

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

Form 10-K

(Mark One)

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

For the fiscal year ended March 31, 2022

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

For transition period from _____ to _____

Commission File Number: 001-33216

SONOMA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware

68-0423298

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

645 Molly Lane, Suite 150
Woodstock, Georgia 30189

(Address of principal executive offices) (Zip Code)

(800) 759-9305

(Registrant's telephone number, including area code)

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

Common Stock, \$0.0001 par value
(Title of Each Class)

SNOA
(Trading Symbol(s))

The Nasdaq Stock Market LLC
(Name of Each Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the 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
Non-accelerated Filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant on September 30, 2021, was \$16,658,750 based on a total of 2,985,439 non-affiliate shares of the registrant's common stock held by non-affiliates on September 30, 2021, at the closing price of \$5.58 per share, as reported on the Nasdaq Capital Market.

There were 3,100,937 shares of the registrant's common stock issued and outstanding on July 11, 2022.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III will incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2021 annual meeting of stockholders.

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PART I

This report includes “forward-looking statements.” The words “may,” “will,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “aim,” “seek,” “should,” “likely,” and similar expressions as they relate to us or our management are intended to identify these forward-looking statements. All statements by Sonoma regarding expected financial position, revenues, cash flows and other operating results, business strategy, legal proceedings and similar matters are forward-looking statements. Our expectations expressed or implied in these forward-looking statements may not turn out to be correct. Our results could be materially different from our expectations because of various risks, including the risks discussed in this report under “Part I — Item 1A — Risk Factors.” Any forward-looking statement speaks only as of the date as of which such statement is made, and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances, including unanticipated events, after the date as of which such statement was made.

ITEM 1. Business

Corporate Information

We originally incorporated as Micromed Laboratories, Inc. in 1999 under the laws of the State of California. We changed our name to Oculus Innovative Sciences, Inc. in 2001. In December 2006 we reincorporated under the laws of the State of Delaware, and in December 2016 we changed our name to Sonoma Pharmaceuticals, Inc.

In June 2020, we relocated our principal executive offices from 1129 N. McDowell Blvd., Petaluma, California, 94954 to 645 Molly Lane, Suite 150, Woodstock, Georgia, 30189. We have two active wholly-owned subsidiaries: Oculus Technologies of Mexico, S.A. de C.V., and Sonoma Pharmaceuticals Netherlands, B.V. Our fiscal year end is March 31. Our corporate telephone number is (800) 759-9305. Our websites are www.sonomapharma.com and www.sonomapharma.eu. The websites and any information contained therein or connected thereto is not intended to be incorporated into this report.

Overview

We are a global healthcare leader for developing and producing stabilized hypochlorous acid, or HOCl, products for a wide range of applications, including wound care, animal health care, eye care, oral care and dermatological conditions. Our products reduce infections, itch, pain, scarring and harmful inflammatory responses in a safe and effective manner. In-vitro and clinical studies of HOCl show it to have impressive antipruritic, antimicrobial, antiviral and anti-inflammatory properties. Our stabilized HOCl immediately relieves itch and pain, kills pathogens and breaks down biofilm, does not sting or irritate skin and oxygenates the cells in the area treated, assisting the body in its natural healing process. We sell our products either directly or via partners in 54 countries worldwide.

Business Update

After two years of restructuring the Company, we are now focused on growing our revenues while maintaining costs. During 2021, we built out our Boulder, Colorado office with new sales and marketing staff. We are beginning to see growth in the U.S. market with new customer and distributor relationships while concurrently building on organic growth from existing customers. We have also focused on introducing new products into multiple markets around the world and increasing our regulatory reach by seeking new approvals and clearances.

Some of our recent business updates include:

- In January 2022, Sonoma partnered with Anlicare International to seek regulatory clearance for oral and dental products in China. Anlicare will bear the costs of the regulatory process. The regulatory clearance is expected in 2024.
- On March 20, 2022, Sonoma launched Microdox®, a urinary tract infection, catheter, and bladder rinse. This new indication for Microdox® based on Sonoma's patented Microcyn® Technology is intended to treat and prevent infections in the urinary tract and bladder and is currently available for immediate use through Sonoma's partners, Te Arai BioFarma in New Zealand and Australia, and NuAngle in South Africa.
- In spring 2022, our animal healthcare partner Manna Pro, began selling our HOCl-products through Cabela's and Bass Pro Shops introducing new customers to our Microcyn® technology.
- On May 3, 2022, Sonoma expanded its successful partnership with MicroSafe Group DMCC with the announcement of the EPA Approval for Nanocyn® Hospital-Grade Disinfectant in the United States. The EPA approval process was a coordinated effort by Sonoma and MicroSafe Group. MicroSafe Group managed and financed the regulatory process with the EPA in exchange for non-exclusive rights to distribute Nanocyn in the United States. Sonoma provided expertise and manufactured the required product samples.
- In June 2022, Sonoma Pharmaceuticals and MicroSafe Group DMCC announced Nanocyn® hospital grade disinfectant has been added to the list of COVID-19 disinfectants maintained by the U.S. Environmental Protection Agency's List N. The addition to the COVID-19 disinfectant list represents an extension of the EPA approval for this product. Also in June, the EPA added Nanocyn® to List-Q as a disinfectant for Emerging Viral Pathogens, including Monkeypox.

We continue to invest in research and development, both in the U.S. and internationally, for our core performance-stabilized hypochlorous acid, or HOCl, technology. We have an active pipeline of products and are engaged in on-going studies either independently or with partners to increase applications of our technology. Additionally, we continue to seek new regulatory clearances to expand potential markets we can sell our products into.

The COVID-19 pandemic still affects our business and presents new challenges. Whereas in the beginning of the pandemic, we had to manage closures and shelter-in-place orders, we now face higher shipping costs, shipping delays and higher labor costs driven by inflation and a surplus of opportunities for job seekers.

As we move into our new fiscal year, our path forward will consist of looking for U.S. and international distribution partners, developing new products to bring to market and expanding further into U.S. over-the-counter markets.

Business Channels

Our core market differentiation is based on being the leading developer and producer of stabilized hypochlorous acid, or HOCl, solutions. Unlike many of our competitors, we have been in business for over 20 years, and in that time we have developed significant scientific knowledge of how best to develop and manufacture HOCl products backed by decades of studies and data collection. HOCl is known to be among the safest and most-effective ways to relieve itch, inflammation and burns while stimulating natural healing through increased oxygenation and eliminating persistent microorganisms and biofilms.

We sell our products into many markets both in the U.S. and internationally. In international markets, we ship products to 54 countries. Our core strategy is to work with partners both in the United States and around the world to market and distribute our products. In some cases, we market and sell our own products.

Dermatology

Sonoma Dermatology has developed unique, differentiated, prescription-strength and safe dermatologic products that support paths to healing among various key dermatologic conditions. Our products are primarily targeted at the treatment of acne, the management of scars and atopic dermatitis. We are strategically focused on introducing innovative new products that are supported by human clinical data with applications that address specific dermatological procedures currently in demand. In addition, we look for markets where we can provide effective product line extensions and pricing to new product families.

In the United States, we partner with EMC Pharma, LLC to sell our prescription products for an initial term of five years, subject to meeting minimum purchase and other requirements. Pursuant to our agreement with EMC Pharma, we manufacture products for EMC Pharma and EMC Pharma markets, sells and distributes them to patients and customers.

On September 28, 2021, we launched a new over-the-counter product, Regenacyn® Advanced Scar Gel, which is clinically proven to improve the overall appearance of scars while reducing pain, itch, redness, and inflammation. Additionally, on the same day, we launched Regenacyn® Plus, a prescription-strength scar gel which is available as an office-dispense product through physician offices. Our consumer products are available through Amazon.com, our website and U.S.-based distributors.

We sell dermatology products in Europe, Asia, and Brazil through a distributor network. In these international markets, we have a network of partners, ranging from country specific distributors to large pharmaceutical companies to full-service sales and marketing companies. We work with our international partners to create products they can market in their home country. Some products we develop and manufacture are private label while others use branding we have already developed. We have created or co-developed a wide range of products for international markets using our core HOCl technology.

First Aid and Wound Care

Our HOCl-based wound care products are intended for the treatment of acute and chronic wounds as well as first- and second-degree burns. They work by first removing foreign material and debris from the skin surface and moistening the skin, thereby improving wound healing. Second, our HOCl products assist in the wound healing process through their antimicrobial properties by removing microorganisms. Since HOCl is an important constituent of our innate immune system and is formed and released by the macrophages during phagocytosis, it is advantageous to other wound-irrigation and antiseptic solutions as highly organized cell structures such as human tissue can tolerate the action of our wound care solution while single-celled microorganisms cannot. Due to its unique chemistry, our wound treatment solution is much more stable than similar products on the market and therefore maintains much higher levels of hypochlorous acid over its shelf life.

In the United States, we sell our wound care products directly to hospitals, physicians, nurses, and other healthcare practitioners and indirectly through several non-exclusive distribution arrangements.

To respond to market demand for our HOCl technology-based products, we launched our first direct to consumer over-the-counter product in the United States in February 2021. Microcyn® OTC Wound and Skin Cleanser is formulated for home use without prescription to help manage and cleanse wounds, minor cuts, and burns, including sunburns and other skin irritations. Microcyn® OTC Wound and Skin Cleanser is available without prescription through Sonoma's online store.

In Europe, we rely on agreements with country-specific distributors for the sale of our wound care products under a variety of brand names into 27 countries, including Austria, Belgium, Croatia, Italy, the Netherlands, Germany, Greece, Hungary, the Czech Republic, Spain, Norway, Switzerland, Poland, Portugal, Slovenia, the Slovak Republic, Finland, Denmark, Montenegro and Serbia.

In March 2021, we received approval to market and use our HOCl products as biocides under Article 95 of the European Biocidal Products Regulation in France, Germany and Portugal. The approval applies to our products MucoClyns™ for human hygiene to be marketed and commercialized by us, MicrocynAH® for animal health marketed and commercialized through our partner, Petagon Limited, and MicroSafe for disinfectant use to be marketed and commercialized through our partner, MicroSafe Group Dubai.

Eye Care

Our prescription product Acuicyn™ is an antimicrobial prescription solution for the treatment of blepharitis and the daily hygiene of eyelids and lashes and helps manage red, itchy, crusty and inflamed eyes. It is strong enough to kill the bacteria that causes discomfort, fast enough to provide near instant relief, and gentle enough to use as often as needed. In the United States, our partner EMC Pharma is selling our prescription-based eye care product through its distribution network.

On September 28, 2021, we launched Ocucyn Eyelid & Eyelash Cleanser, which is sold directly to consumers on Amazon.com. Ocucyn Eyelid & Eyelash Cleanser, designed for everyday use, is a safe, gentle, and effective solution for good eyelid & eyelash hygiene.

In international markets we rely on a network of distribution partners to sell our eye products. On May 19, 2020, we entered into an expanded license and distribution agreement with our existing partner, Brill International S.L. for our Microdacyn60® Eye Care HOCl-based product. Under the license and distribution agreement, Brill has the right to market and distribute our eye care product under the private label Ocudox™ in Italy, Germany, Spain, Portugal, France, and the United Kingdom for a period of 10 years, subject to meeting annual minimum sales quantities. In return, Brill will pay us a one-time fee, and the agreed upon supply prices. In parts of Asia, Dyamed Biotech markets our eye product under the private label Ocucyn.

Oral, Dental and Nasal Care

We sell a variety of oral, dental, and nasal products around the world.

In late 2020 we launched two HOCl-based products in the dental, head and neck markets and launched Endocyn®, a biocompatible root canal irrigant. In August 2021, we launched OroGenix Oral Hygiene Rinse. In the U.S., we sell our dental products through U.S.-based distributors.

Internationally, our product Microdacyn60® Oral Care treats mouth and throat infections and thrush. Microdacyn60 solution assists in reducing inflammation, pain, soothing cough relief and does not contain any harmful chemicals. It does not stain teeth, is non-irritating, non-sensitizing, has no contraindications and is ready for use with no mixing or dilution. In New Zealand and Australia, our partner Te Arai BioFarma Ltd. markets our oral product under their label Oracyn® Oral Care. Our partner, Dyamed Biotech, expects to launch Oracyn® Oral Care in parts of Asia this year. On January 18, 2022, we partnered with Anlicare International to seek regulatory clearances for our dental and oral products in China and Macau.

Our international nasal care product Sinudox™ based on our HOCl technology is a solution intended for nasal irrigation. Sinudox Hypotonic Nasal Hygiene clears and cleans a blocked nose, stuffy nose and sinuses by ancillary ingredients that may have a local antimicrobial effect. Sinudox is sold through Amazon in Europe. In New Zealand and Australia, our partner Te Arai markets our nasal product under their label Nasocyn® Nasal Care.

Animal Health Care

MicrocynAH® is a HOCl-based topical product that cleans, debrides and treats a wide spectrum of animal wounds and infections. It is intended for the safe and rapid treatment of a variety of animal afflictions including cuts, burns, lacerations, rashes, hot spots, rain rot, post-surgical sites, pink eye symptoms and wounds to the outer ear of any animal.

For our animal health products sold in the U.S. and Canada, we partnered with Manna Pro Products, LLC to bring relief to pets and peace of mind to their owners. Manna Pro distributes non-prescription products to national pet-store retail chains, farm animal specialty stores, in the United States and Canada, such as Chewy.com, PetSmart, Tractor Supply, Cabela's, PetExpress, and Bass Pro Shops. Additionally, we recently expanded our animal health product offerings by adding a MicrocynAH line for felines at PetSmart.

For the Asian and European markets, on May 20, 2019, we partnered with Petagon, Limited, an international importer and distributor of quality pet food and products for an initial term of five years. We supply Petagon with all MicrocynAH products sold by Petagon. On August 3, 2020, Petagon received a license from the People's Republic of China for the import of veterinary drug products manufactured by us. This is the highest classification Petagon and Sonoma can receive for animal health products in China.

Surface Disinfectants

In-vitro and clinical studies of HOCl show it to have impressive antipruritic, antimicrobial, antiviral and anti-inflammatory properties. HOCl has been formulated as a disinfectant and sanitizer solution for our partner MicroSafe Group, Dubai, and is sold in numerous countries. It is designed to be used to spray in aerosol format to areas and environments which are suspected to serve as a breeding ground for the spread of infectious disease, likely to result in epidemics or pandemics. The medical-grade surface disinfectant solution is used in hospitals worldwide to keep doctors and patients protected and safe. In May 2020, Nanocyn® Disinfectant & Sanitizer, received approval to be entered into the Australian Register of Therapeutic Goods, or ARTG, as well as in Canada, for use against the coronavirus SARS-CoV-2, or COVID-19. Nanocyn has also met the stringent environmental health and social/ethical criteria of Good Environmental Choice Australia, or GECA, becoming one of the very few eco-certified, all-natural disinfectant solutions in Australia.

Through our partner MicroSafe Group DMCC, Dubai, we sell hard surface disinfectant products into the U.S., Europe, the Middle East and Australia.

On July 31, 2021, we granted MicroSafe the non-exclusive right to sell and distribute Nanocyn in the United States provided that MicroSafe secure U.S. EPA approval. In April of 2022, MicroSafe secured the EPA approval for Nanocyn® Disinfectant & Sanitizer, meaning that it can now be sold in the United States as a surface disinfectant, and it was subsequently added to the EPA's list N for use against COVID-19. We intend to build upon this ground-breaking approval by securing further approvals of this nature. Nanocyn® is a hospital-grade disinfectant and manufactured by us using our patented HOCl technology. Nanocyn® is currently sold by MicroSafe in Europe, the Middle East and Australia.

Employees

As of July 11, 2022, we employed a total of 11 full-time employees in the United States, and one full-time employee in the Netherlands. Additionally, we had 165 employees in Mexico, all of which were contracted through an employment agency. We are not a party to any collective bargaining agreements. We believe relations with employees are very good.

Products

Our products are all classified as medical devices and categorized as prescription products, over-the-counter, or OTC, and office dispense. Below are some of our key products that we either sell through our own efforts or through partnership agreements.

Dermatology

In the United States our prescription product offerings are Epicyn™ Antimicrobial Facial Cleanser, Levicyn™ Antimicrobial Dermal Spray, Levicyn™ Antipruritic Gel, Levicyn™ Antipruritic Spray Gel, Celacyn™ Scar Management Gel and Sebuderm™ Topical Gel. We also have our office dispense products Lasercyn™ Dermal Spray, Lasercyn™ Post Procedure Gel and Regenacyn™ Advanced Scar Management. We also offer Regenacyn Advanced Scar Gel for OTC purchase.

Internationally, we offer GramaDerm™ Hydrogel and Solution Combo Pack to assist in the treatment of topical mild to moderate acne, Epicyn™ Scar Management Hydrogel and Pediacyn™ Atopic Dermatitis Hydrogel.

Celacyn® Scar Management Gel



Celacyn® offers scar management by protecting and moisturizing wound and scar sites to promote lighter, flatter, less prominent scarring.

Celacyn®, is a HOCl-based topical prescription product indicated to promote efficient healing through the management of new and old scars resulting from surgical procedures and trauma wounds or burns.



Epicyn™ relieves the common symptoms of irritated skin and dermal lesions. Epicyn™ Antimicrobial Facial cleanser is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from acute and chronic dermal lesions.

Levicy™ Antipruritic Dermal Spray, Antipruritic Spray Gel, and Antipruritic Gel



Levicy™ offers fast itch relief. Levicy™ is a HOCl-based topical prescription product indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses.

Lasercyn™



Lasercyn™ Post Procedure Gel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Lasercyn™ Procedure Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

Wound Care

In the United States we offer Microcyn® wound and skin care both as an OTC, and prescription product.



Microcyn® Wound Care Management



Microcyn® offers enhanced healing properties.

Microcyn® is a HOCl-based topical line of products designed to stimulate expedited healing by targeting a wide range of pathogens including viruses, fungi, spores and bacteria, including antibiotic-resistant strains that slow the natural healing of wounds.

Acuicyn™ Eyelid and Eyelash Hygiene



Acuicyn™ offers safe and effective eyelid and eyelash hygiene. Acuicyn™ is a HOCl-based topical prescription product indicated to relieve itch and inflammation while helping to keep areas around the eye clean. We also offer Ocucyn® Eyelid and Eyelash Cleanser as an OTC version for purchase.

Ocudox™ is substantially the same eye care product marketed by Brill in Europe.



Microdacyn60® Oral Care



Microdacyn60 Oral Care with patented technology supports the treatment of mouth and throat infections and the debridement and moistening of mouth lesions and thrush.

This adjuvant solution assists in reducing inflammation, pain, soothing cough relief and does not contain any harmful chemicals. It does not stain teeth, is non-irritating, non-sensitizing, has no contraindications and is ready for use with no mixing or dilution.

Animal Health Care

In the United States and internationally, our HOCl-based MicrocynAH® line offers topical solutions designed to relieve the common symptoms of hot spots, scratches, skin rashes post-surgical sites and irritated animal skin and promote expedited healing for all animals.



Surface Disinfectants

Through our partner MicroSafe DMCC, Dubai, we sell Nanocyn®. Nanocyn is a hospital-grade disinfectant indicated to sterilize hard surfaces by spraying directly onto the surface, for medical devices by submerging the device in Nanocyn, and also for fumigation into the air.

When fumigated, Nanocyn has demonstrated the ability to kill a wide range of airborne pathogens and significantly reduce the spread of infectious disease.



Research and Development

Research and development expense consists primarily of expenses for clinical studies, personnel, regulatory services and supplies. For the years ended March 31, 2022 and 2021, research and development expense amounted to \$125,000 and \$555,000, respectively. A small percentage of these expenses were borne by our customers.

Manufacturing and Packaging

Through June 23, 2020, we manufactured products at facilities in Petaluma, California and Zapopan, Mexico. On June 24, 2020, we transitioned all of our manufacturing to Zapopan, Mexico and closed our Petaluma facility. We have developed a manufacturing process and conduct quality assurance testing on each production batch in accordance with current U.S., Mexican and international Current Good Manufacturing Practices. Both facilities are required to meet and maintain regulatory standards applicable to the manufacture of pharmaceutical and medical device products. Our Mexican facilities are certified and comply with U.S. Current Good Manufacturing Practices, Quality Systems Regulations for medical devices, and International Organization for Standardization, or ISO, guidelines. Our Mexican facility has been approved by the Ministry of Health and is also ISO 13485 certified.

Our machines are tested regularly, which is part of a validation protocol mandated by U.S., Mexican and international Current Good Manufacturing Practices, Quality Systems Regulation, and ISO requirements. This validation is designed to ensure that the final product is consistently manufactured in accordance with product specifications at all manufacturing sites. Certain materials and components used in manufacturing are proprietary to Sonoma. All other raw materials and supplies utilized in the manufacturing process of our products are available from various third-party suppliers in quantities adequate to meet our needs.

