On [March 19, 2025], the Company and the Guarantors entered into the First Amendment to Term Loan Agreement with the Agent and the lenders party thereto from time to time, which amended the CRG Term Loan Agreement to, among other things, (i) entitle the Company to two additional borrowings following the Second Borrowing, which borrowings must occur on or prior to December 31, 2025, if at all, and (ii) remove the requirement that any borrowing be in whole multiples of $5.0 million.

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

None.

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, 2024, pursuant to Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of December 31, 2024, 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, 2024 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, 2024.

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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

On March 19, 2025, the Company and the Guarantors entered into the CRG Amendment, which amended the CRG Term Loan Agreement to, among other things, (i) entitle the Company to two additional borrowings following the Second Borrowing, which borrowings must occur on or prior to December 31, 2025, if at all, and (ii) remove the requirement that any borrowing be in whole multiples of $5.0 million.

Except as expressly amended pursuant to the CRG Amendment, the terms and conditions of the CRG Term Loan Agreement remain in full force and effect.

The foregoing description of the CRG Amendment is qualified in its entirety by reference to the full text of the CRG Amendment, which is filed as Exhibit 10.20 to this Annual Report on Form 10-K and is incorporated by reference herein.

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).
2.2#	Agreement and Plan of Merger, dated April 1, 2022, by and among Sanara MedTech Inc., United Wound and Skin Solutions, LLC, Precision Healing Inc., PH Merger Sub I, Inc., PH Merger Sub II, LLC and Furneaux Capital Holdco, LLC (d/b/a BlueIO) (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on April 4, 2022).
2.3#	Membership Interest Purchase Agreement, dated July 1, 2022, by and among Sanara MedTech Inc., Scendia Biologics, LLC and Ryan Phillips (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on July 5, 2022).
2.4#	Asset Purchase Agreement, dated August 1, 2023, by and among Sanara MedTech Inc., Sanara MedTech Applied Technologies, LLC, The Hymed Group Corporation, Applied Nutritionals, LLC and Dr. George D. Petito (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on August 2, 2023).
3.1	Amended and Restated Certificate of Formation of Sanara MedTech Inc. (incorporated by reference to Exhibit 3.1 to the Company's current Report on Form 8-K filed on June 17, 2024).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 22, 2024).
4.1	Description of Securities (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K filed March 30, 2021).
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 10.1.1 to the Company's Annual Report on Form 10-K filed on March 20, 2023).
10.1.2†	Form of Restricted Stock Award Agreement for Employees 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).
10.1.3†	Form of Restricted Stock Award Agreement for Outside Directors under the Sanara MedTech Inc. Restated 2014 Omnibus Long Term Incentive Plan (2022) (incorporated by reference to Exhibit 10.1.3 to the Company's Annual Report on Form 10-K filed on March 20, 2023).
10.1.4†	Form of Restricted Stock Award Agreement for Employees under the Sanara MedTech Inc. Restated 2014 Omnibus Long Term Incentive Plan (2023) (incorporated by reference to Exhibit 10.1.4 to the Company's Annual Report on Form 10-K filed on March 20, 2023).
10.2.1†	Sanara MedTech Inc. 2024 Omnibus Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 18, 2024).
10.2.2†	Form of Restricted Stock Award Agreement under the Sanara MedTech Inc. 2024 Omnibus Long-Term Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.3†	Employment Agreement, effective September 1, 2024, by and between Sanara MedTech Inc. and Ronald T. Nixon (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 23, 2024).
10.4†	Employment Agreement, effective January 15, 2025, by and between Sanara MedTech Inc. and Elizabeth B. Taylor (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2025).

10.5†	Employment Agreement, effective April 15, 2024, by and between Sanara MedTech Inc. and Jacob A. Waldrop (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 5, 2024).
10.6†	Amended and Restated Employment Agreement, effective January 15, 2025, by and between Sanara MedTech Inc. and Michael D. McNeil (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 22, 2025).
10.7†	Amended and Restated Employment Agreement, dated April 28, 2022, by and between Sanara MedTech Inc. and Zachary B. Fleming (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 29, 2022).
10.8†	Separation Agreement and General Release, dated as of May 29, 2024, by and between Sanara MedTech Inc. and Zachary B. Fleming (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.9†	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).
10.9.1	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).
10.10	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).
10.11	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).
10.12†	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).
10.12.1†	First Amendment to Consulting Agreement, dated July 13, 2024, by and between Sanara MedTech Inc. and Ann Beal Salamone (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.13	Precision Healing Inc. 2020 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on April 8, 2022).
10.14	Controlled Equity OfferingSM Sales Agreement, dated February 24, 2023, by and between Sanara MedTech Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on February 24, 2023).
10.15	Transaction Advisory Services Agreement, dated March 1, 2023, by and between Sanara MedTech Inc. and The Catalyst Group, Inc. (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K filed on March 20, 2023).
10.16+	Professional Services Agreement, dated August 1, 2023, by and between Sanara MedTech Inc. and Dr. George D. Petito (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 2, 2023).
10.17+	Term Loan Agreement, dated April 17, 2024, by and among Sanara MedTech Inc., as borrower, the Subsidiary Guarantors party thereto, the lenders party thereto and CRG Servicing LLC, as administrative agent and collateral agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2024).

