

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, 2019

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

(State or other jurisdiction of incorporation or organization)

68-0423298

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

1129 N. McDowell Blvd.
Petaluma, California 94954
(Address of principal executive offices) (Zip Code)

(707) 283-0550
(Registrant's telephone number, including area code)

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

Common Stock, \$0.0001 par value
Warrants (expiring January 26, 2020)
(Title of Each Class)

SNOA
SNOAW
(Trading Symbol(s))

The Nasdaq Stock Market LLC
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 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 28, 2018, was \$9,056,417 based on a total of 689,225 shares of the registrant’s common stock held by non-affiliates on September 28, 2018, at the closing price of \$13.14 per share, as reported on the Nasdaq Capital Market.

There were 1,328,891 shares of the registrant’s common stock issued and outstanding on June 28, 2019.

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 2019 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.

Our principal executive offices are located at 1129 N. McDowell Blvd., Petaluma, California, 94954. 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 (707) 283-0550. Our website is www.sonomapharma.com. The website and any information contained therein or connected thereto is not intended to be incorporated into this report.

Overview

We are a specialty pharmaceutical company dedicated to identifying, developing and commercializing unique, differentiated therapies to millions of patients living with chronic skin conditions. We offer early-intervention relief with virtually no side-effects or contraindications. We believe our products, which are sold throughout the United States and internationally, have improved patient outcomes for more than six million patients by treating and reducing certain skin diseases including acne, atopic dermatitis, scarring, infections, itch, pain and harmful inflammatory responses. Our vision is to be a catalyst for improved care and increased access for all patients.

Business update

In December 2018, our former Chief Executive Officer and Chief Financial Officer resigned and we hired Bubba Sandford as Chief Executive Officer and Interim Chief Financial Officer. During his first three months in office, Mr. Sandford identified and implemented significant cost-cutting measures, including right-sizing the administrative headcount. While we incurred severance costs in this process, we believe the Company is set up for future success. We also are looking at streamlining and improving our production processes while creating efficiencies across the Company. Some of these measures showed early success in the first quarter of 2019 and we believe we will continue to show additional progress in our results of operations in fiscal year 2020. As part of the reorganization of Sonoma, in May 2019 we sold certain of our animal health product rights and assets for the Asian and European markets for \$2.7 million. This is part of our strategic decision to focus on our core business of U.S. dermatology.

During fiscal year ended March 31, 2019 and through June 20, 2019, we achieved several milestones;

- Total revenues increased by 14% from \$16.7 million in fiscal year 2018 to \$19.0 million in fiscal year 2019;
- Launched Epicyn™, a prescription topical cleanser which helps achieve clear skin and provide relief from irritation when used as part of a daily skin care regimen for patients with acute and chronic dermal lesions;
- Right sized work force to fit current company needs; and
- Sold certain animal health product rights and assets for the Asian and European markets to Petagon, Limited for \$2.7 million.

Business Channels

Our core market differentiation is based on being the leading developer and producer of stabilized hypochlorous acid, or HOCl, solutions. 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.

Our core market includes patients who suffer from various skin diseases, including dermatoses, acne, scarring, skin-barrier and scaly skin conditions. Our secondary market includes eye-hygiene and acute care markets. These conditions impact patients worldwide who have had to live with less than optimal solutions or ones that come with significant side-effects. Skin conditions can have significant, multi-dimensional effects on quality of life, including on patient's physical, functional and emotional well-being.

We have also built on our HOCl technology foundation by adding two complementary technology platforms: Lipogrid® Skin Barrier solutions and Exuvimax™ Skin de-scaling solutions. Lipogrid is a lipid structural matrix of solid lipid particles and vesicles containing phospholipids, ceramides, fatty acids and cholesterol-type stabilizers that deliver building blocks to the dermis and protect the skin. Exuvimax contains a combination of dicaprylyl carbonate (Cetiol® Oil) and dimethicones that provide a patented formulation designed for a very effective but safe keratolytic effect which is the shedding of the top layer of skin. Our product Loyon® is based on the Exuvimax technology and its key benefit is to remove scale and therefore allow the topical treatments to work more effectively and faster on the underlying condition.

Dermatology

In the United States, we sell into dermatology markets with an in-house sales team that visits or calls dermatologists. Our dermatology products are primarily purchased by distributors, wholesalers, and pharmacies.

Although specific customer requirements can vary depending on applications, customers generally demand quality, innovation, affordability and clinically-supported efficacy. We have responded to these customer demands by introducing new products that treat persistent and common dermatological afflictions, as well as promote healing and improve results for patients opting for cosmetic dermatology procedures. 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.

We seek to extend and expand our strong ongoing relationships with customers through new products, sales of existing products, ongoing training and support, and distribution of skincare products. We primarily target practitioners through office visits, workshops, trade shows, webinars and trade journals. We also market to potential patients through brochures, workshops and websites. In addition, we offer clinical forums with recognized expert panelists to promote advanced treatment.

Eye Care and Advanced Tissue Care

Our eye care and advanced tissue care products provide patients similar benefits to those in dermatology. We support the eye care and advanced tissue care markets with a dedicated in-house sales force and through an inside call center. We have also entered into strategic partnerships with respected and influential physicians and surgeons to promote our products. Our eye care products include prescription and dispensing solutions prescribed mainly by ophthalmologists and optometrists supported by pharmacies and, in some cases, sold through wholesale networks. Our tissue care products are primarily purchased by hospitals, physicians, nurses, and other healthcare practitioners.

Animal Health Care

Our animal healthcare products provide similar benefits to those in human dermatology. 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, farm animal veterinarians, grocery stores and mass retailers in the United States and Canada.