We believe we own a sufficient factory space and equipment to produce an adequate amount of product to meet anticipated future requirements for at least the next two years. With expansion into new geographic markets, we may establish additional manufacturing facilities to better serve those new markets.

U.S. Regulatory Approvals and Clearances

To date, we have obtained 21 U.S. Food and Drug Administration, or FDA, clearances permitting the sale of products as medical devices for Section 510(k) of the Federal Food, Drug and Cosmetic Act in the United States.

Outside the United States, we sell products for dermatological and advanced tissue care with a European Conformity marking, Conformité Européenne, or CE. On April 9, 2020, we received an updated EC certificate covering 39 products in 54 countries with various approvals in Brazil, China, Southeast Asia, South Korea, India, Australia, New Zealand, and the Middle East.

The following table summarizes our current material regulatory approvals and clearances by brand.

Brand	Approval Type	Summary Indication
HOCl-based Products:		
Lasercyn™ Gel, Levicyn™ Gel	U.S. 510(k) EU CE Mark	Prescription and OTC product, intended for use to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns, such as sunburn. As a prescription product it is also intended for sores, injuries, ulcers of dermal tissue and exuding wounds.
Sebuderm™	U.S. 510(k) EU CE Mark	Prescription-only product, manages and relieves the burning, itching, erythema, scaling, and pain experienced with seborrhea and seborrheic dermatitis. It also helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.
Celacyn® Scar Management Gel,	U.S. 510(k)	Prescription and OTC product, for the management of old and new hypertrophic and keloid scarring resulting from burns, general surgical procedures and trauma wounds.
Levicyn™ SG	U.S. 510(k) EU CE Mark	Prescription and OTC product, for the management and relief of burning and itching associated with many common types of skin irritation, lacerations, abrasions and minor burns. As a prescription product it also relieves burning and itching and pain associated with various types of dermatoses, including radiation dermatitis and atopic dermatitis.
Epicyn™ Antimicrobial Facial Cleanser	U.S. 510(k) EU CE Mark	Prescription and OTC product, management of skin abrasions, lacerations, minor irritations, cuts and intact skin. As a prescription product it is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, first- and second-degree burns and other skin irritations.
Lasercyn™ Gel	U.S. 510(k)	Prescription and OTC product, intended for the management of minor skin irritations following post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels, and to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.
Levicyn™ Dermal Spray, Lasercyn™ Dermal Spray	U.S. 510(k)	Prescription and OTC product, for the management of skin abrasions, lacerations, minor irritations, cuts and intact skin. As a prescription product it is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including microorganisms and debris from exudating wounds, acute and chronic dermal lesions, burns, and other skin irritations.

Acucyn Antimicrobial Eyelid & Eyelash Hygiene	U.S. 510(k)	<p>Prescription product, Under the supervision of a healthcare professional, Acucyn Antimicrobial Eyelid & Eyelash Hygiene is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.</p> <p>OTC product, Ocucyn Antimicrobial Eyelid & Eyelash Hygiene is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.</p>
Endocyn Root Canal Irrigation Solution	U.S.510(k)	Endocyn Root Canal Irrigation Solution is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy. It is also intended to provide for lubrication and irrigation during root canal instrumentation.
Gramaderm®	EU CE Mark	Various product formulations for the topical treatment of mild to moderate acne.
Microdacyn60®	EU CE Mark	Various product formulations for the management of itching, burning and other skin irritations.
MucoClyns™	EU CE Mark	Indicated for the use in emergencies and safe to use on mucous membranes, cuts, abrasions, burns and body surfaces for the treatment immediately after an unexpected exposure to infection risk, and professional medical attention.
Sinudox™	EU CE Mark	Solution intended for nasal irrigation, including the moistening of cuts, abrasions and lacerations located in the nasal cavity.

Significant Customers

We rely on certain key customers for a significant portion of revenues. In the U.S., our key customers are EMC Pharma, LLC with which we partnered in March 2021 to sell our prescription dermatology and eye care products and Manna Pro, our partner for our animal health care products. Our wound care products are purchased by hospitals, physicians, nurses, and other healthcare practitioners from us directly. At March 31, 2022, one customer represented 20% of our net accounts receivable balance, one customer represented 15% of our net accounts receivable balance, and one customer represented 14% of our net accounts receivable balance. At March 31, 2021, one customer represented 17% of our net accounts receivable balance, one customer represented 16% of our net accounts receivable balance, and one customer represented 14% of our net accounts receivable balance. For the year ended March 31, 2022, one customer represented 10%, one customer represented 17%, and one customer represented 21% of net revenues. For the year ended March 31, 2021, one customer represented 32%, and one customer represented 15% of net revenues.

Intellectual Property

Our success depends in part on an ability to obtain and maintain proprietary protection for product technology and know-how, to operate without infringing proprietary rights of others, and to prevent others from infringing on our proprietary rights. We seek to protect a proprietary position by, among other methods, filing, when possible, U.S. and foreign patent applications relating to our technology, inventions and improvements that are important to the business. We have patented certain aspects of our HOCl technology in the United States and worldwide. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain a proprietary position.

Although we work diligently to protect proprietary technology, there are no assurances that any patent will be issued from currently pending patent applications or from future patent applications. The scope of any patent protection may not exclude competitors or provide competitive advantages, and any patent may not be held valid if subsequently challenged, and others may claim rights in or ownership of patents and proprietary rights. Furthermore, others may develop products similar to ours and may duplicate any of the products or design around patents.

We have also filed for trademark protection for marks used with products in each of the following regions: United States, Europe, Canada, certain countries in Central and South America, including Mexico and Brazil, certain countries in the Middle East and certain countries in Asia, including Japan, China, Hong Kong, the Republic of Korea, India and Australia. In addition to patents and trademarks, we rely on trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect intellectual property rights. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of technologies. Employees, consultants and advisors are required to execute confidentiality agreements in connection with their employment, consulting or advisory relationships. Employees, consultants and advisors with whom we expect to work with are also required to disclose and assign to us all inventions made in the course of a working relationship with them, while using intellectual property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of the products or to wrongfully obtain or use information that regarded as proprietary.

Competition

We compete globally across five main channels: dermatology, eye, nasal and oral care, wound and acute care, animal health and surface disinfectants with our HOCl technology.

Dermatology

Our dermatology products are at the forefront of HOCl-based solutions, a safe and highly effective active ingredient designed to relieve itching, burning and inflammation and acts as a highly effective antimicrobial agent. We believe no other solutions on the market provide the same patient benefits at the levels of safety and cost. Our HOCl-based solutions face significant competition in the United States from prescription products including corticosteroids, topical steroids and topical antibiotics. Our opportunity as an adjunct to these steroids is based on the insight that many doctors and patients limit steroid and antibiotic use due to potential side effects. These side effects include bacterial resistance, stinging, burning and inflammation for topical antibiotics and stretch marks, easy bruising, tearing of the skin and, to a lesser extent, enlarged of blood vessels for topical steroids. Our HOCl-based products are safe, non-toxic and have shown few side effects in clinical studies.

Wound and Acute Care Markets

Similar to our dermatology products, our HOCl-based wound and acute care solutions provide improved efficacy at lower costs than traditional acute care products. Our HOCl-based solutions compete with topical anti-infectives and antibiotics, as well as some advanced wound technologies, such as skin substitutes, growth factors and delayed release silver-based dressings. Our opportunity in this space relative to antibiotics is based on the insight that competing antibiotic solutions may have resistance-building properties.

Factors Affecting Competitive Position

While some other companies are able to produce small molecule, HOCl-based formulations, based on our research, their products may become unstable after a relatively short period of time or have large ranges of effectiveness. We believe our HOCl-based solutions are among the most stable therapeutics available.

Some of our competitors in the dermatology, wound care, eye, nasal and oral care, animal health care and surface disinfectant markets enjoy several competitive advantages. These include:

- greater name recognition;
- established relationships with healthcare professionals, patients and third-party payors;
- established distribution networks;
- additional product lines and the ability to offer rebates or bundle products to offer discounts or incentives;
- experience in conducting research and development, manufacturing, obtaining regulatory approval for products and marketing; and
- financial and human resources for product development, sales and marketing and patient support.

Government Regulation

Government authorities in the United States, at the federal, state and local levels, and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, and import and export of pharmaceutical products, biologics and medical devices. All of our products in development will require regulatory approval or clearance by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. Various federal, state, local and foreign statutes and regulations also govern testing, manufacturing, safety, labeling, storage, distribution and record-keeping related to such products and their marketing. The process of obtaining these approvals and clearances, and the subsequent process of maintaining substantial compliance with appropriate federal, state, local, and foreign statutes and regulations, require the expenditure of substantial time and financial resources. In addition, statutes, rules, regulations and policies may change and new legislation or regulations may be issued that could delay such approvals.

Medical Device Regulation

To date, we have received 21 510(k) clearances for use of products as medical devices in tissue care management, such as cleaning, debridement, lubricating, moistening and dressing, including for acute and chronic wounds, and in dermatology applications. Any future product candidates or new applications classified as medical devices will require clearance by the FDA.

Medical devices are subject to FDA clearance and extensive regulation under the Federal Food Drug and Cosmetic Act. Under the Federal Food Drug and Cosmetic Act, medical devices are classified into one of three classes: Class I, Class II or Class III. The classification of a device into one of these three classes generally depends on the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness. Devices may also be designated unclassified. Unclassified devices are legally marketed pre-amendment devices for which a classification regulation has yet to be finalized and for which a pre-market approval is not required.

Class I devices are devices for which safety and effectiveness can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation, which sets forth good manufacturing practice requirements; facility registration, device listing and product reporting of adverse medical events; truthful and non-misleading labeling; and promotion of the device only for its cleared or approved intended uses. Class II devices are also subject to these general controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Review and clearance by the FDA for these devices is typically accomplished through the 510(k) pre-market notification procedure. When 510(k) clearance is sought, a sponsor must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a legally marketed device. If the FDA agrees that the proposed device is substantially equivalent to the predicate device, then 510(k) clearance to market will be granted. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a pre-market approval.

Clinical trials are almost always required to support a pre-market approval application and are sometimes required for a 510(k) pre-market notification. These trials generally require submission of an application for an investigational device exemption. An investigational device exemption must be supported by pre-clinical data, such as animal and laboratory testing results, which show that the device is safe to test in humans and that the study protocols are scientifically sound. The FDA must approve an investigational device exemption, in advance, for a specified number of patients, unless the product is deemed a non-significant risk device and is eligible for more abbreviated investigational device exemption requirements.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with the Quality System Regulation, which sets forth the Current Good Manufacturing Practice requirements that govern the methods used in, and the facilities and controls used for the design, manufacture, packaging, servicing, labeling, storage, installation and distribution of all finished medical devices intended for human use.

FDA regulations prohibit the advertising and promotion of a medical device for any use outside the scope of a 510(k) clearance or pre-market approval or for unsupported safety or effectiveness claims. Although the FDA does not regulate physicians' practice of medicine, the FDA does regulate manufacturer communications with respect to off-label use.

If the FDA finds that a manufacturer has failed to comply with FDA laws and regulations or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions such as:

- imposing fines, injunctions and civil penalties
- requiring a recall or seizure of products
- implementing operating restrictions, which can include a partial suspension or total shutdown of production
- refusing requests for 510(k) clearance or pre-market approval of new products
- withdrawing 510(k) clearance or pre-market approval approvals already granted
- criminal prosecution

The FDA also has the authority to require a company to repair, replace, or refund the cost of any medical device.

The FDA also administers certain controls over the export of medical devices from the United States, as international sales of medical devices that have not received FDA clearance are subject to FDA export requirements. Additionally, each foreign country subjects such medical devices to its own regulatory requirements. In the European Union, there is a single regulatory approval process and approval is represented by the presence of a CE marking.

Other Regulation in the United States

The Physician Payments Sunshine Act

The Physician Payments Sunshine Act signed into law in 2010 as part of the Affordable Care Act requires manufacturers of medical devices, drugs, biologicals, and medical supplies to track and report certain payments made to and transfers of value provided to physicians and teaching hospitals as well as to report certain ownership and investment interests held by physicians and their immediate family members. These manufacturers must report annually to the Center for Medicare & Medicaid Services any direct or indirect payments and transfers of value of \$10 or more, or annual aggregate of \$100 or more, made to physicians or to a third party at the request of or on behalf of a physician, including dentists. Payment includes: consulting fees, compensation for services other than consulting, honoraria, gifts, entertainment, food, travel (including the specified destinations), education, research, charitable contribution, royalty or license, current or prospective ownership or investment interest, direct compensation for serving as faculty or as a speaker for a medical education program, grants, any other nature of the payment, or other transfer of value. Manufacturers face monetary penalties for non-compliance. Certain payments related to research must be reported separately. Product samples intended for patient use need not be reported.

Health Care Coverage and Reimbursement by Third-Party Payors

Commercial success in marketing and selling products depends, in part, on the availability of adequate coverage and reimbursement from third-party health care payors, such as government and private health insurers and managed care organizations. Third-party payors are increasingly challenging the pricing of medical products and services. Government and private sector initiatives to limit the growth of health care costs, including price regulation, competitive pricing, and managed-care arrangements, are continuing in many countries where we do business, including the United States. These changes are causing the marketplace to be more cost-conscious and focused on the delivery of more cost-effective medical products. Government programs, including Medicare and Medicaid, private health care insurance companies, and managed-care plans control costs by limiting coverage and the amount of reimbursement for particular procedures or treatments. This has created an increasing level of price sensitivity among customers for our products. Some third-party payors also require that a favorable coverage determination be made for new or innovative medical devices or therapies before they will provide reimbursement of those medical devices or therapies. Even though a new medical product may have been cleared or approved for commercial distribution, we may find limited demand for the product until adequate coverage and reimbursement have been obtained from governmental and other third-party payors.

Fraud and Abuse Laws

In the United States, we are subject to various federal and state laws pertaining to healthcare fraud and abuse, which, among other things, prohibit the offer or acceptance of remuneration intended to induce or in exchange for the purchase of products or services reimbursed under a federal healthcare program and the submission of false or fraudulent claims with the government. These laws include the federal Anti-Kickback Statute, the False Claims Act and comparable state laws. These laws regulate the activities of entities involved in the healthcare industry, such as Sonoma, by limiting the kinds of financial arrangements such entities may have with healthcare providers who use or recommend the use of medical products, including, for example, sales and marketing programs, advisory boards and research and educational grants. In addition, in order to ensure that healthcare entities comply with healthcare laws, the Office of Inspector General of the U.S. Department of Health and Human Services recommends that healthcare entities institute effective compliance programs. To assist in the development of effective compliance programs, the Office of Inspector General has issued model Compliance Program Guidance, materials for a variety of healthcare entities which, among other things, identify practices to avoid that may implicate the federal Anti-Kickback Statute and other relevant laws and describes elements of an effective compliance program. While compliance with the Compliance Program Guidance materials is voluntary, a California law requires pharmaceutical and devices manufacturers to initiate compliance programs that incorporate the Compliance Program Guidance and the July 2002 Pharmaceuticals Research and Manufacturers of America Code on Interactions with Healthcare Professionals.

Due to the scope and breadth of the provisions of some of these laws, it is possible that some of our practices might be challenged by the government under one or more of these laws in the future. Violations of these laws, which are discussed more fully below, can lead to civil and criminal penalties, damages, imprisonment, fines, exclusion from participation in Medicare, Medicaid and other federal health care programs, and the curtailment or restructuring of operations. Any such violations could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Anti-Kickback Laws

Our operations are subject to federal and state anti-kickback laws. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly to induce either the referral of an individual for a good or service reimbursed under a federal healthcare program, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The definition of “remuneration” has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, waiver of co-payments, and providing anything at less than its fair market value. Because the Anti-Kickback Statute makes illegal a wide variety of common, even beneficial, business arrangements, the Office of Inspector General was tasked with issuing regulations, commonly known as “safe harbors,” that describe arrangements where the risk of illegal remuneration is minimal. As long as all of the requirements of a particular safe harbor are strictly met, the entity engaging in that activity will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the Office of Inspector General. Our agreements to pay compensation to our advisory board members and physicians who provide other services for we may be subject to challenge to the extent they do not fall within relevant safe harbors under state and federal anti-kickback laws. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute, which apply to the referral of patients for health care services reimbursed by Medicaid, and some have adopted such laws with respect to private insurance. Violations of the Anti-Kickback Statute are subject to significant fines and penalties and may lead to a company being excluded from participating in federal health care programs.

False Claims Laws

The federal False Claims Act prohibits knowingly filing a false claim, knowingly causing the filing of a false claim, or knowingly using false statements to obtain payment from the federal government. Certain violations of the Anti-Kickback Statute constitute per se violations of the False Claims Act. Under the False Claims Act, such suits are known as “qui tam” actions. Individuals may file suit on behalf of the government and share in any amounts received by the government pursuant to a settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act under the Deficit Reduction Act of 2005, where the federal government created financial incentives for states to enact false claims laws consistent with the federal False Claims Act. As more states enact such laws, we expect the number of qui tam lawsuits to increase. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend false claims actions, pay fines or be excluded from Medicare, Medicaid or other federal or state government healthcare programs as a result of investigations arising out of such actions.

HIPAA

Two federal crimes were created under the Health Insurance Portability and Accountability Act of 1996, or HIPAA: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Individually, identifiable health information is subject to an array of federal and state regulation. Federal rules promulgated pursuant to HIPAA regulate the use and disclosure of health information by “covered entities.” Covered entities include individual and institutional health care providers from which we may receive individually identifiable health information. These regulations govern, among other things, the use and disclosure of health information for research purposes, and require the covered entity to obtain the written authorization of the individual before using or disclosing health information for research. Failure of the covered entity to obtain such authorization could subject the covered entity to civil and criminal penalties. We may experience delays and complex negotiations in dealing with each entity’s differing interpretation of the regulations and what is required for compliance. Also, where our customers or contractors are covered entities, including hospitals, universities, physicians or clinics, we may be required by the HIPAA regulations to enter into “business associate” agreements that subject the company to certain privacy and security requirements. In addition, many states have laws that apply to the use and disclosure of health information, and these laws could also affect the manner in which we conduct research and other aspects of business. Such state laws are not preempted by the federal privacy law when such laws afford greater privacy protection to the individual than the federal law. While activities to assure compliance with health information privacy laws are a routine business practice, we are unable to predict the extent to which resources may be diverted in the event of an investigation or enforcement action with respect to such laws.

Foreign Regulation

Whether or not we obtain FDA approval for a product, approval of a product by the applicable regulatory authorities of foreign countries must be obtained before clinical trials or marketing of the product in those countries can begin. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered under a three-phase sequential process similar to that discussed above for medical devices.

European Union Regulation

Medical Device Regulation

Our products are classified as medical devices in the European Union. In order to sell medical device products within the European Union, we are required to comply with the requirements of the Medical Devices Directive, and its national implementations, including affixing CE markings on products. The CE marking indicates a product’s compliance with EU legislation and so enables the sale of products throughout the European Economic Area, or the EEA, comprising the 28 Member States of the EU and European Free Trade Association, or EFTA, countries Iceland, Norway, and Liechtenstein. In order to comply with the Medical Devices Directive, we must meet certain requirements relating to the safety and performance of products and, prior to marketing products, we must successfully undergo verification of products’ regulatory compliance, or conformity assessment.

On May 26, 2017, the new Medical Devices Directive became effective in the EEA, becoming fully applicable after a transition period of three years, on May 26, 2020. Under the new Medical Devices Directive, certain devices will be classified in higher classes, new devices will become classified, and certain new obligations are imposed on manufacturers and distributors. Manufacturers will be required to engage a medical device expert and carry insurance for possible liability claims. In addition, the pre-market approval and post-market surveillance requirements were enhanced. The European Database for Medical Devices, or Eudamed, will hold and publish information on medical devices collected from the European Commission and the national authorities.

Medical devices are divided into three regulatory classes: Class I, Class IIB and Class III. The nature of the conformity assessment procedures depends on the regulatory class of the product. In order to comply with the examination, we completed, among other things, a risk analysis and presented clinical data, which demonstrated that our products met the performance specifications claimed by us, provided sufficient evidence of adequate assessment of unwanted side effects and demonstrated that the benefits to the patient outweigh the risks associated with the device. We are subject to continued supervision and are required to report any serious adverse incidents to the appropriate authorities. We are also required to comply with additional national requirements that are beyond the scope of the Medical Devices Directive.

We received a CE certificate for 39 of our Class IIB medical devices, which allows us to affix CE markings on these products and sell them in Europe. We may not be able to maintain the requirements established for CE markings for any or all of our products or be able to produce these products in a timely and profitable manner while complying with the requirements of the Medical Devices Directive and other regulatory requirements.

European Good Manufacturing Process

In the European Union, the manufacture of pharmaceutical products and clinical trial supplies is subject to good manufacturing practice as set forth in the relevant laws and guidelines. Compliance with good manufacturing practice is generally assessed by the competent regulatory authorities. They may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further inspections may occur over the life of the product.