10.18+	Form of Security Agreement, by and among Sanara MedTech Inc., the Subsidiary Guarantors party thereto and CRG Servicing LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 18, 2024).
10.19*+	Share Subscription and Shareholders' Agreement, by and among the Company, The Russell Revocable Living Trust, Biomimetic Innovation Limited and the existing shareholders of Biomimetic Innovation Limited.
10.20*	First Amendment to Term Loan Agreement, dated March 19, 2025, by and among Sanara MedTech Inc., as borrower, the Subsidiary Guarantors party thereto, the lenders party thereto and CRG Servicing LLC, as administrative agent and collateral agent.
19.1*	Insider Trading Policy.
21.1*	List of Subsidiaries.
23.1*	Consent of Weaver and Tidwell, L.L.P.
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.
97.1	Sanara MedTech Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on March 25, 2024).
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.

\# Certain schedules and exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission or its staff upon request. If indicated on the first page of such agreement, certain confidential information has been excluded pursuant to Item 601(b)(2)(ii) of Regulation S-K. Such excluded information is not material and is the type that the Company treats as private or confidential.

\+ Certain schedules and exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission or its staff upon request. If indicated on the first page of such agreement, certain confidential information has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K. Such excluded information is not material and is the type that the Company treats as private or confidential.

** 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 25, 2025

By: */s/ Elizabeth B. Taylor*
Elizabeth B. Taylor
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/ Ronald T. Nixon Ronald T. Nixon	Chairman and Chief Executive Officer (Principal Executive Officer)	March 25, 2025
/s/ Elizabeth B. Taylor Elizabeth B. Taylor	Chief Financial Officer (Principal Financial Officer)	March 25, 2025
/s/ Michael D. McNeil Michael D. McNeil	Chief Accounting Officer and Chief Administrative Officer (Principal Accounting Officer)	March 25, 2025
/s/ Robert DeSutter Robert DeSutter	Director	March 25, 2025
/s/ Roszell Mack III Roszell Mack III	Director	March 25, 2025
/s/ Eric D. Major Eric D. Major	Director	March 25, 2025
/s/ Sara Ortwein Sara Ortwein	Director	March 25, 2025
/s/ Ann Beal Salamone Ann Beal Salamone	Director	March 25, 2025
/s/ Keith G. Myers Keith G. Myers	Director	March 25, 2025
/s/ Eric D. Tanzberger Eric D. Tanzberger	Director	March 25, 2025

CORPORATE INFORMATION

Corporate Headquarters

1200 Summit Ave, Suite 414

Fort Worth, Texas 76102

Phone: (817) 529-2300

www.sanaramedtech.com

Transfer Agent and Registrar

Broadridge Financial Solutions, Inc.

51 Mercedes Way

Edgewood, NY 11717

Phone: (844) 942-0759

www.broadridge.com

Independent Registered Public Accounting Firm

Weaver and Tidwell, L.L.P.

Austin, Texas

Stock Symbol

Common Stock: SMTI

The Nasdaq Capital Market

Board of Directors

Ronald T. Nixon – Executive Chairman

Robert A. DeSutter

Roszell Mack III

Eric D. Major

Keith G. Myers

Sara N. Ortwein

Ann Beal Salamone

Eric D. Tanzberger

Executive Officers

Ronald T. Nixon

Chief Executive Officer

Elizabeth B. Taylor

Chief Financial Officer

Jacob A. Waldrop

Chief Operating Officer

Michael D. McNeil

Chief Accounting and Chief Administrative Officer

Sam V. Muppalla

President and Chief Executive Officer, THP

Seth D. Yon

President and Chief Commercial Officer

Available Information

Sanara MedTech Inc. makes available, free of charge, its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, press releases, the Code of Ethics and Business Conduct and other company information. Such information will be furnished upon written request to:

Sanara MedTech Inc.

1200 Summit Ave, Suite 414

Fort Worth, Texas 76102

Attn: Corporate Secretary

This information also is available on our website, www.sanaramedtech.com. Reports we file with the Securities and Exchange Commission also are available at www.sec.gov.

Sanara MedTech

Evidence Based Healing

Sanara MedTech Inc.

1200 Summit Avenue, Suite 414

Fort Worth, TX 76102 | (817) 529-2300

Jack Powell or Mike Piccinino, ICR Healthcare

IR@sanaramedtech.com