On May 20, 2019, we sold certain animal health product rights and assets for the Asian and European markets to Petagon, Limited, an international importer and distributor of quality pet food and products. The purchase price for the assets is \$2,700,000. We agreed that we will continue to supply products to Petagon for five years at certain agreed upon transfer prices. The sale involves certain Asian patents and trademarks and the exclusive right to distribute animal health care products in Asia and Europe.

International

We sell products internationally through a worldwide distributor network in 48 countries. In these international markets, we have a network of partners, ranging from country specific distributors to large pharmaceutical companies and to full-service sales and marketing companies.

Europe

We rely on agreements with country-specific distributors for the sale of products in Europe, 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.

Mexico

On October 27, 2016, we sold certain parts of our Latin American business to Invekra S.A.P.I de C.V., an affiliate of Laboratorios Sanfer, with the ability of Invekra to set up its own manufacturing using some of our know-how and technology. During a transitional time period, we will provide technical assistance and supply products to Invekra at a reduced price from current list prices. We expect that revenues will decrease and cease if Laboratorios Sanfer begins to manufacture its own product. We are also entitled to receive a royalty of \$2,500,000 to be paid in Mexican currency in quarterly installments over a period of ten years from closing as consideration for the provision of certain services and providing technical assistance, calculated as three per cent on net sales of certain products in Latin America, excluding Mexico. Since the \$2,500,000 is to be paid in foreign currency, we may receive more or less than \$2,500,000 due to currency fluctuations. During the year ended March 31, 2019, we received royalties of \$250,000.

Rest of the World

Throughout the rest of the world, we use strategic partners and distributors for the sale of products into Brazil, South Korea, Japan, the People's Republic of China, Singapore, Taiwan, Malaysia, Indonesia, the Philippines, India, Bangladesh, Sri Lanka, Australia, New Zealand, Thailand, United Arab Emirates, Saudi Arabia, Kuwait, Bahrain, South Africa, Jordan and Lebanon.

On June 4, 2018, we entered into a 5-year exclusive license and distribution agreement with EMS S.A., headquartered in Sao Paulo, Brazil. Pursuant to the license and distribution agreement with EMS, we granted EMS the exclusive right to purchase, import, distribute, sell and promote certain of our dermatology products within Brazil for a period of five years, with the possibility of renewal. We also agreed to assign our trademarks filed or registered in Brazil to EMS on a royalty-free basis for the purpose of marketing, distributing, and selling our products in Brazil. EMS agreed to minimum annual purchase amounts of \$100,000 in year one; \$250,000 in year two; \$500,000 in year three; \$750,000 in year four; and \$1,000,000 in year five, respectively. During the year ended March 31, 2019, EMS purchased \$586,000 of our products, exceeding the year one minimum annual purchase amount.

Employees

As of March 31, 2019, we employed a total of 62 full-time employees and one part-time employee in the United States and the Netherlands. Additionally, we had 191 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.

U.S. Products

U.S. Dermatology - Epicyn™ Antimicrobial Facial Cleanser



- 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.

U.S. Dermatology - Levicyc™ Dermal Spray, Antipruritic Spray Gel, and Antipruritic Gel (formerly Alevicyc)



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

U.S. Dermatology - Celacyn® Scar Management Gel



- Celacyn® offers scar management.
- 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.

U.S. Dermatology - SebuDerm™ Topical Gel



- SebuDerm™ offers fast itch and pain relief.
- SebuDerm™ is a HOCl-based topical prescription product indicated to manage and relieve the burning, itching, pain and distraction associated with seborrhea and seborrheic dermatitis.

U.S. Dermatology - Ceramax™ – Skin Barrier Cream



- Ceramax™ helps manage dry, itchy skin.
- Ceramax™ is a Lipogrid® based topical prescription skin barrier cream indicated to relieve and manage the burning and itching associated with various skin conditions, including atopic dermatitis, and other dry skin conditions.

U.S. Dermatology - Mondoxyne™ – Oral Antibiotic



- Mondoxyne™ helps manage acne.
- Mondoxyne™ is a doxycycline-based prescription oral tetracycline antibiotic that contain a broad spectrum antibacterial synthetically derived from oxytetracycline, the second of the broad-spectrum tetracycline group of antibiotics to be discovered, used as a treatment for acne vulgaris.

U.S. Dermatology - Loyon®



- Loyon® for the management of scaling and itch.
- LOYON® is indicated to manage and relieve the itching, erythema, and scaling experienced with various types of dermatoses, including seborrhea and seborrheic dermatitis.

U.S. Eye Care - 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.

U.S. Wound Care - Microcyn® Advanced Tissue 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.

U.S. Animal Health – MicrocynAH® (retail) / MicrocynVS (veterinarian)



- MicrocynAH® and MicrocynVS offer enhanced healing properties for animals.
- MicrocynAH® and MicrocynVS® are HOCl-based 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

International Products

Pediacyc™, Epicyn™, Gramaderm™, Microdacyn®



- Outside the United States, we sell mainly advanced tissue care and dermatology solutions.
- Pediacyc™, Epicyn™ and Gramaderm™ offer relief for dermatoses, scar management and acne respectively.
- Microdacyn® offers enhanced wound healing properties.
- We partner with distributors in Europe, Brazil and Asia for the sale of our products.



Research and Development

Research and development expense consists primarily of personnel expenses, clinical and regulatory services and supplies. For the years ended March 31, 2019 and 2018, research and development expense amounted to \$1,518,000 and \$1,575,000, respectively. None of these expenses were borne by our customers.

Manufacturing and Packaging

We manufacture products at facilities in Petaluma, California and Zapopan, Mexico. 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 United States 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.

We believe we own a sufficient number of machines 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.