Mexican Regulation

The Ministry of Health is the authority in charge of sanitary controls in Mexico. Sanitary controls are a group of practices related to the orientation, education, testing, verification and application of security measures and sanctions exercised by the Ministry of Health. The Ministry of Health is responsible for the issuance of Official Mexican Standards and specifications for drugs subject to the provisions of the General Health Law, which govern the process and specifications of drugs, including the obtaining, preparing, manufacturing, maintaining, mixing, conditioning, packaging, handling, transporting, distributing, storing and supplying of products to the public at large. In addition, a medical device is defined as a device that may contain antiseptics or germicides used in surgical practice or in the treatment of continuity solutions, skin injuries or its attachments.

Under the General Health Law, a business that manufactures drugs is either required to obtain a “Sanitary Authorization” or to file an “Operating Notice.” Our Mexican subsidiary, Oculus Technologies of Mexico, S.A. de C.V., is considered a business that manufactures medical devices and therefore is not subject to a Sanitary Authorization, but rather only required to file an Operating Notice.

In addition to its Operating Notice, our Mexico subsidiary has obtained a “Good Processing Practices Certificate” issued by Mexican Federal Commission for the Protection against Sanitary Risks, which demonstrates that the manufacturing at our facility located in Zapopan, Mexico, operates in accordance with the applicable official standards.

In addition, regulatory approval of prices is required in most countries other than the United States, which could result in lengthy negotiations delaying our ability to commercialize products. We face the risk that the prices which result from the regulatory approval process would be insufficient to generate an acceptable return.

Available Information

We make available on sonomapharma.com, free of charge, copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports, as soon as reasonably practicable after electronically filing or furnishing such materials to the Securities and Exchange Commission, or SEC. sonomapharma.com and the information contained therein or connected thereto are not intended to be incorporated into this annual report on Form 10-K. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

ITEM 1A. Risk Factors

Risks Related to Our Business

We have a history of losses, we expect to continue to incur losses and we may never achieve profitability and our March 31, 2022 audited consolidated financial statements included disclosure that casts substantial doubt regarding our ability to continue as a going concern.

We reported a loss from continuing operations of \$5,086,000 and \$4,615,000 for the years ended March 31, 2022 and 2021, respectively. At March 31, 2022 and 2021, our accumulated deficit amounted to \$184,363,000 and \$179,277,000, respectively. We had working capital of \$10,611,000 and \$8,905,000 as of March 31, 2022 and 2021, respectively. During the years ended March 31, 2022 and 2021, net cash used in operating activities amounted to \$4,248,000 and \$3,378,000, respectively. As of March 31, 2022, we had cash and cash equivalents of \$7,396,000. We spent the most recent two fiscal years working to reduce our losses and have made significant progress. However, we expect to continue incurring losses for the foreseeable future. We may never achieve or sustain profitability. We must raise additional capital to pursue our product development initiatives, penetrate markets for the sale of our products and continue as a going concern. We cannot provide any assurance that we will raise additional capital. We believe that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, or other means. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to further commercialize our products, which are critical to the realization of our business plan and to our future operations. These matters raise substantial doubt about our ability to continue as a going concern or become profitable.

We derived a significant amount of revenue from our contract with Invekra during the fiscal years ended March 31, 2022 and 2021, and our revenues from Invekra will decline following the transition of Invekra towards their own manufacturing.

Our revenues from our Latin American business that we sold to Invekra on October 27, 2016 were \$2,095,000 and \$5,876,000 for the years ended March 31, 2022 and 2021, respectively. Most of the revenues from fiscal year 2021 were from orders prior to the ending of our transition agreement with Invekra on October, 27, 2020. Our arrangement with Invekra required us to supply product at close to our cost until October 2020 while Invekra built their own manufacturing. Since then, our revenues related to Invekra declined because we only process overflow orders for Invekra. We may continue to manufacture for Invekra at prices commensurate with the market. We expect that our overall revenues from Invekra will decrease while our margins, if any, will increase. If we are unable to increase our sales to replace the outgoing Invekra revenues, our results of operations and financial condition may be adversely affected.

We depend on third party distributors and intend to continue to license or collaborate with third parties in various potential markets, and events involving these strategic partners or any future collaboration could delay or prevent us from developing or commercializing products.

Our business strategy and our short- and long-term operating results depend in part on our ability to execute on existing strategic collaborations and to license or partner with new strategic partners. We believe collaborations allow us to leverage our resources and technologies and to access markets that are compatible with our own core areas of expertise while avoiding the cost of establishing or maintaining a direct sales force in each market. We may incur significant costs in the use of third parties to identify and assist in establishing relationships with potential collaborators. We currently use distributors for most of our products.

We have limited control over the amount and timing of resources that our current partners or any future collaborators devote to our collaborations or potential products. These partners may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our partners may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products.

To penetrate our target markets, we may need to enter into additional collaborative agreements to assist in the development and commercialization of products. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property filings and next generation formations. By entering into collaboration, we may preclude opportunities to collaborate with other third parties who do not wish to associate with our existing third-party strategic partners. Moreover, in the event of termination of a collaboration agreement, termination negotiations may result in less favorable terms.

Mexican tax law prevents us from deducting intercompany interest expense incurred by our Mexico subsidiary Oculus Technologies of Mexico, S.A. de C.V and requires withholding tax on payments remitted to the US. At the same time, we are unable to recognize tax benefits for foreign tax credits for U.S. tax purposes.

Since 2004, we loaned substantial amounts to our Mexico subsidiary Oculus Technologies of Mexico, S.A. de C.V. at various interest rates to fund their operations. As of March 31, 2022, our Mexico subsidiary owes approximately \$11.2 million in principal, \$7.3 million in technical assistance payments and \$18.3 million in accrued interest. The intercompany loans mature in 2027. There is no guarantee that our Mexican subsidiary will be able to pay any or all of the amounts due. If we were to forgive the debt or if we were to convert the debt to equity, it would be subject to Mexico income tax at 30%, or approximately \$11.0 million, as well as Mexican withholding tax of 15%.

Mexico's thin capitalization rules also require taxpayers to maintain a debt-to-equity ratio of 3:1. Any interest paid to foreign related parties that results in indebtedness exceeding a ratio of 3:1 to their stockholder's equity is not deductible for Mexican corporate income tax purposes and we did not meet that condition. Therefore, we have not been able to deduct the intercompany interest on our Mexico tax returns since 2004. It has prevented our Mexico subsidiary from accruing net operating losses in Mexico to offset potential future profits. At the same time the intercompany interest income in the United States decreases our U.S. net operating losses and reduces our ability to apply these carryforwards to offset future taxable income in the United States.

In addition, any interest paid to a foreign lender is subject to Mexico withholding tax of 15%. We also have interest owed on our intercompany technical assistance agreement and royalty withholding of 10% on our technical assistance agreement. This would amount to approximately \$3.9 million in Mexico withholding tax at March 31, 2022, if all of the interest and technical assistance were to be repaid to us. In general, the foreign related party parent can then claim a credit for these withholding taxes on their U.S. income tax return. However, because of our substantial U.S. net operating losses, we are prevented from claiming any credit on any withholding tax for U.S. income tax purposes. Any such failure to pay intercompany debt, inability to deduct income taxes or apply credits, or liability for tax payments could have a material adverse effect on our business, financial condition, and results of operations.

A majority of our business is conducted outside of the United States, exposing us to additional risks that may not exist in the United States, which in turn could cause our business and operating results to suffer.

We have material international operations in Mexico, Asia and Europe. During the years ended March 31, 2022 and 2021, approximately 70% and 71% of our total revenue, respectively, were generated from sales outside of the United States. Our business is highly regulated for the use, marketing and manufacturing of our HOC1-based products both domestically and internationally. Our international operations are subject to risks, including:

- local political or economic instability;
- continuing restrictions related to the Covid-19 pandemic;
- changes in exchange rates;
- changes in governmental regulation;
- changes in import/export duties;
- trade restrictions;
- lack of experience in foreign markets;
- difficulties and costs of staffing and managing operations in certain foreign countries;
- work stoppages or other changes in labor conditions;
- difficulties in collecting accounts receivables on a timely basis or, at all; and
- adverse tax consequences or overlapping tax structures.

We plan to continue to market and sell our products internationally to respond to customer requirements and market opportunities. We currently have manufacturing facilities in Mexico. Establishing operations in any foreign country or region presents risks such as those described above as well as risks specific to the particular country or region. In addition, until a payment history is established over time with customers in a new geographic area or region, the likelihood of collecting receivables generated by such operations could be less than our expectations. As a result, there is a greater risk that the reserves set with respect to the collection of such receivables may be inadequate. If our operations in any foreign country are unsuccessful, we could incur significant losses and we may not achieve profitability.

In addition, changes in policies or laws of the United States or foreign governments resulting in, among other things, changes in regulations and the approval process, higher taxation, currency conversion limitations, restrictions on fund transfers or the expropriation of private enterprises, could reduce the anticipated benefits of our international expansion. If we fail to realize the anticipated revenue growth of our future international operations, our business and operating results could suffer.

Our ability to generate revenue will be diminished if we or our partners are unable to obtain acceptable prices or an adequate level of reimbursement from third-party payors, or our partners may face pricing pressure from private third-party payors, including customers, from rebates and restrictive reimbursement practices.

Currently, none of our products are reimbursed by federal healthcare programs, such as Medicare and Medicaid, and we do not anticipate that they will be reimbursed by such programs in the future. Our partner's ability to commercialize our products successfully will depend in part on the extent to which appropriate coverage and reimbursement levels for the cost of our products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. In the United States, governmental and private payors have limited the growth of health care costs through price regulation or controls, competitive pricing programs and drug rebate programs.

There is significant uncertainty concerning third-party coverage and reimbursement of newly approved medical products. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed healthcare in the United States and the concurrent growth of organizations such as HMOs, as well as the "Affordable Care Act," or any new healthcare laws may result in lower prices for or rejection of our products. The cost containment measures that health care payors and providers are instituting and the effect of any healthcare reform or changes to managed healthcare could materially and adversely affect our ability to generate revenues.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our partner's abilities to sell our products profitably, and thus lead to decreased demand for our products and revenues for us. We were able to negotiate minimum purchase requirements in certain of our third-party distributor agreements. However, we have limited control over purchases by our distributors, to meet the minimum purchase thresholds or above the minimum purchase thresholds.

Increasingly, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries and looking for other ways to shift more of the cost burden to manufacturers and patients. This cost shifting has given consumers greater control of medication choices, as they pay for a larger portion of their prescription costs and may cause consumers to favor lower cost generic alternatives to branded pharmaceuticals. Additionally, patients continue to face cost reduction pressures that may cause them to curtail their use of, or seek reimbursement for, our products, to negotiate reduced fees or other concessions or to delay payment. Third-party payors may reduce or limit reimbursement for our products in the future, such as by withdrawing their coverage policies, canceling any future contracts, reviewing and adjusting the rate of reimbursement, or imposing limitations on coverage. Any such changes could negatively impact the sales of our products by our partners, and therefore, have a material adverse effect on our revenues.

Our ability to generate revenue will be diminished if we or our partners are unable to manage customer product substitutions for our prescription products.

Similar to other pharmaceutical companies, patients are increasingly seeking lower-cost substitutes to our products. Even if our patients have a prescription for our product, the pharmacist may recommend a less expensive product even if that product is less effective or designed for conditions different from what the patient is seeking to treat. As a result, the patient may choose to abandon purchasing our prescribed product for a less expensive alternative product resulting in a lost sale for our partners. If the number of consumers substituting our products increases, it could have a material adverse effect on sales of our products by our partners, and therefore, our revenues, financial position, cash flows and results of operations.

If we fail to obtain, or experience significant delays in obtaining, additional regulatory clearances or approvals to market our current or future products, we may be unable to commercialize these products.

The developing, testing, manufacturing, marketing and selling of medical technology products is subject to extensive regulation by numerous governmental authorities in the United States and other countries. The process of obtaining regulatory clearance and approval of medical technology products is costly and time consuming. Even though their underlying product formulations may be the same or similar, our products are subject to different regulations and approval processes depending upon their intended use.

The FDA generally clears marketing of a medical device through the 510(k) pre-market clearance process if it is demonstrated the new product has the same intended use and the same or similar technological characteristics as another legally marketed Class II device, such as a device already cleared by the FDA through the 510(k) premarket notification process, and otherwise meets the FDA's requirements. Product modifications, including labeling the product for a new intended use, may require the submission of a new 510(k) clearance and FDA approval before the modified product can be marketed.

In addition, we do not know whether the necessary approvals or clearances will be granted or delayed for future products. The FDA could request additional information, changes to product formulation(s) or clinical testing that could adversely affect the time to market and sale of products as drugs. If we do not obtain the requisite regulatory clearances and approvals, we will be unable to commercialize our products and may never recover any of the substantial costs we have invested in the development of HOCl.

Distribution of our products outside the United States is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance 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 regulatory approvals in such countries or that we will not be required to incur significant costs in obtaining or maintaining these regulatory approvals. In addition, the export by us of certain of our products that have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements would have a material adverse effect on our future business, financial condition, and results of operations.

If our products do not gain market acceptance, our business will suffer because we might not be able to fund future operations.

A number of factors may affect the market acceptance of our products or any other products we develop or acquire, including, among others:

- the price of our products relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the healthcare community of the effectiveness and safety of our products for their indicated applications and treatments;
- changes in practice guidelines and the standard of care for the targeted indication;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts or our partners' sales and marketing efforts.

Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement, if any. In addition, our efforts to educate the medical community on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful. If our products do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new product candidates and expanding our sales and marketing efforts for our approved products, which would cause our business to suffer.

If our competitors develop products with similar characteristics to HOCl, we may need to modify or alter our business strategy, which may delay the achievement of our goals.

Competitors have and may continue to develop products with similar characteristics to HOCl. Such similar products marketed by larger competitors can hinder our or our partners' efforts to penetrate the market. As a result, we may be forced to modify or alter our business and regulatory strategy and sales and marketing plans, as a response to changes in the market, competition and technology limitations, among others. Such modifications may pose additional delays in achieving our goals.

We rely on a number of key customers who may not consistently purchase our products in the future and if we lose any one of these customers, our revenues may decline.

Although we have a significant number of customers in each of the geographic markets that we operate in, we rely on certain key customers for a significant portion of our revenues. For the year ended March 31, 2022 one customer represented 21%, one customer represented 17%, and one customer represented 10% of net revenues. For the year ended March 31, 2021, one customer represented 32%, and one customer represented 15% of net revenues. In the future, a small number of customers may continue to represent a significant portion of our total revenues in any given period. These customers may not consistently purchase our products at a particular rate over any subsequent period. The loss of any of these customers could adversely affect our revenues.

Negative economic conditions increase the risk that we could suffer unrecoverable losses on our customers' accounts receivable which would adversely affect our financial results.

We grant credit to our business customers, which are primarily located in Mexico, Europe and the United States. Collateral is generally not required for trade receivables. We maintain allowances for potential credit losses. At March 31, 2022, one customer represented 20% of the Company's net accounts receivable balance, one customer represented 15% of the Company's net accounts receivable balance, and one customer represented 14% of the Company's net accounts receivable balance. At March 31, 2021, three customers each and individually represented more than 10% of net accounts receivable balance. While we believe we have a varied customer base and have experienced strong collections in the past, if current economic conditions disproportionately impact any one of our key customers, including reductions in their purchasing commitments to us or their ability to pay their obligations, it could have a material adverse effect on our revenues and liquidity. We have not purchased insurance on our accounts receivable balances.

If we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Regulatory approvals or clearances that we currently have and that we may receive in the future are subject to limitations on the indicated uses for which the products may be marketed, and any future approvals could contain requirements for potentially costly post-marketing follow-up studies. If the FDA determines that our promotional materials or activities constitute promotion of an unapproved use or we otherwise fail to comply with FDA regulations, we may be subject to regulatory enforcement actions, including warning letters, injunctions, seizures, civil fines or criminal penalties. In addition, the manufacturing, labeling, packaging, adverse event reporting, storing, advertising, promoting, distributing and record-keeping for approved products are subject to extensive regulation. We are subject to continued supervision by European regulatory agencies relating to our CE markings and are required to report any serious adverse incidents to the appropriate authorities. Our manufacturing facilities, processes and specifications are subject to periodic inspection by the FDA, Mexican and other regulatory authorities and, from time to time, we may receive notices of deficiencies from these agencies as a result of such inspections. Our failure to continue to meet regulatory standards or to remedy any deficiencies could result in restrictions being imposed on our products or manufacturing processes, fines, suspension or loss of regulatory approvals or clearances, product recalls, termination of distribution, product seizures or the need to invest substantial resources to comply with various existing and new requirements. In the more egregious cases, criminal sanctions, civil penalties, disgorgement of profits or closure of our manufacturing facilities are possible. The subsequent discovery of previously unknown problems with HOC1, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of our products, and could include voluntary or mandatory recall or withdrawal of products from the market.

New government regulations may be enacted and changes in FDA policies and regulations and, their interpretation and enforcement, could prevent or delay regulatory approval of our 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 will be able to continue to comply with any regulations or that the costs of such compliance will not have a material adverse effect on our future business, financial condition, and results of operations. If we are not able to maintain regulatory compliance, we will not be permitted to market our products and our business would suffer.

We may experience difficulties in manufacturing our products, which could prevent us from commercializing one or more of our products.

The machines used to manufacture our products are complex, use complicated software and must be monitored by highly trained engineers. Slight deviations anywhere in our manufacturing process, including quality control, labeling, and packaging, could lead to a failure to meet the specifications required by the FDA, the Environmental Protection Agency, European notified bodies, Mexican regulatory agencies and other foreign regulatory bodies, which may result in lot failures or product recalls. If we are unable to obtain quality internal and external components, mechanical and electrical parts, if our software contains defects or is corrupted, or if we are unable to attract and retain qualified technicians to manufacture our products, our manufacturing output of HOC1, or any other product candidate based on our platform that we may develop, could fail to meet required standards, our regulatory approvals could be delayed, denied or revoked, and commercialization of one or more of our products may be delayed or foregone. Manufacturing processes that are used to produce the smaller quantities of HOC1-based products needed for clinical tests and current commercial sales may not be successfully scaled up to allow production of significant commercial quantities. Any failure to manufacture our products to required standards on a commercial scale could result in reduced revenues, delays in generating revenue and increased costs.

Our competitive position depends on our ability to protect our intellectual property and our proprietary technologies.

Our ability to compete and to achieve and maintain profitability depends on our ability to protect our intellectual property and proprietary technologies. We currently rely on a combination of patents, patent applications, trademarks, trade secret laws, confidentiality agreements, license agreements and invention assignment agreements to protect our intellectual property rights. We also rely upon unpatented know-how and continuing technological innovation to develop and maintain our competitive position. These measures may not be adequate to safeguard our HOC1 technology. If we do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced.

Our pending patent applications and any patent applications we may file in the future may not result in issued patents, and we do not know whether any of our in-licensed patents or any additional patents that might ultimately be issued by the U.S. Patent and Trademark Office or foreign regulatory body will protect our HOC1 technology. Any claims that are issued may not be sufficiently broad to prevent third parties from producing competing substitutes and may be infringed, designed around, or invalidated by third parties. Even issued patents may later be found to be invalid or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our European patent that was initially issued on May 30, 2007 was revoked by the Opposition Division of the European Patent Office in December 2009 following opposition proceedings instituted by a competitor.

The degree of future protection for our proprietary rights is more uncertain in part because legal means afford only limited protection and may not adequately protect our rights, and we will not be able to ensure that:

- we were the first to invent the inventions described in patent applications;
- we were the first to file patent applications for inventions;
- others will not independently develop similar or alternative technologies or duplicate our products without infringing our intellectual property rights;
- any patents licensed or issued to us will provide us with any competitive advantages;
- we will develop proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our ability to do business.

The policies we use to protect our trade secrets may not be effective in preventing misappropriation of our trade secrets by others. In addition, confidentiality and invention assignment agreements executed by our employees, consultants and advisors may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosures.

We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property in the United States, or in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

We may face intellectual property infringement claims that could be time-consuming, costly to defend and could result in our loss of significant rights and, in the case of patent infringement claims, the assessment of treble damages.

On occasion, we may receive notices of claims of infringement, misappropriation, or misuse of other parties' proprietary rights. We may have disputes regarding intellectual property rights with the parties that have licensed those rights to us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of its outcome, is expensive and time-consuming, and could divert management's attention from our business and have a material negative effect on our business, operating results, or financial condition. In addition, the outcome of such litigation may be unpredictable. If there is a successful claim of infringement against us, we may be required to pay substantial damages, including treble damages if we were to be found to have willfully infringed a third party's patent, to the party claiming infringement, develop non-infringing technology, stop selling our products or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, modifying our products to exclude infringing technologies could require us to seek re-approval or clearance from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business.

We could be required to indemnify third parties for alleged intellectual property infringement, which could cause us to incur significant costs.

Some of our distribution agreements contain commitments to indemnify our distributors against liability arising from infringement of third-party intellectual property, such as patents. We may be required to indemnify our customers for claims made against them or to contribute to license fees they are required to pay. If we are forced to indemnify for claims or to pay license fees, our business and financial condition could be substantially harmed.

Our international operations are subject to trade policies and trade agreements and unfavorable changes could harm our business.

We have significant international operations in Mexico and Europe, and we manufacture products for export in Mexico. There may be changes to existing trade agreements, like the, the USMCA, which went to effect on July 1, 2020, greater restrictions on free trade generally, and significant increases in tariffs on goods imported into the United States, particularly tariffs on products manufactured in Mexico, among other possible changes. Any changes to USMCA (or subsequent trade agreements) could impact our operations in countries where we manufacture or sell products or source components, or materials, which could adversely affect our operating results and our business.

Our sales in international markets subject us to foreign currency exchange and other risks and costs which could harm our business.

A substantial portion of our revenues are derived from outside the United States, primarily from Mexico and Europe. We anticipate that revenues from international customers will continue to represent a substantial portion of our revenues for the foreseeable future. Because we generate revenues in foreign currencies, we are subject to the effects of exchange rate fluctuations. The functional currency of our Mexican subsidiary is the Mexican Peso and the functional currency of our Netherlands subsidiary is the Euro. For the preparation of our consolidated financial statements, the financial results of our foreign subsidiaries are translated into U.S. dollars using average exchange rates during the applicable period. If the U.S. dollar appreciates against the Mexican Peso or the Euro, as applicable, the revenues we recognize from sales by our subsidiaries will be adversely impacted. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our revenues. Additionally, if the effective price of our products were to increase as a result of fluctuations in foreign currency exchange rates, demand for our products could decline and adversely affect our results of operations and financial condition.

The markets in which we operate are highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are less expensive or more effective than any products that we may develop, our commercial opportunity may be reduced or eliminated.

Our success depends, in part, upon our ability to stay at the forefront of technological change and to maintain a competitive position. We compete with large healthcare, pharmaceutical and biotechnology companies, along with smaller or early-stage companies that have collaborative arrangements with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Our competitors may:

- develop and patent processes or products earlier than we will;
- develop and commercialize products that are less expensive or more efficient than any products that we may develop;
- obtain regulatory approvals for competing products more rapidly than we will; and
- improve upon existing technological approaches or develop new or different approaches that render our technology or products obsolete or non-competitive.

As a result, we may not be able to successfully commercialize any future products.

The success of our research and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful, our research and development efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.

An important element of our business strategy is to enter into collaborative or license arrangements under which we license our HOC1 technology to other parties for development and commercialization. We expect to seek collaborators for our potential products because of the expense, effort and expertise required to conduct clinical trials and further develop those potential product candidates. Because collaboration arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. If we need third party assistance in identifying and negotiating one or more acceptable arrangements, it might be costly. Also, we may not have products that are desirable to other parties, or we may be unwilling to license a potential product because the party interested in it is a competitor. The terms of any arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are unable to establish collaborative agreements, we may not be able to develop and commercialize new products, which would adversely affect our business and our revenues.

In order for any of these collaboration or license arrangements to be successful, we must first identify potential collaborators or licensees whose capabilities complement and integrate well with ours. We may rely on these arrangements for not only financial resources, but also for expertise or economies of scale that we expect to need in the future relating to clinical trials, manufacturing, sales and marketing, and for licensing technology rights. However, it is likely that we will not be able to control the amount and timing or resources that our collaborators or licensees devote to our programs or potential products. If our collaborators or licensees prove difficult to work with, are less skilled than we originally expected, or do not devote adequate resources to the program, the relationship will not be successful. If a business combination involving a collaborator or licensee and a third party were to occur, the effect could be to diminish, terminate or cause delays in development of a potential product.

If we are unable to comply with broad and complex federal and state fraud and abuse laws, including state and federal anti-kickback laws, we could face substantial penalties and our products could be excluded from government healthcare programs.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, which include, among other things, “anti-kickback” laws that prohibit payments to induce the referral of products and services, and “false claims” statutes that prohibit the fraudulent billing of federal healthcare programs. Our operations are subject to the Federal Anti-Kickback Statute, a criminal statute that, subject to certain statutory exceptions, prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward a person either (i) for referring an individual for the furnishing of items or services for which payment may be made in whole or in part by a government healthcare program such as Medicare or Medicaid, or (ii) for purchasing, leasing, ordering or arranging for or recommending the purchasing, leasing or ordering of an item or service for which payment may be made under a government healthcare program. Because of the breadth of the Federal Anti-Kickback Statute, the Office of Inspector General of the U.S. Department of Health and Human Services, was authorized to adopt regulations setting forth additional exceptions to the prohibitions of the statute commonly known as “safe harbors.” If all of the elements of an applicable safe harbor are fully satisfied, an arrangement will not be subject to prosecution under the Federal Anti-Kickback Statute.

In addition, if there is a change in law, regulation or administrative or judicial interpretations of these laws, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a negative effect on our business, financial condition and results of operations.

Healthcare fraud and abuse laws are complex, and even minor, inadvertent irregularities can potentially give rise to claims that a statute or regulation has been violated. The frequency of suits to enforce these laws has increased significantly in recent years and has increased the risk that a healthcare company will have to defend a false claim action, pay fines or be excluded from the Medicare, Medicaid or other federal and state healthcare programs as a result of an investigation arising out of such action. We cannot guarantee that we will not become subject to such litigation. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could harm our reputation, be costly to defend and divert management's attention from other aspects of our business. Similarly, if the physicians or other providers or entities with which we do business are found to have violated abuse laws, they may be subject to sanctions, which could also have a negative impact on us.

We may not be able to maintain sufficient product liability insurance to cover claims against us.

Product liability insurance for the healthcare industry is generally 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 if the 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. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage and not subject to any indemnification or contribution could have a material adverse effect on our future business, financial condition, and results of operations.

If any of our third-party contractors fail to perform their responsibilities to comply with FDA rules and regulations, the manufacture, marketing and sales of our products could be delayed, which could decrease our revenues.

Supplying the market with our HOC1 technology products requires us to manage relationships with an increasing number of collaborative partners, suppliers and third-party contractors. As a result, our success depends partially on the success of these third parties in performing their responsibilities to comply with FDA rules and regulations. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. For example, we and our suppliers are required to comply with the FDA's quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections.

If any of our partners or contractors fail to perform their obligations in an adequate and timely manner or fail to comply with the FDA's rules and regulations, including failure to comply with quality systems regulations or a corrective action submitted to the FDA after notification by the FDA of a deficiency is deemed insufficient, then the manufacture, marketing and sales of our products could be delayed. Our products could be detained or seized, the FDA could order a recall, or require our partner to replace or offer refunds for our products. The FDA could also require our partner, and depending on our agreement with our partner, us, to notify healthcare professionals and others that the products present unreasonable risks of substantial harm to the public health. If any of these events occur, the manufacture, marketing and sales of our products could be delayed which could decrease our revenues.

If we fail to comply with the FDA's rules and regulations and are subject to an FDA recall as part of an FDA enforcement action, the associated costs could have a material adverse effect on our business, financial position, results of operations and cash flows.

Our Company, our products, the manufacturing facilities for our products, the distribution of our products, and our promotion and marketing materials are subject to strict and continual review and periodic inspection by the FDA and other regulatory agencies for compliance with pre-approval and post-approval regulatory requirements.

If we fail to comply with the FDA's rules and regulations, we could be subject to an enforcement action by the FDA. The FDA could undertake regulatory actions, including seeking a consent decree, recalling or seizing our products, ordering a total or partial shutdown of production, delaying future marketing clearances or approvals, and withdrawing or suspending certain of our current products from the market. A product recall, restriction, or withdrawal could result in substantial and unexpected expenditures, destruction of product inventory, and lost revenues due to the unavailability of one or more of our products for a period of time, which could reduce profitability and cash flow. In addition, a product recall or withdrawal could divert significant management attention and financial resources. If any of our products are subject to an FDA recall, we could incur significant costs and suffer economic losses. Production of our products could be suspended and we could be required to establish inventory reserves to cover estimated inventory losses for all work-in-process and finished goods related to products we, or our third-party contractors, manufacture. A recall of a material amount of our products could have a significant, unfavorable impact on our future gross margins.

If our products fail to comply with FDA and other governmental regulations, or our products are deemed defective, we may be required to recall our products and we could suffer adverse public relations that could adversely impact our sales, operating results, and reputation which would adversely affect our business operations.

We may be exposed to product recalls, including voluntary recalls or withdrawals, and adverse public relations if our products are alleged to cause injury or illness, or if we are alleged to have mislabeled or misbranded our products or otherwise violated governmental regulations. Governmental authorities can also require product recalls or impose restrictions for product design, manufacturing, labeling, clearance, or other issues. For the same reasons, we may also voluntarily elect to recall, restrict the use of a product or withdraw products that we consider below our standards, whether for quality, packaging, appearance or otherwise, in order to protect our brand reputation.

Product recalls, product liability claims, even if unmerited or unsuccessful, or any other events that cause consumers to no longer associate our brand with high quality and safe products may also result in adverse publicity, hurt the value of our brand, harm our reputation among our customers and other healthcare professionals who use or recommend the products, lead to a decline in consumer confidence in and demand for our products, and lead to increased scrutiny by federal and state regulatory agencies of our operations, any of which could have a material adverse effect on our brand, business, performance, prospects, value, results of operations and financial condition.

Our inability to raise additional capital on acceptable terms in the future may cause us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations, in order to reduce costs and sustain the business, and such inability would have a material adverse effect on our business and financial condition.

We expect capital outlays and operating expenditures to increase over the next several years as we work to expand our sales force, conduct regulatory trials, commercialize our products and expand our infrastructure. We may need to raise additional capital in order to, among other things:

- increase our sales and marketing efforts to drive market adoption and address competitive developments;
- sustain commercialization of our current products or new products;
- acquire or license technologies;
- develop new products;
- expand our manufacturing capabilities; and
- finance capital expenditures and our general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment required to maintain and improve our technology position;
- cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our efforts to acquire or license complementary technologies or acquire complementary businesses;
- changes in product development plans needed to address any difficulties in commercialization;
- competing technological and market developments; and
- changes in regulatory policies or laws that affect our operations.

If we raise additional funds by issuing equity securities, it will result in dilution to our stockholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations or licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. A failure to obtain adequate funds may cause us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations, in order to reduce costs and sustain our business, and would have a material adverse effect on our business and financial condition.

Our information technology and infrastructure may be breached or attacked.

In the ordinary course of our business, we collect and store a limited amount of sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers, business partners, and personally identifiable information of our customers and employees, in our data centers and on our networks. The secure processing, maintenance, and transmission of this information is critical to our operations and business strategy. 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 legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and the services we provide to customers, and damage our reputation, and cause a loss of confidence in our products and services, which could adversely affect our business, revenues and competitive position.

Risks Related to Our Common Stock

The market price of our common stock may be volatile, and the value of your investment could decline significantly.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospects. It is impossible to assure you that the market price of our shares of common stock will not fall in the future.

Our operating results may fluctuate, which could cause our stock price to decrease.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

- demand by physicians, other medical staff and patients for our HOC1-based products;
- reimbursement decisions by third-party payors and announcements of those decisions;
- clinical trial results published by others in our industry and publication of results in peer-reviewed journals or the presentation at medical conferences;
- the inclusion or exclusion of our HOC1-based products in large clinical trials conducted by others;
- actual and anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- issues in manufacturing our product candidates or products;
- new or less expensive products and services or new technology introduced or offered by our competitors or by us;
- the development and commercialization of product enhancements;
- changes in the regulatory environment;
- delays in establishing our sales force or new strategic relationships;
- costs associated with collaborations and new product candidates;
- introduction of technological innovations or new commercial products by us or our competitors;
- litigation or public concern about the safety of our product candidates or products;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel; and
- general market conditions.

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, The Nasdaq Capital Market, in general, and the market for life sciences companies, in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies.

Anti-takeover provisions in our certificate of incorporation and bylaws and under Delaware law may make it more difficult for stockholders to change our management and may also make a takeover difficult.

Our corporate documents and Delaware law contain provisions that limit the ability of stockholders to change our management and may also enable our management to resist a takeover. These provisions include:

- the ability of our Board of Directors to issue and designate, without stockholder approval, the rights of up to 714,286 shares of convertible preferred stock, which rights could be senior to those of common stock;
- limitations on persons authorized to call a special meeting of stockholders; and
- advance notice procedures required for stockholders to make nominations of candidates for election as directors or to bring matters before meetings of stockholders.

We are subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits “business combinations” between a publicly-held Delaware corporation and an “interested stockholder,” which is generally defined as a stockholder who became a beneficial owner of 15% or more of a Delaware corporation’s voting stock for a three-year period following the date that such stockholder became an interested stockholder.

These provisions might discourage, delay or prevent a change of control in our management. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and cause us to take other corporate actions. In addition, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with our Board of Directors.

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock or other securities convertible into common stock.

Our Restated Certificate of Incorporation, as amended, allows us to issue up to 24,000,000 shares of our common stock and to issue and designate, without stockholder approval, the rights of up to 714,286 shares of preferred stock. In the event we issue additional shares of our capital stock, dilution to our stockholders could result. In addition, if we issue and designate a class of convertible preferred stock, these securities may provide for rights, preferences or privileges senior to those of holders of our common stock. Additionally, if we issue preferred stock, it may convert into common stock at a ratio of 1:1 or greater because our Restated Certificate of Incorporation, as amended, allows us to designate a conversion ratio without limitations.

Shares issuable upon the conversion of warrants or preferred stock or the exercise of outstanding options may substantially increase the number of shares available for sale in the public market and depress the price of our common stock.

As of March 31, 2022, we had outstanding warrants exercisable for an aggregate of 108,000 shares of our common stock at a weighted average exercise price of approximately \$10.33 per share. We also had units convertible into 46,000 shares of common stock at an exercise price of \$11.25 per unit. In addition, as of March 31, 2022, options to purchase an aggregate of 466,000 shares of our common stock were outstanding at a weighted average exercise price of \$12.09 per share and a weighted average contractual term of 8.89 years. In addition, 982,000 shares of our common stock were available on March 31, 2022 for future option grants under our 2016 Equity Incentive Plan and our 2021 Equity Incentive Plan. To the extent any of these warrants or options are exercised and any additional options are granted and exercised, there will be further dilution to stockholders and investors. Until the options and warrants expire, these holders will have an opportunity to profit from any increase in the market price of our common stock without assuming the risks of ownership. Holders of options and warrants may convert or exercise these securities at a time when we could obtain additional capital on terms more favorable than those provided by the options or warrants. The exercise of the options and warrants will dilute the voting interest of the owners of presently outstanding shares by adding a substantial number of additional shares of our common stock.

We have filed several registration statements with the SEC, so that substantially all of the shares of our common stock which are issuable upon the exercise of outstanding warrants and options may be sold in the public market. The sale of our common stock issued or issuable upon the exercise of the warrants and options described above, or the perception that such sales could occur, may adversely affect the market price of our common stock.

ITEM 2. Properties

At March 31, 2022, we have a corporate office in Woodstock, Georgia, an office in Boulder, Colorado for our sales and marketing team, and our manufacturing facility in Zapopan, Mexico. We currently lease the following material properties:

Location	Rent per month	Purpose
360 Molly Lane, Suite 150, Woodstock, GA 30189	USD 5,507	Principal executive office
5445 Conestoga Court, Unit 150, Boulder, CO 80301	USD 3,680	Offices
Industria Vidriera 81, & 87 Zapopan Industrial Norte, Zapopan, Jalisco, 45135, Mexico	MXN 173,063	Office, manufacturing
Industria Maderera 124, 106, 115 & 815 Zapopan Industrial Norte, Zapopan, Jalisco, 45135, Mexico	MXN 191,036	Warehouse

We believe that our properties will be adequate to meet our needs for at least the next 12 months.

ITEM 3. Legal Proceedings

We may be involved in legal matters arising in the ordinary course of our business including matters involving proprietary technology. While management believes that such matters are currently insignificant, matters arising in the ordinary course of business for which we are or could become involved in litigation may have a material adverse effect on our business, financial condition or results of comprehensive (loss) income.

ITEM 4. Mine Safety Disclosures.

Not applicable.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "SNOA." Previously, it traded under the symbol "OCLS" until December 6, 2016. Our common stock has been trading since our initial public offering on January 25, 2007.

Holders

As of July 11, 2022, we had approximately 298 holders of record of our common stock. Holders of record include nominees who may hold shares on behalf of multiple owners.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all future earnings for the operation of our business and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," is incorporated herein by reference. Refer to Item 12 of Part III of this annual report on Form 10-K for additional information.

Recent Sales of Unregistered Securities

We did not issue any unregistered securities during the year ended March 31, 2022 and through July 11, 2022.

ITEM 6. Selected Financial Data

As a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this Item.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to exercise its judgment. We exercise considerable judgment with respect to establishing sound accounting policies and in making estimates and assumptions that affect the reported amounts of our assets and liabilities, our recognition of revenues and expenses, and disclosure of commitments and contingencies at the date of the consolidated financial statements.

On an ongoing basis, we evaluate our estimates and judgments. Areas in which we exercise significant judgment include, but are not necessarily limited to, our valuation of accounts receivable, inventory, income taxes, equity transactions (compensatory and financing) and contingencies.

We base our estimates and judgments on a variety of factors including our historical experience, knowledge of our business and industry, current and expected economic conditions, the attributes of our products, the regulatory environment, and in certain cases, the results of outside appraisals. We periodically re-evaluate our estimates and assumptions with respect to these judgments and modify our approach when circumstances indicate that modifications are necessary.

While we believe that the factors we evaluate provide us with a meaningful basis for establishing and applying sound accounting policies, we cannot guarantee that the results will always be accurate. Since the determination of these estimates requires the exercise of judgment, actual results could differ from such estimates.

For a Summary of Critical Accounting Policies, please refer to Notes to Consolidated Financial Statements, Note 3.

Results of Continuing Operations

Comparison of the Year Ended March 31, 2022 and 2021

Revenue

The following table shows our consolidated total revenue and revenue by geographic region for the year ended March 31, 2022 and 2021:

<i>(In thousands)</i>	Years Ended March 31,		\$ Change	% Change
	2022	2021		
United States	\$ 3,807	\$ 5,419	\$ (1,612)	(30%)
Latin America	2,095	5,976	(3,881)	(65%)
Europe and Rest of the World	6,726	7,234	(508)	(7%)
Total	<u>\$ 12,628</u>	<u>\$ 18,629</u>	<u>\$ (6,001)</u>	<u>(32%)</u>

The decrease in United States revenues for the year ended March 31, 2022 compared to the same period in the prior year of \$1.6 million, is primarily the result of our transition from a direct sales force to a distributor model for our dermatology and eye care prescription products in the United States. Under the old direct sales model, our revenues were higher due to higher retail pricing than what we agreed to with the distributors. However, our operating expenses are also much lower under this new arrangement as we do not have to manage a sales force, provide patient rebates or manage product substitutions. Revenue for our animal health products declined slightly. Revenue for wound care products increased 19% from the prior year.

As a result of the asset purchase agreement and arrangement we entered into on October 27, 2016 with Invekra, with our assistance Invekra built up their own manufacturing of HOCI products and we manufactured products for Invekra at cost during the transition time. Invekra began their own manufacturing in November 2020. As we previously disclosed, we expected our revenues to decline following the transition of Invekra towards their own manufacturing. Since November 2020, we continue to process overflow orders for Invekra but we do so at market prices and at lower volumes. As a result of the foregoing, Latin America revenue declined by \$3.9 million during the year ended March 31, 2022 compared to the year ended March 31, 2021.

The decrease in Europe and Rest of the World revenues for the year ended March 31, 2022 compared to the prior year was primarily the result of decreases in disinfectant sales in the Middle East due to the pandemic receding and to a lesser extent a slight decline in European sales.

Cost of Revenue and Gross Profit

The cost of revenue and gross profit metrics are as follows:

<i>(In thousands, except for percentages)</i>	Year ended March 31,		Change	% Change
	2022	2021		
Cost of Revenue	\$ 8,635	\$ 12,070	\$ (3,435)	(28)%
Cost of Revenue as a % of Revenue	68%	65%	3%	
Gross Profit	\$ 3,993	\$ 6,559	\$ (2,566)	(39)%
Gross Profit as a % of Revenue	32%	35%	(3)%	

The gross margin decrease of 3% for the year ended March 31, 2022 compared to the year ended March 31, 2021 is a result of product mix and higher sales to distributors versus sales through our direct sales force.