International Regulatory Approvals and Clearances

Outside the United States, we sell products for dermatological and advanced tissue care with a European Conformity marking, Conformité Européenne, or CE. These CEs cover 25 products in 47 countries with various approvals in Brazil, China, Southeast Asia, South Korea, India, Australia, New Zealand, and the Middle East.

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

Brand	Approval Type	Year of Approval	Summary Indication
Loyon®	U.S. 510(k)	2017	Intended to manage skin scaling experienced with various types of dermatoses.
Lasercyn™	U.S. 510(k)	2016	Indicated for the management of 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.
	EU CE Mark	2016	
MucoClyns™	EU CE Mark	2016	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	2016	Solution intended for nasal irrigation, including the moistening of cuts, abrasions and lacerations located in the nasal cavity.
Ceramax™ Skin Barrier Cream	U.S. 510(k)	2015	Management of dry itchy skin, minor skin irritations, rashes, and inflammation caused by various skin conditions based on patented Lipogrid® Technology.
Sebuderm™ Topical Gel	U.S. 510(k)	2015	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®	U.S. 510(k)	2013	As hydrogel for the management of old and new hypertrophic and keloid scarring resulting from burns, general surgical procedures and trauma wounds.
Alevicyn™	U.S. 510(k)	2011	As hydrogel for the management and relief of burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis and radiation dermatitis.
	EU CE Mark	2013	
Epicyn™	U.S. 510(k)	2011	Manages and relieves itching, burning and pain experienced with various types of dermatoses, including atopic dermatitis, first- and second-degree burns. Indicated as an adjuvant in the wound healing process with wounds that can only heal by secondary intention in maturation phase. Epicyn™ is effective for the management and reduction of new and existing hypertrophic and keloid scars.
	EU CE Mark	2013	
Gramaderm®	EU CE Mark	2013	As a dermatological solution or hydrogel for the topical treatment of mild to moderate acne.
Microcyn™ Antimicrobial Hydrogel	U.S. 510(k)	2018	Manages minor skin irritations following post non ablative laser therapy procedures, post microdermabrasion therapy or superficial chemical peels. Relieves itch and pain from minor skin irritations, lacerations, abrasions, and minor burns.
Microcyn™ Antimicrobial Skin and Wound Cleanser	U.S. 510(k)	2017	Cleansing, irrigation, moistening, debridement and removal of foreign material from wounds, including stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first- and second-degree burns, grafted and donor sites as preservative, abrasions, minor irritations of the skin.

Significant Customers

We rely on certain key customers for a significant portion of revenues. In the US, our key customers are pharmaceutical wholesalers, independent pharmacies, including AmerisourceBergen, McKesson and Cardinal, that purchase our products and resell to retail pharmacies like CVS, Walgreens and Walmart. At March 31, 2019, no customer represented more than 10% of the net accounts receivable balance. For the year ended March 31, 2019, one customer represented 18%, and one customer represented 10% of net revenues. At March 31, 2018, one customer represented 36%, and one customer represented 18% of the net accounts receivable balance. For the year ended March 31, 2018, one customer represented 22%, one customer represented 19%, one customer represented 13%, and one customer represented 12% of net revenues.

Contract Testing

We also operate a microbiology contract testing laboratory division that provides consulting and laboratory services to medical companies that design and manufacture biomedical devices and drugs, as well as testing our current and potential products. This testing laboratory complies with U.S. Current Good Manufacturing Practices and Quality Systems Regulations.

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 technology, inventions and improvements that are important to the business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain a proprietary position.

As of June 13, 2019, we own a total of 76 issued patents, consisting of 15 issued U.S. patents and 61 issued foreign patents. We also have 17 pending U.S. and foreign patent applications. All patent applications as well as issued patents are directed at our HOCl technology. The issued U.S. and foreign patents expire in 2022-2029.

In addition to our patents and applications, there is licensed technology developed in Japan relating to an electrolyzed water solution, methods of manufacture and electrolytic cell designs. This license includes three issued Japanese patents.

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 four main channels: dermatology, eye care, advanced tissue care and animal health with three main technology platforms: Stabilized Hypochlorous Acid, also referred to as HOCl Fast-Relief Technology, Lipogrid® Skin-Barrier Technology and Exuvimax™ Scale-Removal 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.

Advanced Tissue Care Markets

Similar to our dermatology products, our HOCl-based advanced tissue care solutions provide improved efficacy at low 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 the competitors in the dermatology, advanced tissue care markets and animal health care 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.

Health Information Privacy and Security

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 25 of its 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.

We reported a loss from continuing operations of \$11,798,000 and \$14,328,000 for the years ended March 31, 2019 and 2018, respectively. At March 31, 2019 and 2018, our accumulated deficit amounted to \$169,238,000 and \$157,440,000, respectively. We had working capital of \$8,905,000 and \$12,933,000 as of March 31, 2019 and 2018, respectively. During the year ended March 31, 2019 and 2018, net cash used in operating activities amounted to \$11,717,000 and \$12,439,000, respectively. As of March 31, 2019, we had cash and cash equivalents of \$3,689,000. We expect to continue incurring losses for the foreseeable future and may never achieve or sustain profitability.

Our accounts receivable, net increased from fiscal year 2018 to fiscal year 2019 and if we do not manage our accounts receivables our ability to generate revenue may be diminished.

We reported accounts receivable, net of \$3,481,000 and 1,537,000 as of March 31, 2019 and 2018, respectively. We periodically review our 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. If we do not manage our accounts receivable, our ability to generate revenue may be diminished. This could have a material adverse effect on our revenues, financial position, cash flows and results of operations.

Our ability to generate revenue will be diminished if we are unable to obtain acceptable prices or an adequate level of reimbursement from third-party payors, or if the number of people with insurance were to drop significantly.

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. In addition, our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or group purchasing organizations, as these payors continue to reduce costs, may significantly affect our future revenue and profitability. 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. Our 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.