Research and Development Expense

The research and development metrics are as follows:

<i>(In thousands, except for percentages)</i>	Year ended March 31,		Change	% Change
	2022	2021		
Research and Development Expense	\$ 125	\$ 555	\$ (430)	(77)%
Research and Development Expense as a % of Revenue	1%	3%	(2)%	

For the year ended March 31, 2022, research and development expenses decreased as a result the closure of our research and development facility in Seattle, Washington and its relocation to our facility in Mexico.

Selling, General and Administrative Expense

The selling, general and administrative expense metrics are as follows:

<i>(In thousands, except for percentages)</i>	Year ended March 31,		Change	% Change
	2022	2021		
Selling, General and Administrative Expense	\$ 9,755	\$ 9,453	\$ 302	3%
Selling, General and Administrative Expense as a % of Revenue	77%	50%	27%	

The increase in Selling, General and Administrative expense for the year ended March 31, 2022 was primarily the result of an increase in our insurance premiums.

Interest (Expense) Income, net

Interest (expense) income, net was \$(10,000) and \$4,000, respectively, for the years ended March 31, 2022 and March 31, 2021.

Forgiveness of PPP loan

On May 1, 2020, we received loan proceeds in the amount of \$1,310,000 under the Paycheck Protection Program (“PPP”), from Coastal States Bank in Atlanta, Georgia. We used the loan amount for eligible purposes, such as payroll expenses. For the year ended March 31, 2022, we received approval for loan forgiveness in the amount of \$723,000.

Other Expense, net

Other expense, net for the year ended March 31, 2022 and 2021, was \$394,000 and \$594,000, respectively. The decrease in other expense, net relates primarily to a reduction in foreign exchange losses.

Gain on Sale of Assets

For the year ended March 31, 2022, we sold equipment for a gain of \$150,000. Gain on the sale of assets for the year ended March 31, 2021 was \$137,000. We sold fixed assets no longer needed after closing our Petaluma manufacturing facility.

Income Tax Benefit (Expense)

Income tax benefit (expense) for the year ended March 31, 2022 was \$332,000 compared to \$(713,000) for the year ended March 31, 2021. The increase in income tax benefit is the result of the reversal of the valuation allowance for Mexico as the result of three years of taxable income.

Net Loss from Continuing Operations

Net loss from continuing operations for the year ended March 31, 2022 and 2021, was \$5,086,000 and \$4,615,000, respectively.

Results of Discontinued Operations

Comparison of Year ended March 31, 2022 and 2021

On June 24, 2020, we closed on an asset purchase agreement with Infinity Labs SD, Inc. We decided to divest our Micromed business, resulting in a strategic shift that had a major effect on our operations and financial results. Therefore, the divested Micromed operations meet the criteria to be reported as discontinued operations.

The related assets, liabilities, results of operations and cash flows for our Micromed business are classified as discontinued operations for all periods presented.

The operations of the Micromed business included in discontinued operations is summarized as follows:

	Year ended March 31,	
	2022	2021
Revenues	\$ –	\$ 214,000
Cost of revenues	–	53,000
Selling general and administrative expenses	–	38,000
Income from discontinued operations before tax	–	123,000
Gain on disposal of discontinued operations before income taxes	–	770,000
Total income from discontinued operating, before tax	–	893,000
Income Tax benefit (expense)	–	(228,000)
Income from discontinued operations, net of tax	<u>\$ –</u>	<u>\$ 665,000</u>

Gain on disposal of discontinued operations for the year ended March 31, 2021, includes \$770,000 of gain primarily from the value of the customer base of Micromed partially offset by a working capital adjustment.

Net Loss

The following table provides the net loss for each period along with the computation of basic and diluted net income per share:

<i>(In thousands, except per share data)</i>	For the Year Ended March 31,	
	2022	2021
Numerator:		
Loss from continuing operations	\$ (5,086)	\$ (4,615)
Income from discontinued operations	–	665
Net loss	<u>\$ (5,086)</u>	<u>\$ (3,950)</u>
Denominator:		
Weighted-average number of common shares outstanding: basic and diluted	<u>2,653</u>	<u>1,996</u>
Loss per share from continuing operations	\$ (1.92)	\$ (2.31)
Income per share from discontinued operations	–	0.33
Net loss per share: basic and diluted	<u>\$ (1.92)</u>	<u>\$ (1.97)</u>

Liquidity and Capital Resources

We reported a net loss of \$5,086,000 and \$3,950,000 for the years ended March 31, 2022 and 2021, respectively. At March 31, 2022 and 2021, our accumulated deficit amounted to \$184,363,000 and \$179,277,000, respectively. As of March 31, 2022, we had cash and cash equivalents of \$7,396,000 compared to \$4,220,000 on March 31, 2021. Since our inception, substantially all of our operations have been financed through sales of equity securities. Other sources of financing that we have used to date include our revenues, as well as various loans and the sale of certain assets to Invekra, Petagon, MicroSafe and Infinity Labs.

Since April 1, 2021, substantially all of our operations have been financed through the following transactions:

- Proceeds of \$7,554,000 from sales on the ATM facility with HC Wainwright; and
- Proceeds of \$217,000 from the exercise of stock options and warrants

The following table presents a summary of our consolidated cash flows for operating, investing and financing activities for the year ended March 31, 2022 and 2021 as well as balances of cash and cash equivalents and working capital:

<i>(In thousands)</i>	Year ended March 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ (4,248)	\$ (3,378)
Investing activities	(99)	388
Financing activities	7,396	3,308
Effect of exchange rates on cash	127	211
Net change in cash and cash equivalents	3,176	529
Cash and cash equivalents, beginning of the period	4,220	3,691
Cash and cash equivalents, end of the period	<u>\$ 7,396</u>	<u>\$ 4,220</u>
Working capital ⁽¹⁾ , end of period	<u>\$ 10,611</u>	<u>\$ 8,905</u>

(1) Defined as current assets minus current liabilities.

As of March 31, 2022, we had cash and cash equivalents of \$7,396,000 compared to \$4,220,000 as of March 31, 2021.

Net cash used in operating activities during the year ended March 31, 2022 was \$4,248,000, primarily due to a net loss of \$5,086,000 and partially offset by an increase from accounts receivable net provision for write-offs and returns and an increase of \$900,000 from deferred revenue.

Net cash used in operating activities during the year ended March 31, 2021 was \$3,378,000, primarily due to a net loss of \$3,950,000 for the period.

Net cash used in investing activities for the year ended March 31, 2022 was \$99,000, primarily related to the purchase of property and equipment.

Net cash provided by investing activities for the year ended March 31, 2021 was \$388,000, primarily related to the proceeds from the sale of our Micromed division of \$610,000 partially offset by the purchase of equipment.

Net cash provided by financing activities for the year ended March 31, 2022 was \$7,396,000 primarily related to proceeds of \$7,554,000 from the sale of common stock on our At-the-Market facility with HC Wainwright, proceeds of \$216,000 from the exercise of stock options and warrants, partially offset by the payments on PPP loan and long term debt.

Net cash provided by financing activities for the year ended March 31, 2021 was \$3,308,000, primarily related to proceeds from the exercise of stock options and warrants of \$2,287,000, and PPP loans of \$1,310,000 partially offset by payments on long term debt.

We expect revenues to fluctuate and may incur losses in the foreseeable future and may need to raise additional capital to pursue our product development initiatives, to penetrate markets for the sale of our products and continue as a going concern. We cannot provide any assurances that we will be able to raise additional capital.

Management believes that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means; however, we cannot provide any assurance that new financing will be available on commercially acceptable terms, if at all. If the economic climate in the U.S. deteriorates, our ability to raise additional capital could be negatively impacted. If we are unable to secure additional capital, we may be required to take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our continued efforts to commercialize our products, which is critical to the realization of our business plan and our future operations. These matters raise substantial doubt about our ability to continue as a going concern.

Capital Expenditures

We currently forecast capital expenditures in order to execute on our business plan and maintain growth; however, the actual amount and timing of such capital expenditures will ultimately be determined by the volume of business. We currently do not anticipate that a material amount will be purchased for the year ended March 31, 2023. If we purchase capital equipment, we expect to pay cash for those expenditures or to finance them through equipment leases.

Material Trends and Uncertainties

We are exposed to risk from decline in foreign currency for both the Euro and the Mexico Peso versus the US dollar. Most recently there has been a sharp decline in the Euro versus the US Dollar which has impacted our financial results.

As we have previously discussed in our annual report on Form 10-K filed with the SEC on July 14, 2021, we face a substantial Mexico tax liability, intercompany debt, unpaid technical assistance charges and accrued interest. These amounts are not due until 2027. At this time, management believes there are sufficient assets on the balance sheet to more than cover any tax obligation without interrupting the Company's operations or business. We have engaged tax professionals to review all options to limit our exposure to these amounts and to proceed in a manner that is most advantageous to the Company.

As the pandemic continues to impact economies worldwide, we are closely watching inflation, increased volatility within financial markets, shipping costs, supply chain issues and labor costs. At this time, the overall impact of these issues has been minimal. The potential impact to our business operations, customer demand and supply chain due to increased shipping costs may ultimately impact sales. We continue to evaluate our end-to-end supply chain and assess opportunities to refine the impact on sales. Currently, most of our customers pay for shipping expenses, including increased shipping costs, if any. We have not yet faced labor shortages however it is possible we may have difficulties retaining and finding qualified employees in a tight labor market in the future. Furthermore, overall inflation tendencies may put pressure on our product pricing and/or costs.

We also closely monitor overall economic conditions and consumer sentiment and the prospect of a recession in the United States which may impact our financial results.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include reserves and write-downs related to receivables and inventories, the recoverability of long-lived assets, the valuation allowance related to our deferred tax assets, valuation of equity and derivative instruments, debt discounts, valuation of investments and the estimated amortization periods of upfront product licensing fees received from customers.

Off-Balance Sheet Transactions

We currently have no off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this Item.

ITEM 8. Consolidated Financial Statements and Supplementary Data

Sonoma Pharmaceuticals, Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Sonoma Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Sonoma Pharmaceuticals, Inc. and Subsidiaries (the "Company") as of March 31, 2022, and the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for the year ended March 31, 2022, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2022, and the results of their operations and cash flows for the year ended March 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Frazier & Deeter, LLC

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

Atlanta, Georgia
July 13, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Sonoma Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Sonoma Pharmaceuticals, Inc. and Subsidiaries (the "Company") as of March 31, 2021, the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flow for the year ended March 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2021, and the results of its operations and its cash flow for the year ended March 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition from Contracts with Customers - Measurement of the Transaction Price, including the Constraint on Variable Consideration for Rebates And Discounts

Critical Audit Matter Description

As discussed in Note 3 to the consolidated financial statements, the Company offers sales incentives and other programs that they may make available to certain customers, which are considered to be a form of variable consideration. The Company maintains estimated accruals and allowances using the expected value method. Revenue recognized varies depending on whether a patient is covered by insurance or is not covered by insurance. In addition, the Company may incur a revenue deductions related to the use of the Company's rebate program.

The principal considerations for our determination that performing procedures relating to the identification of contractual terms in customer arrangements to determine the transaction price is a critical audit matter are there was significant judgment by management in identifying contractual terms due to the volume and customized nature of the Company's customer arrangements. This in turn led to significant effort in performing our audit procedures which were designed to evaluate whether the contractual terms used in the determination of the transaction price and the timing of revenue recognition were appropriately identified and determined by management and to evaluate the reasonableness of management's estimates.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements.

How We Addressed the Matter in Our Audit

Our audit procedures included, amongst others:

- Testing the completeness and accuracy of management's identification of the contractual terms by examining customer arrangements on a test basis
- Testing management's process for determining the appropriate amount and timing of revenue recognition based on the contractual terms identified in the customer arrangements
- We evaluated whether the assumptions used in the estimates were reasonable, including performing lookback analysis, considering actual historical rebates and discount percentages utilized as well as actual collection patterns
- We performed ratio and disaggregated revenue analysis for the Company's product and customer types, comparing reserve balances to gross to net sales
- We confirmed balances due to third party for rebate claims, which are billed to the Company after end user customers submission, in order to perform an analysis on rebates/discounts recorded compared to the Company's revenue recognition

/s/ Marcum LLP

Marcum llp

We are uncertain as to the year we began serving consecutively as the auditor of the Company's financial statements; however, we are aware that we have been the Company's auditor consecutively since at least 2006.

New York, NY
July 14, 2021

SONOMA PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(In thousands, except share amounts)

	March 31, 2022	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,396	\$ 4,220
Accounts receivable, net	2,407	2,806
Inventories, net	2,663	2,530
Prepaid expenses and other current assets	3,746	3,218
Current portion of deferred consideration, net of discount	218	209
Total current assets	16,430	12,983
Property and equipment, net	320	360
Operating lease, right of use assets	559	769
Deferred tax asset	829	-
Deferred consideration, net of discount, less current portion	630	763
Other assets	77	112
Total assets	\$ 18,845	\$ 14,987
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,641	\$ 1,769
Accrued expenses and other current liabilities	1,843	1,154
Deferred revenue	1,223	267
Deferred revenue Invekra	54	52
Current portion of debt-PPP	120	-
Short-term debt	688	596
Operating lease liabilities	250	240
Total current liabilities	5,819	4,078
Long-term deferred revenue Invekra	182	229
Long-term debt, less current portion – PPP	-	1,310
Withholding Tax Payable	3,838	3,478
Operating lease liabilities, less current portion	309	529
Total liabilities	\$ 10,148	\$ 9,624
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Convertible preferred stock, \$0.0001 par value; 714,286 shares authorized at March 31, 2022 and 2021, respectively, no shares issued and outstanding at March 31, 2022 and 2021, respectively	-	-
Common stock, \$0.0001 par value; 24,000,000 shares authorized at March 31, 2022 and 2021, respectively, 3,100,937 and 2,092,909 shares issued and outstanding at March 31, 2022 and 2021, respectively (Note 13)	2	2
Additional paid-in capital	197,370	189,217
Accumulated deficit	(184,363)	(179,277)
Accumulated other comprehensive loss	(4,312)	(4,579)
Total stockholders' equity	8,697	5,363
Total liabilities and stockholders' equity	\$ 18,845	\$ 14,987

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

SONOMA PHARMACEUTICALS, INC., AND SUBSIDIARIES
Consolidated Statements of Comprehensive Income (Loss)
(In thousands, except per share amounts)

	Year ended March 31,	
	2022	2021
Revenues	\$ 12,628	\$ 18,629
Cost of revenues	8,635	12,070
Gross profit	<u>3,993</u>	<u>6,559</u>
Operating expenses		
Research and development	125	555
Selling, general and administrative	9,755	9,453
Total operating expenses	<u>9,880</u>	<u>10,008</u>
Loss from operations	(5,887)	(3,449)
Interest income (expense), net	(10)	4
Forgiveness of PPP Loan	723	–
Other expense, net	(394)	(594)
Gain on sale of assets	150	137
Loss from continuing operations before income taxes	(5,418)	(3,902)
Income tax benefit (expense)	332	(713)
Loss from continuing operations, net of tax	<u>(5,086)</u>	<u>(4,615)</u>
Income from discontinued operations, net of tax	<u>–</u>	<u>665</u>
Net loss	<u>\$ (5,086)</u>	<u>\$ (3,950)</u>
Loss per share: basic and diluted		
Continuing operations	\$ (1.92)	\$ (2.31)
Discontinued operations	–	0.33
Total loss per share	<u>\$ (1.92)</u>	<u>\$ (1.97)</u>
Weighted-average shares outstanding: basic and diluted	<u>2,653</u>	<u>1,996</u>
Other comprehensive loss		
Net loss	\$ (5,086)	\$ (3,950)
Foreign currency translation adjustments	267	1,031
Comprehensive loss	<u>\$ (4,819)</u>	<u>\$ (2,919)</u>

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

SONOMA PHARMACEUTICALS, INC., AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
For the Years Ended March 31, 2022 and 2021
(In thousands, except share amounts)

	Series C Preferred Stock (\$0.0001 par Value)		Common Stock (\$0.0001 par Value)		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount				
Balance March 31, 2021	-	\$ -	2,092,909	\$ 2	\$ 189,217	\$ (179,277)	\$ (4,579)	\$ 5,363
Shares issued in connection with ATM, net of transaction costs	-	-	950,100	-	7,554	-	-	7,554
Shares issued in connection with exercise of stock options	-	-	44,042	-	193	-	-	193
Shares issued in connection with exercise of common stock warrants	-	-	12,290	-	24	-	-	24
Employee stock-based compensation expense	-	-	-	-	372	-	-	372
Stock based compensation related to issuance of common stock restricted stock grants	-	-	1,596	-	10	-	-	10
Foreign currency translation adjustment	-	-	-	-	-	-	267	267
Net loss	-	-	-	-	-	(5,086)	-	(5,086)
Balance, March 31, 2022	-	\$ -	3,100,937	\$ 2	\$ 197,370	\$ (184,363)	\$ (4,312)	\$ 8,697

	Series C Preferred Stock (\$0.0001 par Value)		Common Stock (\$0.0001 par Value)		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount				
Balance March 31, 2020	1.55	\$ -	1,777,483	\$ 2	\$ 186,559	\$ (175,327)	\$ (5,610)	\$ 5,624
Shares issued in connection with exercise of stock options	-	-	93,301	-	511	-	-	511
Shares issued in connection with vesting of restricted stock	-	-	3,919	-	-	-	-	-
Shares issued in connection with exercise of common stock warrants	-	-	200,984	-	1,776	-	-	1,776
Shares issued with conversion of C shares	(1.55)	-	17,222	-	-	-	-	-
Employee stock-based compensation expense	-	-	-	-	332	-	-	332
Stock based compensation related to issuance of common stock restricted stock grants	-	-	-	-	39	-	-	39
Foreign currency translation adjustment	-	-	-	-	-	-	1,031	1,031
Net loss	-	-	-	-	-	(3,950)	-	(3,950)
Balance, March 31, 2021	-	\$ -	2,092,909	\$ 2	\$ 189,217	\$ (179,277)	\$ (4,579)	\$ 5,363

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

SONOMA PHARMACEUTICALS, INC., AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (5,086)	\$ (3,950)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	186	227
Recovery of doubtful accounts	(125)	(903)
Provision for (recovery of) discounts, rebates, distributor fees and returns	(1,407)	259
Stock-based compensation	382	371
Forgiveness of PPP loan	(723)	–
Deferred income tax expense	(829)	–
Operating lease right-of-use asset	223	–
Gain on sale of assets	–	(770)
Changes in operating assets and liabilities:		
Accounts receivable	1,971	2,608
Inventories	(100)	(65)
Prepaid expenses and other current assets	(460)	(5)
Deferred consideration, net of discount	160	143
Accounts payable	(157)	(796)
Accrued expenses and other current liabilities	679	(668)
Withholding tax payable	360	397
Operating lease liabilities	(222)	(215)
Deferred revenue	900	(15)
Net cash used in operating activities	<u>(4,248)</u>	<u>(3,378)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(137)	(179)
Deposits	38	(43)
Proceeds from Micromed Transaction	–	610
Net cash (used in) provided by investing activities	<u>(99)</u>	<u>388</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	7,554	–
Payments on PPP Loan	(467)	–
Proceeds from PPP Loan	–	1,310
Proceeds from exercise of common stock options and purchase warrants	216	2,287
Principal payments on short-term debt	(30)	(481)
Proceeds on short-term debt	123	–
Benefit from lease assumed less principal payments on ROU Assets	–	192
Net cash provided by financing activities	<u>7,396</u>	<u>3,308</u>
Effect of exchange rate on cash and cash equivalents	<u>127</u>	<u>211</u>
Net increase in cash and cash equivalents	3,176	529
Cash and cash equivalents, beginning of year	4,220	3,691
Cash and cash equivalents, end of year	<u>\$ 7,396</u>	<u>\$ 4,220</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	<u>\$ 24</u>	<u>\$ 12</u>
Cash paid for taxes	<u>\$ 767</u>	<u>\$ 941</u>
Non-cash operating and financing activities:		
Insurance premiums financed	<u>\$ 748</u>	<u>\$ 596</u>

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

SONOMA PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – Organization and Recent Developments

Organization

Sonoma Pharmaceuticals, Inc. (the “Company”) was incorporated under the laws of the State of California in April 1999 and was reincorporated under the laws of the State of Delaware in December 2006. The Company’s principal office was moved to Woodstock, Georgia from Petaluma, California in June 2020. The Company is a global healthcare leader for developing and producing stabilized hypochlorous acid (“HOCl”) products for a wide range of applications, including wound care, animal health care, eye care, oral care and dermatological conditions. The Company’s products reduce infections, itch, pain, scarring and harmful inflammatory responses in a safe and effective manner. In-vitro and clinical studies of HOCl show it to have impressive antipruritic, antimicrobial, antiviral and anti-inflammatory properties. The Company’s stabilized HOCl immediately relieves itch and pain, kills pathogens and breaks down biofilm, does not sting or irritate skin and oxygenates the cells in the area treated assisting the body in its natural healing process. The Company sells its products either directly or via partners in 54 countries worldwide.