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 ability to sell our products profitably. These cost reduction initiatives and legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, became law in the United States. The PPACA, among others, has mandated higher Medicaid rebates, expanded the rebate to Medicaid managed care utilization, established annual fees and tax fees for certain pharmaceutical companies, and increased the types of entities eligible for the federal drug discount program. The effects of recently proposed changes to the PPACA are difficult to predict and could adversely affect our business. However, if the number of insured people were to decrease significantly it could have a material adverse effect on our sales of products and our business operations.

Additionally, many states have proposed legislation that seeks to regulate pharmaceutical drug pricing by way of public disclosure or by placing price ceilings on products. If such legislation is passed, it may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our HOC1 based solutions or products.

We expect to experience pricing pressures in connection with the sale of our dermatological products, due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

We face pricing pressure from private third-party payers, including our customers, from rebates and restrictive reimbursement practices.

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 with us, reviewing and adjusting the rate of reimbursement, or imposing limitations on coverage. A high number of concessions or reductions in reimbursement could have a material adverse effect on our revenues, financial position, cash flows and results of operations.

Our ability to generate revenue will be diminished if we are unable to manage customer product substitutions.

Similar to other pharmaceutical companies, our customers are increasingly seeking lower-cost substitutes to our products. Even if our customers 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 customer is seeking to treat. As a result, the customer may choose to abandon purchasing our prescribed product for a less expensive alternative product resulting in a lost sale for us. If the number of customers substituting our products increases, it will have a material adverse effect on our revenues, financial position, cash flows and results of operations.

Because our revenues from the Latin American assets sold to Invekra on October 27, 2016 represented a significant portion of our reported total consolidated revenues during the fiscal years ended March 31, 2019 and 2018, our business following the sale transaction may be substantially reduced and less diversified.

Our revenues from our Latin American business that we sold to Invekra on October 27, 2016, were \$3,376,000 and \$3,007,000 for the years ended March 31, 2019 and 2018, respectively. We will continue to supply products at a reduced price from list prices to Invekra pursuant to our contractual obligations for a transition period until, at the latest, October 27, 2020, while Invekra builds its own manufacturing lines. However, we expect that our future revenues from Latin American sales will be substantially reduced which may adversely affect our results of operations and financial condition. We are also entitled to receive a royalty of \$2,500,000 to be paid in Mexican currency in quarterly installments over a period of ten years from closing as consideration for the provision of certain services and providing technical assistance, calculated as three per cent on net sales of certain products in Latin America, excluding Mexico. Since the \$2,500,000 is to be paid in foreign currency, we may receive more or less than \$2,500,000 due to currency fluctuations. During the year ended March 31, 2019, we received royalties of \$250,000. We intend to use the proceeds from the sale of the assets to grow our U.S. dermatology business. However, we may encounter unanticipated difficulties or challenges as we continue to develop our U.S. dermatology business and internal sales force. We may not be able to grow our dermatology business fast enough to offset the loss of revenue from Latin American sales, or at all. If we are unable to increase our dermatology revenues or international sales, our results of operations and financial condition may be adversely affected.

Our dermatology sales may be subject to seasonal fluctuations.

Sales of our dermatological products depend in part on the type of insurance coverage of patients. With the decrease of managed care plans and the rise of high-deductible insurance plans, we have experienced slower sales for our dermatological products in the beginning of the calendar year or the first quarter of each calendar year, our fourth fiscal quarter. This is due to insurance deductibles being reset at the beginning of each new calendar year and changing copays and patients deciding to withhold purchases of our products. Fluctuations may negatively affect our business and results of operations.

If we are unable to retain our direct domestic sales force, we may not be able to successfully sell our products in the United States.

We currently use a direct sales force to sell our products in the dermatology markets. Our domestic sales force competes with the sales operations of our competitors, which are better funded and more experienced. We may not be able to expand or retain our domestic sales capacity on a timely basis, or in the markets that we desire, or at all.

Our Petaluma facility is vulnerable to natural disasters and other unexpected events, any of which could result in an interruption in our business and harm to our operating results.

A disruption or failure of our business and operations because of a major earthquake, weather event, cyber-attack, or other catastrophic event could disrupt or cause delays in performing critical functions of our business. Our corporate headquarters, a portion of our research and development activities, substantially all of our U.S. manufacturing, and other essential business operations are in Petaluma, California.

We suffered flooding of our Petaluma facility over 10 years ago, which led to a shutdown of our manufacturing facilities for 12 months. Also, in late 2016, heavy rain nearly caused flooding of our facility. A catastrophic event that results in the destruction or disruption of any of our critical business or manufacturing could harm our ability to conduct normal business operations. If any of these events result in damage to our facilities or systems, we may experience interruptions in our business until the damage is repaired, resulting in the potential loss of customers and revenues. Additionally, we may incur costs in repairing any damage beyond our applicable insurance coverage. While we have taken precautions against flooding, we cannot assure that heavy rain will not cause significant disruption to our business. We have also obtained flood and business interruption insurance, but such insurance may not cover all expenses associated with a natural disaster or the complete shut-down of our Petaluma facility. We are currently looking to move to new facilities after our lease ends, and are also considering expanding our manufacturing facilities in Mexico. Moving our manufacturing facility is a lengthy and expensive process due to getting all necessary FDA approvals.

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 HOC1.

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 HOC1, 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 HOC1. Such similar products marketed by larger competitors can hinder our 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 depend on third parties 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 have a direct sales force, which sells our products in the tissue care and dermatology markets, and we use distributors for sales in the animal health care market.

To penetrate our target markets, we may need to enter into additional collaborative agreements to assist in the development and commercialization of products. For example, depending upon our analysis of the time and expense involved in obtaining FDA approval to sell a product to treat open wounds, we may choose to license our technology to a third party as opposed to pursuing commercialization ourselves, or in-license technologies that complement our 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. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborations or potential products. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators 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. 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.

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, 2019, one customer represented 18%, and one customer represented 10% of net revenues. For the year ended March 31, 2018, one customer represented 22%, one customer represented 19%, one customer represented 13%, and one customer represented 12% 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, 2019, no customer represented more than 10% of the net accounts receivable balance. At March 31, 2018, one customer represented 36%, and one customer represented 18% of the 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.

Although we have filed several U.S. and foreign patent applications related to our HOC1-based products, the manufacturing technology for making the products, and their uses, only 15 U.S. patents have been issued from these applications to date.

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 operate in the State of California. The laws of California prevent us from imposing a delay before an employee, who may have access to trade secret and propriety know-how, can commence employment with a competing company. Although we may be able to pursue legal action against competitive companies improperly using our proprietary information, we may not be aware of any use of our trade secrets and proprietary know-how until after significant damages has been done to our Company.

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.

A significant part 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 and Europe. During the years ended March 31, 2019 and 2018, approximately 49% and 47% of our total product related 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;
- 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 and the United States. 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 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. If trade policies or trade agreements, such as the North American Free Trade Agreement, or NAFTA, were to change unfavorably, or protectionist measures or tariffs were enacted, our business, financial condition and results of operations could be adversely affected.

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 loss of key members of our senior management team, any of our directors, or our highly skilled scientists, technicians and salespeople could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team, including Bubba Sandford, our Chief Executive and Interim Chief Financial Officer. The efforts of these people will be critical to us as we continue to develop our products and attempt to commercialize products in the tissue and dermatology markets. If we were to lose one or more of these individuals, we might experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among medical technology businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified personnel. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in dermatology or in the markets we seek, and who have close relationships with the medical community, including physicians and other medical staff. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our products. If we are unable to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our research, development and sales programs.

The dermatology, tissue and animal healthcare industries 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 drug candidates and for a number of our potential products because of the expense, effort and expertise required to conduct additional 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.

We currently have significant “equity overhang” which could adversely affect the market price of our common stock and impair our ability to raise additional capital through the sale of equity securities in the future.

We currently have significant “equity overhang.” The possibility that substantial amounts of our common stock may be issued to and then sold by investors, or the perception that such issuances and sales could occur, often called “equity overhang,” could adversely affect the market price of our common stock and could impair our ability to raise additional capital through the sale of equity securities in the future. The consummation of the exercise of warrants for common stock would significantly increase the number of issued and outstanding shares of our common stock.

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, 2019, we had outstanding warrants exercisable for an aggregate of 462,000 shares of our common stock at a weighted average exercise price of approximately \$10.10 per share. In addition, as of March 31, 2019, options to purchase an aggregate of 165,000 shares of our common stock were outstanding at a weighted average exercise price of approximately \$8.09 per share and a weighted average contractual term of 7.48 years. We also had outstanding shares of preferred stock exercisable for an aggregate amount of 17,222 shares of our common stock. In addition, 343,000 shares of our common stock were available on March 31, 2019 for future option grants under our 2011 Stock Incentive Plan and 2016 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

We currently lease the following material properties:

Location	Rent per month	Purpose
1129 North McDowell Blvd., Petaluma, CA 94954, USA	USD 11,072	Principal executive office, also used for research and manufacturing
Industria Vidriera 81, Zapopan Industrial Norte, Zapopan, Jalisco, 45135, Mexico	MXN 113,543	Office, manufacturing
Industria Maderera 124 & 106 & 815 Zapopan Industrial Norte, Zapopan, Jalisco, 45135, Mexico	MXN 141,506	Warehouse

As we expand, we may need to establish manufacturing facilities in other countries. 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. The warrants we issued in connection with our January 2015 offering are traded on The Nasdaq Capital Market under the symbol "SNOAW" since January 21, 2015.

Holders

As of June 28, 2019, we had approximately 303 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 unregistered securities during the quarter ended March 31, 2019.

Issuer Purchases of Equity Securities

There were no repurchases made by us or on our behalf, or by any "affiliated purchaser," of shares of our common stock during the quarter ended March 31, 2019.

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 have also adopted certain policies with respect to our recognition of revenue that we believe are consistent with the guidance provided under Securities and Exchange Commission Staff Accounting Bulletin No. 104.

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 Operations

Comparison of the Year Ended March 31, 2019 and 2018

Total revenues for the year ended March 31, 2019 of \$18,970,000 increased by \$2,312,000, or 14%, as compared to \$16,658,000 for the year ended March 31, 2018. Product revenues for the year ended March 31, 2019 of \$17,881,000 increased by \$2,218,000, or 14%, as compared to \$15,663,000 for the year ended March 31, 2018. This increase was primarily the result of growth in product revenue of \$668,000, or 8%, in the United States, growth in product revenue of \$955,000, or 32%, in Latin America, and growth of product revenue of \$595,000, or 14%, in Europe and Rest of World.

Product revenues in the United States for the year ended March 31, 2019 of \$9,040,000 increased by \$668,000, or 8%, as compared to \$8,372,000 for the year ended March 31, 2018. This increase was primarily the result of an increase of \$631,000, or 74%, in sales of our animal health care products, and an increase of \$173,000, or 10%, in sales of our acute care products. Our dermatology sales were flat year over year.

As a result of the asset purchase agreement and arrangement we entered into on October 27, 2016 with Invekra, we will continue to supply Invekra with product at a reduced price until they set up their manufacturing facility. We expect our revenues in Latin America will decrease significantly once Invekra has set up their manufacturing facility. During the year ended March 31, 2019, we reported \$3,376,000 of Latin America product revenue related to Invekra as compared to \$3,007,000 during the year ended March 31, 2018. Additionally, we reported \$586,000 of Latin America product revenue related to dermatology products sold in Brazil exceeding the year one minimum purchase amount of \$100,000.