NOTE 2 – Liquidity and Financial Condition

The Company reported a net loss of \$5,086,000 for the year ended March 31, 2022. At March 31, 2022 and 2021, the Company’s accumulated deficit amounted to \$184,363,000 and \$179,277,000, respectively. The Company had working capital of \$10,611,000 and \$8,905,000 as of March 31, 2022 and 2021, respectively.

Management believes that the Company has access to additional capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means; however, the Company cannot provide any assurance that other new financings will be available on commercially acceptable terms, if needed. If the economic climate in the U.S. deteriorates, the Company’s ability to raise additional capital could be negatively impacted. If the Company is unable to secure additional capital, it may be required to take additional measures to reduce costs in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These measures could cause significant delays in the Company’s continued efforts to commercialize its products, which is critical to the realization of its business plan and the future operations of the Company. These matters raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

COVID – 19

On March 11, 2020 the World Health Organization declared the novel strain of coronavirus (“COVID-19”) a global pandemic and recommended containment and mitigation measures worldwide. In an effort to mitigate the continued spread of the virus, federal, state and local governments, as well as certain private entities have mandated various restrictions, including travel restrictions, restrictions on public gatherings and quarantining of people who may have been exposed to the virus. As a result of these restrictions, together with a general fear of the impact on the global economy and financial markets, there is significant uncertainty surrounding the potential impact on the Company. As events are rapidly changing, the Company is unable to accurately predict the impact that COVID-19 will have on its business due to uncertainties including, but not limited to, the duration of quarantines and other travel restrictions within China, the U.S. and other affected countries, the ultimate geographical spread of the virus, the severity of the disease, the duration of the outbreak and the public’s response to the outbreak.

NOTE 3 – Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Aquamed Technologies, Inc. (“Aquamed”), Oculus Technologies of Mexico S.A. de C.V. (“OTM”), and Sonoma Pharmaceuticals Netherlands, B.V. (“SP Europe”). Aquamed has no current operations. All significant intercompany accounts and transactions have been eliminated in consolidation. The functional currency for the Company’s wholly-owned subsidiaries incorporated outside the United States (“U.S.”) is denominated in local currency. All intercompany transactions and balances have been eliminated in consolidation.

Basis of presentation

The accompanying consolidated financial statements have been prepared by the Company pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) and are in conformity with U.S. generally accepted accounting principles (“GAAP”). The Company’s fiscal year end is March 31. Unless otherwise stated, all years and dates refer to the fiscal year.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and all highly liquid investments with an original maturity of three months or less when purchased. The Company’s cash equivalents are held in prime money market investments with strong sponsor organizations which are monitored on a continuous basis.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include reserves and write-downs related to receivables and inventories, the recoverability of long-lived assets, the valuation allowance relating to the Company’s deferred tax assets, valuation of equity, fair value allocation of assets sold to Invekra, and the estimated amortization periods of upfront product licensing fees received from customers. Periodically, the Company evaluates and adjusts estimates accordingly.

Revenue Recognition

On April 1, 2018, the Company adopted Accounting Standards Update (“ASU”), “Revenue from Contracts with Customers Topic 606” (“Topic 606”) using the modified retrospective method. There was no material impact to the Company upon the adoption of Topic 606. Revenue is recognized when the Company transfers promised goods or services to the customer, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under the agreement, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company derives the majority of its revenue through sales of its products directly to end users and to distributors. The Company also sells products to a customer base, including hospitals, medical centers, doctors, pharmacies, distributors and wholesalers. The Company also has entered into agreements to license its technology and products.

The Company considers customer purchase orders, which in some cases are governed by master sales agreements, to be the contracts with a customer. For each contract, the Company considers the promise to transfer products, each of which are distinct, to be the identified performance obligations. In determining the transaction price the Company evaluates whether the price is subject to refund or adjustment to determine the net consideration to which it expects to be entitled.

For all of its sales to non-consignment distribution channels, revenue is recognized when control of the product is transferred to the customer (i.e. when its performance obligation is satisfied), which typically occurs when title passes to the customer upon shipment but could occur when the customer receives the product based on the terms of the agreement with the customer. For product sales to its value-added resellers, non-stocking distributors and end-user customers, the Company grants return privileges to its customers, and because the Company has a long history with its customers, the Company is able to estimate the amount of product that will be returned. Sales incentives and other programs that the Company may make available to these customers are considered to be a form of variable consideration, and the Company maintains estimated accruals and allowances using the expected value method.

The Company has entered into consignment arrangements, in which goods are left in the possession of another party to sell. As products are sold from the customer to third parties, the Company recognizes revenue based on a variable percentage of a fixed price. Revenue recognized varies depending on whether a patient is covered by insurance or is not covered by insurance. In addition, the Company may incur a revenue deduction related to the use of the Company's rebate program.

Sales to stocking distributors are made under terms with fixed pricing and limited rights of return (known as "stock rotation") of the Company's products held in their inventory. Revenue from sales to distributors is recognized upon the transfer of control to the distributor.

The Company assessed the promised goods and services in the technical support to Invekra for a ten-year period as being a distinct service that Invekra can benefit from on its own and is separately identifiable from any other promises within the contract. Given that the distinct service is not substantially the same as other goods and services within the Invekra contract, the Company accounted for the distinct service as a performance obligation.

Service revenue from testing contracts is recognized as tests are completed and a final report is sent to the customer.

Concentration of Credit Risk and Major Customers

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents and accounts receivable. Cash and cash equivalents are maintained in financial institutions in the United States, Mexico and the Netherlands. The Company is exposed to credit risk in the event of default by these financial institutions for amounts in excess of the Federal Deposit Insurance Corporation insured limits. Cash and cash equivalents held in foreign banks are intentionally kept at minimal levels, and therefore have minimal credit risk associated with them.

The Company grants credit to its business customers, which are primarily located in Mexico, Europe and the United States. Collateral is generally not required for trade receivables. The Company maintains allowances for potential credit losses. At March 31, 2022, one customer represented 20% of our net accounts receivable balance, one customer represented 15% of our net accounts receivable balance, and one customer represented 14% of our net accounts receivable balance. At March 31, 2021, one customer represented 17% of our net accounts receivable balance, one customer represented 16% of our net accounts receivable balance, and one customer represented 14% of our net accounts receivable balance. For the year ended March 31, 2022, one customer represented 10%, one customer represented 17%, and one customer represented 21% of net revenues. For the year ended March 31, 2021, one customer represented 32%, and one customer represented 15% of net revenues.

Accounts Receivable

Trade accounts receivable are recorded net of allowances for cash discounts for prompt payment, doubtful accounts, and sales returns. Estimates for cash discounts and sales returns are based on analysis of contractual terms and historical trends.

The Company's policy is to reserve for uncollectible accounts based on its best estimate of the amount of probable credit losses in its existing accounts receivable. The Company periodically reviews its accounts receivable to determine whether an allowance for doubtful accounts is necessary based on an analysis of past due accounts and other factors that may indicate that the realization of an account may be in doubt. Other factors that the Company considers include its existing contractual obligations, historical payment patterns of its customers and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region, and a review of the local economic environment and its potential impact on government funding and reimbursement practices. Account balances deemed to be uncollectible are charged to the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The allowance for doubtful accounts represents probable credit losses at March 31, 2022 and 2021 in the amounts of \$0 and \$125,000, respectively. Additionally, at March 31, 2022 and 2021, the Company has allowances of \$81,000 and \$1,488,000, respectively, related to potential discounts, returns, distributor fees and rebates. The allowances are included in Accounts Receivable, net in the accompanying consolidated balance sheets.

Inventories

Inventories are stated at the lower of cost, cost being determined on a standard cost basis (which approximates actual cost on a first-in, first-out basis), or net realizable value.

Due to changing market conditions, estimated future requirements, age of the inventories on hand and production of new products, the Company regularly reviews inventory quantities on hand and records a provision to write down excess and obsolete inventory to its estimated net realizable value. The Company recorded a provision to reduce the carrying amounts of inventories to their net realizable value in the amounts of \$218,000 and \$223,000 at March 31, 2022 and 2021, respectively, which is included in cost of revenues on the Company's accompanying consolidated statements of comprehensive (loss) income.

Financial Assets and Liabilities

Financial instruments, including cash and cash equivalents, accounts receivable and accounts payable are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of capital lease obligations and equipment loans approximates their carrying amounts as a market rate of interest is attached to their repayment. The Company measures the fair value of financial assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. The Company uses three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

Level 3 liabilities are valued using unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the liabilities. For fair value measurements categorized within Level 3 of the fair value hierarchy, the Company's accounting and finance department, who report to the Chief Financial Officer, determine its valuation policies and procedures. The development and determination of the unobservable inputs for Level 3 fair value measurements and fair value calculations are the responsibility of the Company's accounting and finance department and are approved by the Chief Financial Officer.

As of March 31, 2022 and 2021, there were no transfers in or out of Level 3 from other levels in the fair value hierarchy.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation of leasehold improvements is computed using the straight-line method over the lesser of the estimated useful life of the improvement or the remaining term of the lease. Estimated useful asset life by classification is as follows:

	Years
Office equipment	3
Manufacturing, lab and other equipment	5
Furniture and fixtures	7

Upon retirement or sale, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company periodically reviews the carrying values of its long-lived assets when events or changes in circumstances would indicate that it is more likely than not that their carrying values may exceed their realizable values, and records impairment charges when considered necessary. Specific potential indicators of impairment include, but are not necessarily limited to:

- a significant decrease in the fair value of an asset;
- a significant change in the extent or manner in which an asset is used or a significant physical change in an asset;
- a significant adverse change in legal factors or in the business climate that affects the value of an asset;
- an adverse action or assessment by the U.S. Food and Drug Administration or another regulator; and
- an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset; and operating or cash flow losses combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with an income-producing asset.

When circumstances indicate that an impairment may have occurred, the Company tests such assets for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of such assets and their eventual disposition to their carrying amounts. In estimating these future cash flows, assets and liabilities are grouped at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows generated by other such groups. If the undiscounted future cash flows are less than the carrying amount of the asset, an impairment loss, measured as the excess of the carrying value of the asset over its estimated fair value, will be recognized. The cash flow estimates used in such calculations are based on estimates and assumptions, using all available information that management believes is reasonable.

During the years ended March 31, 2022 and 2021, the Company had noted no indicators of impairment.

Research and Development

Research and development expenses are charged to operations as incurred and consists primarily of personnel expenses, clinical and regulatory services and supplies. For the years ended March 31, 2022 and 2021, research and development expense amounted to \$125,000 and \$555,000, respectively.

Advertising Costs

Advertising costs are charged to operations as incurred. Advertising costs amounted to \$86,000 and \$41,000, for the years ended March 31, 2022 and 2021, respectively. Advertising costs are included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive (loss) income.

Shipping and Handling Costs

The Company classifies amounts billed to customers related to shipping and handling in sale transactions as product revenues. The corresponding shipping and handling costs incurred are recorded in cost of product revenues. For the years ended March 31, 2022 and 2021, the Company recorded revenue related to shipping and handling costs of \$52,000 and \$37,000, respectively. These amounts are included in product revenues in the accompanying consolidated statements of comprehensive (loss) income.

Foreign Currency Reporting

The Company's subsidiary, OTM, uses the local currency (Mexican Pesos) as its functional currency and its subsidiary, SP Europe, uses the local currency (Euro) as its functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date, and revenue and expense accounts are translated at average exchange rates during the period. Resulting translation adjustments amounted to \$267,000 and \$1,031,000 for the years ended March 31, 2022 and 2021, respectively. These amounts were recorded in other comprehensive loss in the accompanying consolidated statements of comprehensive loss for the years ended March 31, 2022 and 2021.

Foreign currency transaction gains (losses) relate primarily to trade payables and receivables and intercompany transactions between subsidiaries OTM and SP Europe. These transactions are expected to be settled in the foreseeable future. The Company recorded foreign currency transaction losses of \$579,000 for the year ended March 31, 2022, and foreign currency transaction losses of \$690,000, for the year ended March 31, 2021. The related amounts were recorded in other expense in the accompanying consolidated statements of comprehensive (loss) income.

Stock-Based Compensation

The Company accounts for share-based awards exchanged for employee services at the estimated grant date fair value of the award. The Company estimates the fair value of employee stock option awards using the Black-Scholes option pricing model. The Company amortizes the fair value of employee stock options on a straight-line basis over the requisite service period of the awards. Compensation expense includes the impact of an forfeitures for all stock options as incurred.

The Company accounts for equity instruments issued to non-employees at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests or becomes non-forfeitable. Non-employee stock-based compensation charges are amortized over the vesting period or as earned.

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Tax benefits claimed or expected to be claimed on a tax return are recorded in the Company's consolidated financial statements. A tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. Uncertain tax positions have had no impact on the Company's consolidated financial condition, results of comprehensive (loss) income or cash flows.

Comprehensive Loss

Other comprehensive loss includes all changes in stockholders' equity during a period from non-owner sources and is reported in the consolidated statement of changes in stockholders' equity. To date, other comprehensive loss consists of changes in accumulated foreign currency translation adjustments. Accumulated other comprehensive losses at March 31, 2022 and 2021 were \$4,312,000, and \$4,579,000 respectively.

Net Income Loss per Share

The Company computes basic net loss per share by dividing net loss per share available to common stockholders by the weighted average number of common shares outstanding for the period and excludes the effects of any potentially dilutive securities. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the “treasury stock” and/or “if converted” methods as applicable.

<i>(In thousands, except per share data)</i>	For the Year Ended March 31,	
	2022	2021
Loss from continuing operations	\$ (5,086)	\$ (4,615)
Income from discontinued operations	–	665
Net loss	<u>\$ (5,086)</u>	<u>\$ (3,950)</u>
Weighted-average shares outstanding: basic and diluted	<u>2,653</u>	<u>1,996</u>
Loss per share from continuing operations	\$ (1.92)	\$ (2.31)
Income per share from discontinued operations	–	0.33
Net loss per share: basic and diluted	<u>\$ (1.92)</u>	<u>\$ (1.97)</u>

The computation of basic loss per share for the years ended March 31, 2022 and 2021 excludes the potentially dilutive securities summarized in the table below because their inclusion would be anti-dilutive.

<i>(In thousands)</i>	March 31,	
	2022	2021
Common stock to be issued upon vesting of restricted stock units	1	1
Common stock to be issued upon exercise of options	466	268
Common stock to be issued upon exercise of warrants	108	119
Common stock to be issued upon conversion of Series C	–	–
Common stock to be issued upon exercise of common stock units (1)	46	46
	<u>621</u>	<u>434</u>

(1) Consists of 30,668 restricted stock units and warrants to purchase 15,332 shares of common stock

Common Stock Purchase Warrants and Other Derivative Financial Instruments

The Company classifies common stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions as either an asset or a liability. The Company assesses classification of its freestanding derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required. The Company determined that its freestanding derivatives, which principally consist of warrants to purchase common stock, satisfied the criteria for classification as equity instruments, other than certain warrants that contained reset provisions and certain warrants that required net-cash settlement that the Company classified as derivative liabilities. The company currently does not have any active derivative financial instruments.

Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of its preferred stock. Shares that are subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

Subsequent Events

Management has evaluated subsequent events or transactions occurring through the date these consolidated financial statements were issued.

Recent Accounting Standards

The Company has evaluated all the recent accounting standards and determined that none of them are material to it.

NOTE 4 – Sale of Assets – Discontinued Operations

Sale of Assets to Infinity Labs SD, Inc. and Discontinued Operations

On June 24, 2020, the Company closed on an asset purchase agreement for the sale of its Micromed Laboratories division and testing facility, including all of Micromed's assets, such as testing equipment, certain office furniture and customer list, with Infinity Labs SD Inc. ("Infinity") for an aggregate purchase price of \$850,000. On the closing date, the Company received \$610,000 in cash from this sale which was adjusted for working capital, a credit of \$100,000 for future testing services from Infinity over the next two years in lieu of cash, and \$60,000 held in escrow for one year, subject to adjustment for certain indemnity claims or purchase price adjustments. The Company also retained its accounts receivables outstanding on the date of closing in the amount of approximately \$81,000 and an insignificant amount of liabilities. As part of the transaction, Infinity also assumed the Petaluma lease for the office and lab space. The Company retained the warehouse space to store inventory and assets until September 30, 2020.

Accounting for the disposition

For accounting purposes, the Company determined that there was only one discrete component of the sale to Infinity. This component was the customer base and related services to be provided.

<u>Component of Sale</u>	<u>Methodology to Estimate Selling Price</u>
Customer Base	Based upon revenues expected from a market participant to provide technical services at expected service levels

The Company determined an arm's length selling price for each component of the sale and then allocated the net proceeds received to the components on a relative selling price basis. The Company estimated the selling prices of each component as described below:

Proceeds were allocated to the components of the sale based upon their relative selling prices are as follows:

Customer base	\$	850,000
Less: Funds remaining in escrow		(60,000)
Less: Services due from buyer		(100,000)
Less: Working capital adjustment		(80,000)
Total proceeds	\$	<u>610,000</u>

Discontinued operations

As of June 24, 2020, the Company determined that the sale of its Micromed division to Infinity qualified as a sale of a component of its business and, as such, all such activity prior to consummation of the sale is required to be included in discontinued operations on the Company's statement of operations.

There were no carrying value of the assets and liabilities of discontinued operations on the consolidated balance sheets as of March 31, 2022 and 2021.

The operations of the Micromed business included in discontinued operations is summarized as follows:

	Year ended March 31,	
	2022	2021
Revenues	\$	214,000
Cost of revenues	–	53,000
Selling general and administrative expenses	–	38,000
Income from discontinued operations before tax	–	123,000
Gain on disposal of discontinued operations before income taxes	–	770,000
Total income from discontinued operations, before tax	–	893,000
Income Tax benefit (expense)	–	(228,000)
Income from discontinued operations, net of tax	\$	<u>665,000</u>

NOTE 5 – Accounts Receivable

Accounts receivable, net consists of the following:

	March 31,	
	2022	2021
Accounts receivable	\$ 2,488,000	\$ 4,419,000
Less: allowance for doubtful accounts	–	(125,000)
Less: discounts, rebates, distributor fees and returns	(81,000)	(1,488,000)
	<u>\$ 2,407,000</u>	<u>\$ 2,806,000</u>

NOTE 6 – Inventories

Inventories consist of the following:

	March 31,	
	2022	2021
Raw materials	\$ 1,626,000	\$ 1,670,000
Finished goods	1,037,000	860,000
	<u>\$ 2,663,000</u>	<u>\$ 2,530,000</u>

NOTE 7 – Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31,	
	2022	2021
Prepaid insurance	\$ 755,000	\$ 705,000
Tax prepaid to Mexican tax authorities	2,371,000	1,850,000
Other prepaid expenses and other current assets	620,000	663,000
Total prepaid expenses and other current assets	<u>\$ 3,746,000</u>	<u>\$ 3,218,000</u>

NOTE 8 – Property and Equipment

Property and equipment consists of the following:

	March 31,	
	2022	2021
Manufacturing, lab, and other equipment	\$ 1,281,000	\$ 1,170,000
Office equipment	139,000	109,000
Furniture and fixtures	108,000	66,000
Leasehold improvements	503,000	486,000
	<u>2,031,000</u>	<u>1,831,000</u>
Less: accumulated depreciation and amortization	(1,711,000)	(1,471,000)
	<u>\$ 320,000</u>	<u>\$ 360,000</u>

Depreciation and amortization expense amounted to \$186,000 and \$227,000 for the years ended March 31, 2022 and 2021, respectively.

NOTE 9 – Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31,	
	2022	2021
Salaries and related costs	\$ 1,059,000	\$ 787,000
Other	784,000	367,000
	<u>\$ 1,843,000</u>	<u>\$ 1,154,000</u>

NOTE 10 – Debt*Financing of Insurance Premiums*

On February 1, 2021, the Company entered into a note agreement for \$584,000 with an interest rate of 4.98% per annum with final payment on October 1, 2021. This instrument was issued in connection with financing insurance premiums. The note was payable in three quarterly installment payments of principal and interest of \$199,000, with the first installment beginning April 1, 2021. These amounts were paid off during the year ended March 31, 2022.

On February 1, 2022, the Company entered into a note agreement for \$748,000 with an interest rate of 4.68% per annum with final payment on January 1, 2023. This instrument was issued in connection with financing insurance premiums. The note is payable in ten monthly installment payments of principal and interest of \$76,000, with the first installment beginning March 1, 2022.

Paycheck Protection Program Loan

On May 1, 2020, the Company received loan proceeds in the amount of \$1,310,000 under the Paycheck Protection Program (“PPP”), from Coastal States Bank in Atlanta, Georgia. The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act, “CARES Act”, provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after eight or 24 weeks as long as the Company uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains payroll levels. The amount of loan forgiveness will be reduced if the Company terminated employees or reduced salaries during the applicable period.