Product revenue in Europe and the Rest of the World for the year ended March 31, 2019 of \$4,879,000 increased by \$595,000, or 14%, as compared to \$4,284,000 for the year ended March 31, 2018. This increase was mostly the result increases in Europe product revenue, offset by decreases in Singapore and the Middle East.

The following table shows our product revenues by geographic region:

	<u>Year Ended March 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2019</u>	<u>2018</u>		
United States	\$ 9,040,000	\$ 8,372,000	\$ 668,000	8%
Latin America	3,962,000	3,007,000	955,000	32%
Europe and Rest of the World	4,879,000	4,284,000	595,000	14%
Total	<u>\$ 17,881,000</u>	<u>\$ 15,663,000</u>	<u>\$ 2,218,000</u>	<u>14%</u>

Service revenues for the year ended March 31, 2019 of \$1,089,000 increased by \$94,000, or 9%, when compared to \$995,000 in the prior period. The increase was primarily the result of higher volume of laboratory tests and services in the United States. Additionally, during the year ended March 31, 2019 and 2018, the Company recorded service revenue related to technical services provided to Invekra in the amount of \$56,000 and \$208,000, respectively.

Gross Profit

For the year ended March 31, 2019, we reported total revenues of \$18,970,000 and total cost of revenues of \$10,090,000, resulting in total gross profit of \$8,880,000 or 47% of total revenues, compared to a gross profit of \$7,310,000 or 44% of total revenues, for the same period in the prior year.

For the year ended March 31, 2019, we reported product revenues of \$17,881,000 and cost of product revenues of \$9,334,000, resulting in product gross profit of \$8,547,000, or 48% of product revenues, compared to product gross profit of \$6,944,000, or 45% of product revenues, for the same period in the prior year.

For the year ended March 31, 2019, we reported service revenues of \$1,089,000 and cost of service revenues of \$756,000, resulting in service gross profit of \$333,000, or 31% of service revenues, compared to service gross profit of \$316,000, or 32% of service revenues, for the same period in the prior year.

Research and Development Expense

Research and development expenses for the year ended March 31, 2019 of \$1,518,000 decreased \$57,000, or 4% as compared to \$1,575,000 for the year ended March 31, 2018. As expected, research and development expenses were relatively consistent in the current period as compared to the same period in the prior year.

Selling, General and Administrative Expense

Selling, general and administrative expenses for the year ended March 31, 2019 of \$18,620,000 decreased by \$1,304,000, or 7%, when compared to \$19,924,000 for the year ended March 31, 2018. The decrease in selling, general and administrative expenses was primarily the result of certain cost savings measures implemented during fiscal year 2019. The decrease was offset in part by severance costs of \$881,000 related to a reduction in headcount including the resignations of our former Chief Executive Officer, Chief Financial Officer, and other executive officers as well as a reduction in other selling, general and administrative headcount.

Interest Expense

Interest expense for the year ended March 31, 2019 of \$33,000 decreased \$7,000, or, 18%, when compared to \$40,000 for the year ended March 31, 2018.

Interest Income

Interest income for the year ended March 31, 2019 of \$190,000 decreased by \$68,000, or 26%, when compared to \$258,000 for the year ended March 31, 2018. The decrease is primarily due to interest income reported related to a discount on deferred revenue from our agreement with Invekra.

Other Expense

Other expense for the year ended March 31, 2019 of \$239,000 decreased by \$68,000 when compared to other expense of \$307,000 for the year ended March 31, 2018. The decrease in other expense relates primarily to fluctuations in foreign exchange.

Net Loss

Net Loss for the year ended March 31, 2019 of \$11,798,000 decreased \$2,530,000, or 18% when compared to net loss of \$14,328,000 for the year ended March 31, 2018. The decrease in net loss is primarily due to a decrease in operating loss of \$2,931,000 due to an increase in sales and gross profitability of \$1,570,000. Additionally, we reported a decrease in operating expenses of \$1,361,000 primarily due to certain cost savings measures implemented during fiscal year 2019.

Liquidity and Capital Resources

We reported a net loss of \$11,798,000 and \$14,328,000 for the year ended March 31, 2019 and 2018, respectively. At March 31, 2019 and March 31, 2018, our accumulated deficit amounted to \$169,238,000 and \$157,440,000, respectively. At March 31, 2019 and March 31, 2018, our working capital amounted to \$8,905,000 and \$12,993,000, respectively.

We expect to continue incurring losses for 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.

Sources of Liquidity

As of March 31, 2019, we had cash and cash equivalents of \$3,689,000. 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 Latin American assets to Invekra.

Since April 1, 2017, substantially all of our operations have been financed through the following transactions:

- proceeds of \$52,000 received from the exercise of common stock purchase warrants and options;
- net proceeds of \$1,925,000 received from the sale of common stock through our At Market Issuance Sales Agreement dated December 8, 2017;
- net proceeds of \$4,500,000 received from the sale of common stock through a registered direct offering which closed on March 6, 2018; and
- net proceeds of \$4,743,000 received from the sale of common stock and preferred stock units through a public offering which closed on November 21, 2018.

Cash Flows

As of March 31, 2019, we had cash and cash equivalents of \$3,689,000, compared to \$10,066,000 as of March 31, 2018.

Net cash used in operating activities during the year ended March 31, 2019 was \$11,717,000, primarily due to our net loss of \$11,798,000 offset by stock related compensation of \$1,635,000 in the period. Additionally, we had increases in accounts receivable of \$1,944,000 mostly related to increased sales.