The unsecured loan, which is in the form of a note dated April 29, 2020, matures on April 29, 2022 and bears interest at a rate of 1% per annum, payable monthly commencing on May 1, 2021. The note may be prepaid at any time prior to maturity with no prepayment penalties. The Company has used the loan amount for eligible purposes, such as payroll expenses. The Company met the conditions for \$723,000 in forgiveness of the loan. At March 31, 2022 and 2021 the loan balance amounted to \$120,000 and \$1,310,000, respectively.

NOTE 11 – Leases

The Company's operating leases are comprised primarily of facility leases. Balance sheet information related to the Company's leases is presented below:

	March 31, 2022	March 31, 2021
Operating leases:		
Operating lease right-of-use assets	\$ 559,000	\$ 769,000
Operating lease liabilities – current	250,000	240,000
Operating lease liabilities – non-current	309,000	529,000

Other information related to leases is presented below:

	Year ended March 31, 2022	Year ended March 31, 2021
Lease cost		
Operating lease cost	\$ 367,000	\$ 435,000
As of March 31, 2022		
Other information:		
Operating cash flows from operating leases	\$ (223,000)	\$ (215,000)
Weighted-average remaining lease term – operating leases (in months)	27.3	37.7
Weighted-average discount rate – operating leases	6.00%	6.00%

As of March 31, 2022, the annual future minimum lease payments of the Company's operating lease liabilities were as follows:

For Years Ending March 31,

2023	297,000
2024	210,000
2025	106,000
Thereafter	14,000
Total future minimum lease payments, undiscounted	627,000
Less: imputed interest	(68,000)
Total lease liability	<u>\$ 559,000</u>

NOTE 12 – Commitments and Contingencies

Legal Matters

On occasion, the Company may be involved in legal matters arising in the ordinary course of business including matters involving proprietary technology. While management believes that such matters are currently insignificant, matters arising in the ordinary course of business for which the Company is or could become involved in litigation may have a material adverse effect on its business and financial condition of comprehensive loss.

Employment Agreements

As of March 31, 2022, the Company had employment agreements in place with three of its key executives. These executive employment agreements provide, among other things, for the payment of up to twelve months of severance compensation for terminations under certain circumstances. With respect to these agreements, at March 31, 2022, aggregated annual salaries would be \$775,000 and potential severance payments to these key executives would be \$775,000 if triggered.

Related Party Transactions

Ms. Trombly was appointed the Chief Executive Officer of the Company. Ms. Trombly is the owner of Trombly Business Law, PC which has been retained by the Company to advise on certain corporate and securities law matters. During the years ending March 31, 2022 and 2021, the Company received \$170,000 and \$215,000, respectively, in legal services from Trombly Business Law, PC.

NOTE 13 – Stockholders' Equity

Authorized Capital

Effective September 13, 2018, the Company filed a certificate of amendment to its Restated Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware in order to affect an increase of the total number of shares of common stock, \$0.0001 par value per share, authorized for issuance from 12,000,000 to a total of 24,000,000. Additionally, the Company is authorized to issue 714,286 shares of convertible preferred stock with a par value of \$0.0001 per share.

Description of Common Stock

Each share of common stock has the right to one vote. The holders of common stock are entitled to dividends when funds are legally available and when declared by the board of directors.

Description of Series B Preferred Stock

On October 18, 2016, the Company's board of directors approved, and the Company entered into, a Section 382 rights agreement, or the Rights Agreement, with Computershare Inc., or the Rights Agent. The Rights Agreement provides for a dividend of one preferred stock purchase right, or a Right, for each share of common stock, par value \$0.0001 per share, of the Company outstanding on November 1, 2016, or the Record Date. Each Right entitles the holder to purchase from the Company one one-thousandth of a share of Series B Preferred Stock, par value \$0.0001 per share, or the Preferred Stock, for a purchase price of \$10.00, subject to adjustment as provided in the Rights Agreement. The description and terms of the rights are set forth in the Rights Agreement.

In connection with the adoption of the Rights Agreement, the Company's board of directors adopted a Certificate of Designation of Series B Preferred Stock. The Certificate of Designation was filed with the Secretary of State of the State of Delaware and became effective on October 18, 2016.

The Company's board of directors adopted the Rights Agreement to protect shareholder value by guarding against a potential limitation on the Company's ability to use its net operating loss carryforwards, or NOLs, and other tax benefits, which may be used to reduce potential future income tax obligations. The Company has experienced and continue to experience substantial operating losses, and under the Internal Revenue Code of 1986, as amended, and rules promulgated thereunder, the Company may "carry forward" these NOLs and other tax benefits in certain circumstances to offset any current and future earnings and thus reduce our income tax liability, subject to certain requirements and restrictions. To the extent that the NOLs and other tax benefits do not otherwise become limited, the Company believes that it will be able to carry forward a significant amount of NOLs and other tax benefits, and therefore these NOLs and other tax benefits could be a substantial asset to the Company. However, if the Company experiences an "ownership change," as defined in Section 382 of the Code, its ability to use its NOLs and other tax benefits will be substantially limited. Generally, an ownership change would occur if our shareholders who own, or are deemed to own, 5% or more of the Company's common stock increase their collective ownership in the Company by more than 50% over a rolling three-year period.

Exercise of Series C Preferred Stock Units

During the year ended March 31, 2021, investors who participated in the November 21, 2018 offering exchanged 1.55 shares of Series C into 17,222 shares of common stock. No further shares of Series C are outstanding as of March 31, 2021 or 2022, respectively.

NOTE 14 – Stock-Based Compensation

2006 Stock Plan

The board initially adopted the 2006 Stock Incentive Plan on August 25, 2006. On December 14, 2006, the stockholders approved the 2006 Stock Incentive Plan which became effective at the close of the Company's initial public offering. The 2006 Stock Incentive Plan was later amended and restated by a unanimous board resolution on April 26, 2007, and such amendments were subsequently approved by the stockholders. On September 10, 2009, the Company's shareholders approved a subsequent amendment to the 2006 Stock Incentive Plan. The 2006 Stock Incentive Plan, as amended and restated, is hereafter referred to as the "2006 Plan."

The 2006 Plan provided for the granting of incentive stock options to employees and the granting of non-statutory stock options to employees, non-employee directors, advisors and consultants. The 2006 Plan also provided for grants of restricted stock, stock appreciation rights and stock unit awards to employees, non-employee directors, advisors and consultants.

In accordance with the 2006 Plan the stated exercise price may not be less than 100% and 85% of the estimated fair market value of common stock on the date of grant for ISOs and NSOs, respectively, as determined by the board of directors at the date of grant. With respect to any 10% stockholder, the exercise price of an ISO or NSO shall not be less than 110% of the estimated fair market value per share on the date of grant.

Options issued under the 2006 Plan generally have a ten-year term.

At March 31, 2021, there were no shares available for future issuance.

2011 Stock Plan

On September 12, 2011, upon recommendation of the board, the stockholders approved the Company's 2011 Stock Incentive Plan (the "2011 Plan"). The 2011 Plan is effective as of June 21, 2012.

The 2011 Plan provides for the grant of incentive stock options as defined in Section 422 of the Internal Revenue Code to employees, and the grant of non-statutory stock options and stock purchase rights to employees, non-employee directors, advisors and consultants. The 2011 Plan also permits the grant of stock appreciation rights, stock units and restricted stock.

The board has initially authorized 9,508 of the Company's common stock for issuance under the 2011 Plan, in addition to automatic increases provided for in the 2011 Plan through April 1, 2021. The number of shares of the Company's common stock reserved for issuance under the 2011 Plan will automatically increase, with no further action by the stockholders, at the beginning of each fiscal year by an amount equal to the lesser of (i) 15% of the outstanding shares of the Company's common stock on the last day of the immediately preceding year, or (ii) an amount approved by the Company's board of directors.

Options issued under the 2011 Plan will generally have a ten-year term.

In accordance with the 2011 Plan, the stated exercise price of an employee incentive stock option shall not be less than 100% of the estimated fair market value of a share of common stock on the date of grant, and the stated exercise price of a non-statutory option shall not be less than 85% of the estimated fair market value of a share of common stock on the date of grant, as determined by the board of directors. An employee who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company shall not be eligible for the grant of an employee incentive stock option unless such grant satisfies the requirements of Section 422(c)(5) of the Internal Revenue Code.

Shares subject to awards that expire unexercised or are forfeited or terminated for any other reason will again become available for issuance under the 2011 Plan. No participant in the 2011 Plan can receive option grants, stock appreciation rights, restricted shares, or stock units for more than 2,381 shares in the aggregate in any calendar year. As provided under the 2011 Plan, the aggregate number of shares authorized for issuance as awards under the 2011 Plan automatically increases on April 1 of each year by an amount equal to the lesser of (i) 15% of the outstanding shares on the last day of the immediately preceding year, or (ii) an amount determined by the board. During the year ended March 31, 2019, the board of directors approved an increase of 102,863 shares authorized for issuance. During the year ended March 31, 2020, the board of directors approved an increase of 197,450 shares authorized for issuance.

The plan expired on September 12, 2021 in accordance with its term.

At March 31, 2022, there were no shares available for future issuance.

2016 Stock Plan

On September 2, 2016, upon recommendation of the board, the stockholders approved the Company's 2016 Equity Incentive Plan (the "2016 Plan"). The 2016 Plan is effective as of September 2, 2016.

The 2016 Plan provides for the grant of options, including incentive stock options as defined in Section 422 of the Internal Revenue Code to employees, stock appreciation rights, restricted awards, performance share awards and performance compensation awards to employees, non-employee directors, advisors and consultants.

Options issued under the 2016 Plan will generally have a ten-year term.

In accordance with the 2016 Plan, the stated exercise price of an employee incentive stock option or a non-statutory stock option shall not be less than 100% of the estimated fair market value of a share of common stock on the date of grant. An employee who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company shall not be eligible for the grant of an employee incentive stock option unless such grant satisfies the requirements of Section 422(c)(5) of the Internal Revenue Code.

Shares subject to awards that expire unexercised or are forfeited or terminated for any other reason will again become available for issuance under the 2016 Plan. No participant in the 2016 Plan can receive more than 11,112 option grants, or other awards with respect to more than 13,334 shares in the aggregate in any calendar year.

The board has authorized 44,445 of the Company's common stock for issuance under the 2016 Plan, in addition to automatic increases provided for in the 2016 Plan through April 1, 2026. The number of shares of the Company's common stock reserved for issuance under the 2016 Plan will automatically increase, with no further action by the stockholders, at the beginning of each fiscal year by an amount equal to the lesser of (i) 8% of the outstanding shares of the Company's common stock on the last day of the immediately preceding year, or (ii) an amount determined by the Company's board of directors. During the year ended March 31, 2019, the board of directors approved an increase of 4,860 shares authorized for issuance. During the year ended March 31, 2020, the board of directors approved an increase of 105,306 shares authorized for issuance. During the year ended March 31, 2022, the board of directors approved an increase of 167,432 shares authorized for issuance.

At March 31, 2022 there were 112,106 shares available for future issuance.

2021 Stock Plan

On September 21, 2021, upon recommendation of the board, the stockholders approved the Company's 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan is effective as of September 21, 2021.

The 2021 Plan provides for the grant of options, including incentive stock options as defined in Section 422 of the Internal Revenue Code to employees, stock appreciation rights, restricted awards, performance share awards and performance compensation awards to employees, non-employee directors, advisors and consultants.

Options issued under the 2021 Plan will generally have a ten-year term.

In accordance with the 2021 Plan, the stated exercise price of an employee incentive stock option or a non-statutory stock option shall not be less than 100% of the estimated fair market value of a share of common stock on the date of grant. An employee who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company shall not be eligible for the grant of an employee incentive stock option unless such grant satisfies the requirements of Section 422(c)(5) of the Internal Revenue Code.

Shares subject to awards that expire unexercised or are forfeited or terminated for any other reason will again become available for issuance under the 2021 Plan.

The board has authorized 1,000,000 shares of the Company's common stock for issuance under the 2021 Plan.

At March 31, 2022, there were 869,999 shares available for future issuance.

Stock-Based Compensation

The Company issues service, performance and market-based stock options to employees and non-employees. The Company estimates the fair value of service and performance stock option awards using the Black-Scholes option pricing model. The Company estimates the fair value of market-based stock option awards using a Monte-Carlo simulation. Compensation expense for stock option awards is amortized on a straight-line basis over the awards' vesting period. Compensation expense includes the impact of forfeitures as they are incurred.

The expected term of the stock options represents the average period the stock options are expected to remain outstanding and is based on the expected term calculated using the approach prescribed by the Securities and Exchange Commission's Staff Accounting Bulletin No. 110 for "plain vanilla" options. The expected stock price volatility for the Company's stock options was determined by using an average of the historical volatilities of the Company and its industry peers. The Company will continue to analyze the stock price volatility and expected term assumptions as more data for the Company's common stock and exercise patterns become available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

The Company estimated the fair value of employee and non-employee stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service periods of the respective awards. The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Year Ended March 31,	
	2022	2021
Fair value of the Company's common stock on date of grant	\$ 4.60	\$ 8.03
Expected term	6.00 yrs	6.00 yrs
Risk-free interest rate	1.60%	0.5800%
Dividend yield	0.00%	0.00%
Volatility	123.27%	80.7%
Fair value of options granted	\$ 4.03	\$ 5.48

Share-based awards compensation expense is as follows:

	Year Ended March 31,	
	2022	2021
Cost of revenues	\$ —	\$ (27,000)
Research and development	—	26,000
Selling, general and administrative	382,000	372,000
Total stock-based compensation	<u>\$ 382,000</u>	<u>\$ 371,000</u>

At March 31, 2022, there were unrecognized compensation costs of \$1,325,000 related to stock options which is expected to be recognized over a weighted-average amortization period of 2.14 years.

A tax benefit of \$54,000 has been recognized relating to stock-based compensation as a result of non-qualified stock options and restricted stock exercised during the year ending March 31, 2022. In addition, the stock-based compensation deferred tax asset has been reduced by \$309,000 primarily related to the expiration of stock compensation grants.

Stock-Based Award Activity

Stock-based awards outstanding at March 31, 2022 under the various plans are as follows:

Plan	Stock Options	Unvested		Total
		Restricted Stock		
2006 Plan	2,787	–		2,787
2011 Plan	111,949	–		111,949
2016 Plan	221,497	–		221,497
2021 Plan	130,001	–		130,001
	<u>466,234</u>	<u>–</u>		<u>466,234</u>
Stock-based awards available for grant as of March 31, 2022				<u>982,105</u>

Stock options award activity is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term	Aggregate Intrinsic Value
Outstanding at April 1, 2021	267,569	\$ 25.16		
Options granted	272,958	4.60		
Options exercised	(44,042)	4.38		
Options forfeited	(5,250)	6.89		
Options expired	(25,001)	84.83		
Outstanding at March 31, 2022	<u>466,234</u>	<u>\$ 12.09</u>	<u>8.89</u>	<u>\$ 0</u>
Exercisable at March 31, 2022	<u>115,144</u>	<u>\$ 32.56</u>	<u>6.85</u>	<u>\$ 0</u>

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock, or \$4.01 and \$7.43 per share at March 31, 2022 and 2021, respectively.

Restricted stock award activity is as follows:

	Number of Shares	Weighted Average Award Date Fair Value per Share
Unvested restricted stock awards outstanding at April 1, 2021	833	\$ 13.68
Restricted stock awards granted	1,596	3.05
Restricted stock awards vested	(2,429)	6.70
Unvested restricted stock awards outstanding at March 31, 2022	<u>–</u>	<u>\$ –</u>

The Company did not capitalize any cost associated with stock-based compensation.

The Company issues new shares of common stock upon exercise of stock options or release of restricted stock awards.

NOTE 15 – Income Taxes

The Company has the following net deferred tax assets:

	March 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 28,224,000	\$ 25,687,000
Research and development tax credit carryforwards	1,850,000	1,850,000
Stock-based compensation	309,000	3,120,000
Allowances and accruals	1,336,000	659,000
Other deferred tax assets	–	398,000
Lease liability	63,000	78,000
Gross deferred tax assets	<u>\$ 31,782,000</u>	<u>\$ 31,792,000</u>
Less valuation allowance	<u>(30,613,000)</u>	<u>(31,528,000)</u>
Total deferred tax assets	<u>\$ 1,169,000</u>	<u>\$ 264,000</u>
Deferred tax liabilities:		
Fixed assets	(17,000)	(3,000)
Prepaid expenses	(260,000)	(186,000)
Right of Use asset	(63,000)	(75,000)
Gross deferred tax liabilities	<u>(340,000)</u>	<u>(264,000)</u>
Net deferred tax assets	<u>\$ 829,000</u>	<u>\$ –</u>

The income tax provision (benefit) is based on the following loss before income taxes, which are from domestic sources and foreign loss before income taxes:

	Year Ended March 31,	
	2022	2021
Domestic	\$ (3,516,000)	\$ (2,052,000)
Foreign	(1,883,000)	(1,467,000)
	<u>\$ (5,399,000)</u>	<u>\$ (3,519,000)</u>

The Company's income tax expense/(benefits) consist of the following:

	Year Ended March 31,	
	2022	2021
Current:		
State	\$ 8,000	\$ 1,000
Foreign	469,000	941,000
	<u>477,000</u>	<u>942,000</u>
Deferred:		
Federal	-	-
State	-	-
Foreign	(809,000)	-
	<u>\$ (332,000)</u>	<u>\$ 942,000</u>

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate for continuing operations is as follows:

	Year Ended March 31,	
	2022	2021
Expected federal statutory rate	21.0%	21.0%
State income taxes	5.7%	2.1%
Foreign earnings taxed at different rates	3.7%	3.6%
Foreign tax true-up	-	(12.4%)
Effect of permanent differences	(3.0%)	(9.5%)
Effect of intercompany interest permanent differences	(12.3%)	(17.9%)
True-up of state deferred assets	(25.6%)	(120.7%)
	<u>(10.5%)</u>	<u>(133.8%)</u>
Change in valuation allowance	16.7%	107.1%
Totals	<u>(6.2%)</u>	<u>(26.7%)</u>

As of March 31, 2022, the Company had net operating loss carryforwards for Federal, State and Foreign income tax purposes of approximately \$115.3 million, \$44 million and \$541,000, respectively. Due to the Tax Cuts and Job Act, Federal NOLs generated after March 31, 2018 have an indefinite life. Federal NOL generated on and before March 31, 2017 will begin to expire 2024, if not utilized. State and Foreign NOLs will begin to expire in the year 2029 and 2024, respectively, if not utilized.

As of March 31, 2022, the Company had Federal and California research credit carryforwards of approximately \$1 million and \$790,000, respectively. The Federal research credits will begin to expire in 2024 while the California research credits have no expiration date. In addition, the Company has foreign tax credits of \$50,000, which begin to expire in the year 2023 if not utilized.

Section 382 of the Internal Revenue Code limits the use of the Federal net operating losses in certain situations where changes occur in stock ownership of a company. If the Company should have an ownership change of more than 50% of the value of the Company's capital stock, utilization of the carryforwards could be restricted. The Company is not aware of any changes in ownership that would result in a change in control under Internal Revenue Code section 382.

The Company released the valuation allowance recorded against its Mexico deferred tax assets as of March 31, 2022. Given its recent history of earnings, current earnings and anticipated future earnings, the Company concluded that there is sufficient positive evidence available to reach a conclusion that the valuation allowance is no longer needed in Mexico. The release of the valuation allowance resulted in the recognition of deferred tax assets of \$829,000. The Company, after considering all available evidence, fully reserved against all deferred tax assets in the U.S. and Netherlands since it is more likely than not such benefits will not be realized in future periods. The Company will continue to evaluate its deferred tax assets to determine whether any changes in circumstances could affect the realization of their future benefit.

The Company has filed tax returns for federal, state and foreign jurisdictions. The Company's evaluation of uncertain tax matters was performed for tax years ended through March 31, 2022. Generally, the Company is subject to audit for the years ended March 31, 2021, 2020 and 2019. The Company has elected to retain its existing accounting policy with respect to the treatment of interest and penalties attributable to income taxes and continues to reflect interest and penalties attributable to income taxes, to the extent they arise, as a component of its income tax provision or benefit as well as its outstanding income tax assets and liabilities. The Company believes that its income tax positions and deductions would be sustained on audit and does not anticipate any adjustments to result in a material change to its financial position.

NOTE 16 – Employee Benefit Plan

The Company has a program to contribute and administer a qualified 401(k) plan. Under the 401(k) plan, the Company matches employee contributions to the plan up to 4% of the employee's salary. Company contributions to the plan amounted to an aggregate of \$50,600 and \$89,000 for the years ended March 31, 2022 and 2021, respectively.

NOTE 17 – Revenue Disaggregation

The Company generates product revenues from products which are sold into the human and animal healthcare markets, and the Company generates service revenues from laboratory testing services which are provided to medical device manufacturers.

The following table presents the Company's disaggregated revenues by source:

	Year Ended March 31,	
	2022	2021
Product		
Human Care	\$ 9,010,000	\$ 15,317,000
Animal Care	3,169,000	3,200,000
Total Product Revenue	12,179,000	18,517,000
Service/Royalty	449,000	112,000
Total	<u>\$ 12,628,000</u>	<u>\$ 18,629,000</u>

The following table shows the Company's revenues by geographic region:

	Year Ended March 31,	
	2022	2021
United States	\$ 3,807,000	\$ 5,419,000
Latin America	2,095,000	5,976,000
Europe and Rest of the World	6,726,000	7,234,000
Total	<u>\$ 12,628,000</u>	<u>\$ 18,629,000</u>

The Company's service revenues in Latin America amounted to \$349,000 and \$112,000 for the years ended March 31, 2022 and 2021, respectively.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

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 in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of our most recent fiscal year. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of March 31, 2022.

Notwithstanding the material weaknesses, management believes the consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, the Company's financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. generally accepted accounting principles.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Exchange Act Rule 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in the *2013 Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation, our management concluded that our internal control over financial reporting was not effective as of March 31, 2022. We concluded this because of the errors we found in the Form 10-Q filing from June 30, 2020 that were restated in our 10-Q/A that was filed on November 17, 2020. We have determined that there were inadequate spreadsheet controls, a lack of separation of duties with preparation and review of the reported numbers, and inadequate analysis of revenue reporting among other things. We also determined during the quarter ended March 31, 2021 that there were errors related to income tax withholding accruals that required a revision in these financial statements.

Management's Remediation Measures

Management, with oversight from the Audit Committee of the Board of Directors of the Company, is actively engaged in remediation efforts to address the material weaknesses identified in the management's evaluation of internal controls and procedures. Management has taken a number of actions to remediate the material weaknesses described above, including the following:

- Improved monitoring and risk assessment activities to address these control deficiencies.
- Hired a new full time Chief Financial Officer in September 2020 and a new corporate controller in October 2020 to replace the transitional staff in place while we moved our corporate offices from Petaluma, CA to Woodstock, GA.
- Separated the preparation of the financial reports from review of the financial reports.
- Implemented additional process-level controls over revenue recognition of new contracts.
- Developed and delivered further internal controls training to individuals associated with these control deficiencies and enhance training provided to all personnel who have financial reporting or internal control responsibilities in these areas. The training will include a review of individual roles and responsibilities related to internal controls, proper oversight and reemphasize the importance of completing the control procedures.
- Did a detailed review of income taxes and our intercompany agreements which uncovered the fact that we should be accruing withholding taxes that will be paid to Mexico when intercompany interest and Technical Assistance payments are made to from Mexico to the United States that we will not be eligible for a tax credit in the United States because of our Net Operating Loss positions.

These improvements are targeted at strengthening the Company's internal control over financial reporting and remediating the material weaknesses. We remain committed to an effective internal control environment and management believes that these actions and the improvements management expects to achieve as a result, will effectively remediate the material weaknesses. However, the material weaknesses in the Company's internal control over financial reporting will not be considered remediated until the controls operate for a sufficient period of time and management has concluded, through testing that these controls operate effectively. As of the date of filing this Form 10-K, management is in the process of testing and evaluating these additional controls to determine whether they are operating effectively.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the year ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not finished our testing our remediated controls and sufficient time has not elapsed to make the determination these controls are operating effectively.

ITEM 9B. Other Information

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended March 31, 2022 (the “2022 Proxy Statement”).

Item 405 of Regulation S-K requires the disclosure of, based upon our review of the forms submitted to us during and with respect to our most recent fiscal year, any known failure by any director, officer, or beneficial owner of more than ten percent of any class of our securities, or any other person subject to Section 16 of the Exchange Act (“reporting person”) to file timely a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” in the 2022 Proxy Statement.

Code of Business Conduct

We have adopted a Code of Business Conduct that applies to all of our officers, directors, and employees, including our Chief Executive Officer, Chief Financial Officer, and other employees who perform financial or accounting functions. The Code of Business Conduct sets forth the basic principles that guide the business conduct of our employees. On January 17, 2017, our board of directors adopted changes to our Code of Business Conduct. The changes to the Code of Business Conduct were made to update the code to current best practices. In addition to some clerical changes, the Code of Business Conduct now explicitly requires employees, directors and officers to act honestly and ethically in dealing with customers, business partners and others. Furthermore, the Code of Business Conduct now explicitly extends the confidentiality and conflicts of interest requirements to directors and prohibits company loans. The Code of Business Conduct also updated the disclosure, reporting and enforcement provisions. We filed our Code of Business Conduct with the Securities and Exchange Commission as exhibit 14.1 to the current report on Form 8-K on January 23, 2017, and it is also available on our website at <http://www.ir.sonomapharma.com/governance-documents>. We will provide any person, without charge, copies of our Code of Business Conduct and Ethics upon request. Such requests should be in writing and addressed to: Sonoma Pharmaceuticals, Inc., Attention: Chief Financial Officer, 645 Molly Lane, Suite 150, Woodstock, Georgia, 30189.

To date, there have been no waivers under our Code of Business Conduct. We intend to disclose future amendments to certain provisions of our Code of Business Conduct or any waivers, if and when granted, of our Code of Business Conduct on our website at <http://www.sonomapharma.com> within four business days following the date of such amendment or waiver.

Procedures for Nominating Directors

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors. The Board of Directors will consider candidates for director positions that are recommended by any of our stockholders. Any such recommendation for a director nomination should be provided to our Secretary. The recommended candidate should be submitted to us in writing and addressed to Sonoma Pharmaceuticals, Inc., Attention: Secretary, 645 Molly Lane, Suite 150, Woodstock, Georgia, 30189. The recommendation should include the following information: name of candidate; address, phone and fax number of candidate; a statement signed by the candidate certifying that the candidate wishes to be considered for nomination to our Board of Directors and stating why the candidate believes that he or she would be a valuable addition to our Board of Directors; a summary of the candidate’s work experience for the prior five years and the number of shares of our stock beneficially owned by the candidate. The Board will evaluate the recommended candidate and shall determine whether or not to proceed with the candidate in accordance with our procedures. We reserve the right to change our procedures at any time to comply with the requirements of applicable laws.

ITEM 11. Executive Compensation

The information required by this Item is incorporated by reference to the 2022 Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference to the 2022 Proxy Statement.

The information required to be disclosed by Item 201(d) of Regulation S-K, “Securities Authorized for Issuance Under Equity Compensation Plans,” appears under the caption “Equity Compensation Plan Information” in the 2022 Proxy Statement and such information is incorporated by reference into this report.

ITEM 13. Certain Relationships, Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to the 2022 Proxy Statement.

ITEM 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference to the 2022 Proxy Statement.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report

(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Sonoma Pharmaceuticals, Inc. under Item 8 of Part II hereof.

(2) Financial Statement Schedules

Financial statement schedules have been omitted that are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

(b) Exhibits

Exhibit Index

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc., effective January 30, 2006 (included as exhibit 3.1 of the Company's Annual Report on Form 10-K filed June 20, 2007, and incorporated herein by reference).
3.2	Certificate of Amendment of Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc., effective October 22, 2008 (included as exhibit A in the Company's Definitive Proxy Statement on Schedule 14A filed July 21, 2008, and incorporated herein by reference).
3.4	Certificate of Amendment of Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc., as amended, effective March 29, 2013 (included as exhibit 3.1 to the Company's Current Report on Form 8-K filed March 22, 2013, and incorporated herein by reference).
3.5	Certificate of Amendment of Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc., as amended, effective December 4, 2014 (included as exhibit 3.1 to the Company's Current Report on Form 8-K filed December 8, 2014, and incorporated herein by reference).
3.6	Certificate of Amendment of Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc., as amended, effective October 22, 2015 (included as exhibit 3.1 to the Company's Current Report on Form 8-K filed October 27, 2015, and incorporated herein by reference).
3.7	Certificate of Amendment of Restated Certificate of Incorporation of Oculus Innovative Sciences, Inc., as amended, effective June 24, 2016 (included as exhibit 3.1 to the Company's Current Report on Form 8-K filed June 28, 2016, and incorporated herein by reference).
3.8	Certificate of Amendment of Restated Certificate of Incorporation of Sonoma Pharmaceuticals, Inc., as amended, effective December 6, 2016 (included as exhibit 3.1 to the Company's Current Report on Form 8-K filed December 7, 2016, and incorporated herein by reference).
3.9	Amended and Restated Bylaws, as amended, of Sonoma Pharmaceuticals, Inc., effective December 6, 2016 (included as exhibit 3.2 to the Company's Current Report on Form 8-K filed December 7, 2016, and incorporated herein by reference).
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series A 0% Convertible Preferred Stock, filed with the Delaware Secretary of State on April 24, 2012 (included as exhibit 4.2 to the Company's Current Report on Form 8-K, filed April 25, 2012, and incorporated herein by reference).
3.11	Certificate of Designation of Series B Preferred Stock, effective October 18, 2016 (included as exhibit 3.1 to the Company's Current Report on Form 8-K filed October 21, 2016, and incorporated herein by references).

- 3.12 [Certificate of Amendment of Restated Certificate of Incorporation of Sonoma Pharmaceuticals, Inc., as amended, effective June 19, 2019](#) (included as exhibit 3.1 to the Company's Current Report on Form 8-K filed June 19, 2019, and incorporated herein by reference).
- 4.1 [Specimen Common Stock Certificate](#) (included as exhibit 4.1 to the Company's Annual Report on Form 10-K filed June 28, 2017, and incorporated herein by reference).
- 4.2 [Section 382 Rights Agreement, dated as of October 18, 2016, between Oculus Innovative Sciences, Inc. and Computershare Inc., which includes the Form of Certificate of Designation of Series B Preferred Stock as Exhibit A, the Form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Stock as Exhibit C](#) (included as exhibit 4.1 to the Company's Current Report on Form 8-K filed October 21, 2016, and incorporated herein by reference).
- 4.3 [Form of Placement Agent Warrant granted to Dawson James Securities, Inc. and The Benchmark Company, LLC in connection with the March 2, 2018 public offering, dated March 6, 2018](#) (included as exhibit 4.1 to the Company's Current Report on Form 8-K filed March 6, 2018, and incorporated herein by reference).
- 4.4 [Form of Placement Agent Warrant granted to Dawson James Securities, Inc. in connection with the November 2019 public offering](#) (included as exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 29, 2019, and incorporated herein by reference).
- 10.1 [Form of Indemnification Agreement between Oculus Innovative Sciences, Inc. and its officers and directors](#) (included as exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.2 [Office Lease Agreement, dated May 18, 2006, between Oculus Technologies of Mexico, S.A. de C.V. and Antonio Sergio Arturo Fernandez Valenzuela \(translated from Spanish\)](#) (included as exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.3 [Office Lease Agreement, dated July 2003, between Oculus Innovative Sciences, B.V. and Artikona Holding B.V. \(translated from Dutch\)](#) (included as exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.4 [Form of Director Agreement](#) (included as exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-135584), as amended, declared effective on January 24, 2007, and incorporated herein by reference).
- 10.5 [Amended and Restated Oculus Innovative Sciences, Inc. 2006 Stock Incentive Plan and related form stock option plan agreements](#) (included as exhibit 10.2 to the Company's Current Report on Form 8-K filed May 2, 2007, and incorporated herein by reference).
- 10.6 [Amendment to Office Lease Agreement, effective February 15, 2008, by and between Oculus Innovative Sciences Netherlands B.V. and Artikona Holding B.V. \(translated from Dutch\)](#) (included as exhibit 10.44 to the Company's Annual Report on Form 10-K filed June 13, 2008, and incorporated herein by reference).
- 10.7 [Oculus Innovative Sciences, Inc. 2011 Stock Incentive Plan](#) (included as exhibit A in the Company's Definitive Proxy Statement on Schedule 14A filed July 29, 2011, and incorporated herein by reference).
- 10.8† [Exclusive Sales and Distribution Agreement, dated November 6, 2015, by and between Oculus Innovative Sciences, Inc. and Manna Pro Products, LLC](#) (included as exhibit 10.1 to the Company's 8-K filed March 23, 2016 and incorporated herein by reference).
- 10.9† [Asset Purchase Agreement dated October 27, 2016, between Oculus Innovative Sciences, Inc. and Invektra, S.A.P.I de C.V.](#) (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 31, 2016, and incorporated herein by reference).
- 10.10† [Amendment Agreement to Acquisition Option dated October 27, 2016, by and between More Pharma Corporation S. de R.L. de C.V. and Oculus Technologies of Mexico, S.A. de C.V.](#) (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed October 31, 2016, and incorporated herein by reference).
- 10.11 [2016 Equity Incentive Plan](#) (included as exhibit A in the Company's Definitive Proxy Statement on Schedule 14A filed July 29, 2016, and incorporated herein by reference).
- 10.12 [Securities Purchase Agreement entered into by and between Sonoma Pharmaceuticals, Inc. and Montreux Equity Partners V, L.P., dated March 1, 2018](#) (included as exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 6, 2018, and incorporated herein by reference).
- 10.13† [Exclusive License and Distribution Agreement entered into by and between Sonoma Pharmaceuticals, Inc. and EMS.S.A., dated June 4, 2018](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 5, 2018, and incorporated herein by reference).

- 10.14 [Warrant Agency Agreement entered into by and among Sonoma Pharmaceuticals, Inc., Computershare, Inc. and Computershare Trust Company, N.A., dated November 21, 2018](#) (included as exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 21, 2018, and incorporated herein by reference).
- 10.15+ [Asset Purchase Agreement dated May 14, 2019, between Sonoma Pharmaceuticals, Inc. and Petagon, Ltd.](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 22, 2019, and incorporated herein by reference).
- 10.16+ [Asset Purchase Agreement dated February 21, 2020, between Sonoma Pharmaceuticals, Inc. and MicroSafe Group, DMCC](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 27, 2020, and incorporated herein by reference.)
- 10.17+ [License, Distribution and Supply Agreement by and between Sonoma Pharmaceuticals, Inc. and Brill International, S.L. dated May 19, 2020](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 26, 2020, and incorporated herein by reference.)
- 10.18 [Consulting Agreement between the Company and Dr. Robert Northey, dated May 30, 2020.](#) (included as exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 4, 2020, and incorporated herein by reference.)
- 10.19+ [Asset Purchase Agreement between the Company and Infinity Labs SD, Inc., dated June 24, 2020](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 30, 2020, and incorporated herein by reference.)
- 10.20+ Woodstock Lease Agreement between the Company and Fowler Crossing Partners, LP, dated October 1, 2018.
- 10.21 [Licensing Agreement between Sonoma Pharmaceuticals, Inc. and MicroSafe Group, effective July 27, 2020](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 6, 2020, and incorporated herein by reference).
- 10.22 [Licensing and Distribution Agreement between Sonoma Pharmaceuticals, Inc. and Gabriel Science, LLC, effective December 14, 2020](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 17, 2020, and incorporated herein by reference).
- 10.23 [Exclusive Supply and Distribution Agreement between the Company and EMC Pharma, LLC, dated March 26, 2021](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 31, 2021, and incorporated herein by reference).
- 10.24 [Employment Agreement by and between the Company and Amy Trombly, dated July 1, 2021](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 6, 2021, and incorporated herein by reference).
- 10.25 [Employment Agreement by and between the Company and Jerry Dvonch, dated July 1, 2021](#) (included as exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 6, 2021, and incorporated herein by reference).
- 10.26 [Employment Agreement by and between the Company and Bruce Thornton, dated July 1, 2021](#) (included as exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 6, 2021, and incorporated herein by reference).
- 10.27 [At-The-Market Offering Agreement, by and between the Company and H.C. Wainwright & Co., LLC, dated July 30, 2021](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 30, 2021, and incorporated herein by reference).
- 10.28 2021 Equity Incentive Plan (included as appendix on the Company's proxy statement filed on July 29, 2021 and incorporated herein by reference).
- 10.29+ [Exclusive License and Distribution Agreement between the Company and Dyamed Biotech Pte Ltd., dated November 4, 2021](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 9, 2021, and incorporated herein by reference).
- 10.30+ [Non-Exclusive Distribution and Supply Agreement between the Company and Salus Medical, LLC dated January 19, 2022](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 20, 2022, and incorporated herein by reference).

- 10.31+4 [Exclusive License and Distribution Agreement between Sonoma Pharmaceuticals, Inc. and Anlicare International dated January 18, 2022](#) (included as exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 20, 2022, and incorporated herein by reference).
- 14.1 [Code of Business Conduct](#) (included as Exhibit 14.1 to the Company's Current Report on Form 8-K filed on January 23, 2017, and incorporated herein by reference).
- 21.1 [List of Subsidiaries](#) (included as Exhibit 21.1 to the Company's Annual Report on Form 10-K on June 28, 2017, and incorporated herein by reference).
- 23.1* [Consent of Frazier and Deeter independent registered public accounting firm.](#)
- 23.2* [Consent of Marcum LLP independent registered public accounting firm.](#)
- 31.1* [Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 31.2* [Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1* [Certification of Officers pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)

- 101.INS* XBRL Instance Document.
- 101.SCH* XBRL Taxonomy Extension Schema.
- 101.CAL* XBRL Taxonomy Extension Calculation Linkbase.
- 101.DEF* XBRL Taxonomy Extension Definition Linkbase.
- 101.LAB* XBRL Taxonomy Extension Label Linkbase.
- 101.PRE* XBRL Taxonomy Extension Presentation Linkbase.

- * Filed herewith.
- † Confidential treatment has been granted with respect to certain portions of this agreement.
- + Certain portions of the exhibit have been omitted to preserve the confidentiality of such information. The Company will furnish copies of any such information to the SEC upon request.
- + The schedules to the exhibit have been omitted from this filing pursuant to Item 601(a)(5) of Regulation S-K. The Company will furnish copies of any such schedules to the SEC upon request.

Copies of above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Sonoma Pharmaceuticals, Inc., 645 Molly Lane, Suite 150, Woodstock, Georgia, 30189.

(c) Financial Statements and Schedules

Reference is made to Item 15(a)(2) above.

ITEM 16. Form 10-K Summary.

None.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Sonoma Pharmaceuticals, Inc. on Form S-3 (File No. 333-221477), Form S-8 (333-262144), Form S-8 (File No. 333-228898), Form S-8 (File No. 333-219058), Form S-8 (File No. 333-214760), Form S-8 (File No. 333-205171), Form S-8 (File No. 333-171412), Form S-8 (File No. 333-182263), Form S-8 (File No. 333-195530), Form S-8 (File No. 333-194314), Form S-8 (File No. 333-163988) and Form S-3 (File No. 333-250925) of our report dated July 13, 2022, which includes an explanatory paragraph as to the company's ability to continue as a going concern with respect to our audit of the consolidated financial statements of Sonoma Pharmaceuticals, Inc. and Subsidiaries as of March 31, 2022 and for the year then ended, which report is included in this Annual Report on Form 10-K of Sonoma Pharmaceuticals, Inc. for the year ended March 31, 2022.

/s/ Frazier & Deeter, LLC

Atlanta, Georgia
July 13, 2022

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Sonoma Pharmaceuticals, Inc. on Form S-3 (File No. 333-221477), Form S-8 (333-262144), Form S-8 (File No. 333-228898), Form S-8 (File No. 333-219058), Form S-8 (File No. 333-214760), Form S-8 (File No. 333-205171), Form S-8 (File No. 333-171412), Form S-8 (File No. 333-182263), Form S-8 (File No. 333-195530), Form S-8 (File No. 333-194314), Form S-8 (File No. 333-163988) and Form S-3 (File No. 333-250925) of our report dated July 14, 2021, which includes an explanatory paragraph as to the company's ability to continue as a going concern with respect to our audit of the consolidated financial statements of Sonoma Pharmaceuticals, Inc. and Subsidiaries as of March 31, 2021 and for the year then ended, which report is included in this Annual Report on Form 10-K of Sonoma Pharmaceuticals, Inc. for the year ended March 31, 2022.

/s/ Marcum LLP

Marcum LLP
New York, NY
July 13, 2022

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

I, Amy Trombly, certify that:

1. I have reviewed this annual report on Form 10-K of Sonoma Pharmaceuticals, Inc. for the year ended March 31, 2022;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 13, 2022

By: /s/ Amy Trombly
Amy Trombly
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

I, Jerome Dvonch, certify that:

1. I have reviewed this annual report on Form 10-K of Sonoma Pharmaceuticals, Inc. for the year ended March 31, 2022;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 13, 2022

By: /s/ Jerome Dvonch
Jerome Dvonch
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officers of Sonoma Pharmaceuticals, Inc., a Delaware corporation (the "Company"), do hereby certify, to such officers' knowledge, that:

The Annual Report on Form 10-K for the year ended March 31, 2022 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 13, 2022

By: /s/ Amy Trombly
Amy Trombly
Chief Executive Officer
(Principal Executive Officer)

Date: July 13, 2022

By: /s/ Jerome Dvonch
Jerome Dvonch
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)