Net cash used in operating activities during the year ended March 31, 2018 was \$12,439,000, primarily due to our net loss of \$14,328,000 offset by stock related compensation of \$2,500,000 in the period. Additionally, we had increases in prepaid expenses of \$1,065,000 mostly related to taxes in Mexico and prepaid rebate costs.

Net cash used in investing activities was \$131,000 for the year ended March 31, 2019, primarily related to the purchase of equipment.

Net cash used in investing activities was \$201,000 for the year ended March 31, 2018, primarily related to the purchase of equipment.

Net cash provided by financing activities was \$5,492,000 for the year ended March 31, 2019, primarily related to net proceeds from the sale of common and preferred stock of \$5,700,000.

Net cash provided by financing activities was \$5,240,000 for the year ended March 31, 2018, primarily related to net proceeds from the sale of common stock of \$5,468,000, proceeds of \$52,000 from the exercise of common stock purchase warrants and options, offset by principal payments on debt and capital leases of \$280,000.

Contractual Obligations

As of March 31, 2019, we had contractual obligations as follows (long-term debt and capital lease amounts include principal payments only):

	Payments Due by Period			
	Total	Less Than 1 Year	1-3 Years	After 3 Years
Long-term debt	\$ 334,000	\$ 322,000	\$ 12,000	\$ —
Capital leases	147,000	147,000	—	—
Operating leases	690,000	438,000	252,000	—
Total	\$ 1,171,000	\$ 907,000	\$ 264,000	\$ —

Operating Capital and Capital Expenditure Requirements

We reported a net loss of \$11,798,000 and \$14,328,000 for the year ended March 31, 2019 and 2018, respectively. At March 31, 2019 and March 31, 2018, our accumulated deficit amounted to \$169,238,000 and \$157,440,000, respectively. At March 31, 2019 and March 31, 2018, our working capital amounted to \$8,905,000 and \$12,993,000, respectively.

We expect to continue incurring losses for 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 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 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.

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

- our current and future revenues;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies.

Material Trends and Uncertainties

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

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 assurances 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 curtail our research and development and other business 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 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.

Consistent with other pharmaceutical companies in the United States, we experience seasonal fluctuations due to patients facing the need to satisfy health insurance deductibles, which are reset at the beginning of each year and adjusting to changing copays.

Healthcare providers and insurers heavily influence the price patients pay for our products. Generally, insurers cover a lower percentage of our products compared to other medical products making our products seem relatively more expensive than other medical care. As a result, to remain competitive, we offer rebates on our products directly to patients. Most patients use these rebates to make our products more affordable. While we believe these rebates are necessary for many patients to buy our products and without them our revenues would likely decline, the impact of rebates on our bottom line has been significant.

We continue to work with healthcare providers, insurers, third-party payors, pharmacies and others to manage pricing of our products to the consumer and to reduce the impact of rebates on our overall revenue. However, there is no guarantee we will be successful in reducing patient rebate use. Additionally, the legal landscape in healthcare is constantly changing. Adoption of new legislation at the federal or state level could further affect demand for, or pricing of, our products. For example, we face uncertainties due to federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Affordable Care Act, or ACA, which could leave more patients without insurance coverage, which, in turn, could reduce the price patients are willing to pay for our products if they must bear the entire cost.

During the year ended March 31, 2019, revenue from sales to our Latin America partner Invekra amounted to approximately 18% of our total revenue. We will continue to supply products to Invekra at a reduced price from list prices, pursuant to our contractual obligations for a transition period until, at the latest, October 27, 2020, while Invekra builds its own manufacturing lines. However, we expect that our future revenues from Latin American sales will be substantially reduced.

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 Financial Statements

We have audited the accompanying consolidated balance sheets of Sonoma Pharmaceuticals, Inc. and Subsidiaries (the "Company") as of March 31, 2019 and 2018, and the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended March 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2019, 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our 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 audits provide a reasonable basis for our opinion.

/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 1, 2019

SONOMA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	March 31	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,689	\$ 10,066
Accounts receivable, net	3,481	1,537
Inventories	3,409	2,865
Prepaid expenses and other current assets	1,694	1,547
Current portion of deferred consideration, net of discount	223	239
Total current assets	<u>12,496</u>	<u>16,254</u>
Property and equipment, net	727	1,136
Deferred consideration, net of discount, less current portion	1,103	1,322
Other assets	122	494
Total assets	<u>\$ 14,448</u>	<u>\$ 19,206</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,255	\$ 1,272
Accrued expenses and other current liabilities	1,501	1,406
Deferred revenue	47	147
Deferred revenue Invekra	55	59
Current portion of long-term debt	322	230
Current portion of capital leases	141	147
Common stock liability (Note 9)	270	-
Total current liabilities	<u>3,591</u>	<u>3,261</u>
Long-term deferred revenue Invekra	356	443
Long-term debt, less current portion	12	32
Long-term capital leases, less current portion	-	144
Total liabilities	<u>3,959</u>	<u>3,880</u>
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Convertible preferred stock, \$0.0001 par value; 714,286 shares authorized at March 31, 2019 and March 31, 2018, respectively, 1.55 shares issued and outstanding at March 31, 2019 and no shares issued and outstanding at March 31, 2018	-	-
Common stock, \$0.0001 par value; 24,000,000 and 12,000,000 shares authorized at March 31, 2019 and March 31, 2018, respectively, 1,316,335 and 685,747 shares issued and outstanding at March 31, 2019 and March 31, 2018, respectively (Note 12)	2	1
Additional paid-in capital	184,074	176,740
Accumulated deficit	(169,238)	(157,440)
Accumulated other comprehensive loss	(4,349)	(3,975)
Total stockholders' equity	<u>10,489</u>	<u>15,326</u>
Total liabilities and stockholders' equity	<u>\$ 14,448</u>	<u>\$ 19,206</u>

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

SONOMA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(In thousands, except per share amounts)

	Year Ended March 31,	
	2019	2018
Revenues		
Product	\$ 17,881	\$ 15,663
Service	1,089	995
Total revenues	<u>18,970</u>	<u>16,658</u>
Cost of revenues		
Product	9,334	8,669
Service	756	679
Total cost of revenues	<u>10,090</u>	<u>9,348</u>
Gross profit	<u>8,880</u>	<u>7,310</u>
Operating expenses		
Research and development	1,518	1,575
Selling, general and administrative	18,620	19,924
Total operating expenses	<u>20,138</u>	<u>21,499</u>
Loss from operations	(11,258)	(14,189)
Interest expense	(33)	(40)
Interest income	190	258
Other expense	(239)	(307)
Loss before income taxes	(11,340)	(14,278)
Income tax expense	(458)	(50)
Net loss	<u>(11,798)</u>	<u>(14,328)</u>
Net loss per share: basic and diluted	<u>\$ (12.77)</u>	<u>\$ (28.49)</u>
Weighted-average number of shares used in per common share calculations: basic and diluted	924	503
Other comprehensive loss		
Net loss	\$ (11,798)	\$ (14,328)
Foreign currency translation adjustments	(374)	203
Comprehensive loss	<u>\$ (12,172)</u>	<u>\$ (14,125)</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, 2019 and 2018
(In thousands, except share amounts)

	Series A 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, April 1, 2017	-	\$ -	476,591	\$ 1	\$ 168,709	\$ (143,101)	\$ (4,178)	\$ 21,431
Cumulative adjustment to April 1, 2017 resulting from adoption of ASU No. 2016-09	-	-	-	-	11	(11)	-	-
Issuance of common stock in connection with December 8, 2017 closing of offering, net of commissions, expenses and other offering costs	-	-	25,333	-	968	-	-	968
Issuance of common stock in connection with March 6, 2018 closing of offering, net of commissions, expenses and other offering costs	-	-	158,730	-	4,500	-	-	4,500
Issuance of common stock upon exercise of common stock purchase warrants	-	-	1,027	-	47	-	-	47
Issuance of common stock upon exercise of common stock options	-	-	100	-	5	-	-	5
Issuance of common stock for service fees	-	-	1,768	-	90	-	-	90
Stock based compensation related to issuance of common stock restricted stock grants	-	-	22,198	-	1,179	-	-	1,179
Stock based compensation, net of forfeitures	-	-	-	-	1,231	-	-	1,231
Foreign currency translation adjustment	-	-	-	-	-	-	203	203
Net loss	-	-	-	-	-	(14,328)	-	(14,328)
Balance March 31, 2018	-	\$ -	685,747	\$ 1	\$ 176,740	\$ (157,440)	\$ (3,975)	\$ 15,326

SONOMA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (continued)
For the Years Ended March 31, 2019 and 2018
(In thousands, except share amounts)

	Series A 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, 2018	—	\$ —	685,747	\$ 1	\$ 176,740	\$ (157,440)	\$ (3,975)	\$ 15,326
Rounding adjustment related to 1-for-9 common stock split, effected June 19, 2019	—	—	(1,442)	—	—	—	—	—
Issuance of common stock in connection with December 8, 2017 At Market Issuance Sales Agreement, net of commissions, expenses and other offering costs	—	—	29,710	—	957	—	—	957
Issuance of common stock and common stock purchase warrants in connection with December 8, 2017 At Market Issuance Sales Agreement, net of commissions, expenses and other offering costs	—	—	507,156	1	3,881	—	—	3,882
Issuance of Series B convertible preferred stock in connection with November 21, 2018 closing of offering, net of commissions, expenses and other offering costs	9.65	—	—	—	861	—	—	861
Conversion of Series B convertible preferred stock into common stock	(8.10)	—	90,000	—	—	—	—	—
Issuance of common stock for service fees	—	—	2,736	—	59	—	—	59
Stock based compensation related to issuance of common stock restricted stock grants	—	—	2,428	—	117	—	—	117
Stock based compensation, net of forfeitures	—	—	—	—	1,459	—	—	1,459
Foreign currency translation adjustment	—	—	—	—	—	—	(374)	(374)
Net loss	—	—	—	—	—	(11,798)	—	(11,798)
Balance, March 31, 2019	1.55	\$ —	1,316,335	\$ 2	\$ 184,074	\$ (169,238)	\$ (4,349)	\$ 10,489

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,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (11,798)	\$ (14,328)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	453	490
Provision for (recovery of) doubtful accounts	(7)	4
Provision for discounts, rebates, distributor fees and returns	(832)	603
Provision for obsolete inventory	77	44
Stock-based compensation	1,635	2,500
Loss on disposal of equipment	21	-
Changes in operating assets and liabilities:		
Accounts receivable	(1,164)	11
Inventories	(779)	(583)
Deferred consideration, net of discount	135	222
Prepaid expenses and other current assets	574	(1,065)
Accounts payable	5	9
Accrued expenses and other current liabilities	115	48
Deferred revenue	(152)	(394)
Net cash used in operating activities	<u>(11,717)</u>	<u>(12,439)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(100)	(187)
Deposits	(31)	(14)
Net used in investing activities	<u>(131)</u>	<u>(201)</u>
Cash flows from financing activities:		
Proceeds from sale of common stock in connection with at market issuances, net of offering costs	957	968
Proceeds from sale of common stock and preferred stock units, net of offering costs	4,743	4,500
Proceeds from exercise of common stock options	-	5
Proceeds from exercise of common stock purchase warrants	-	47
Proceeds from common stock liability	270	-
Principal payments on long-term debt	(154)	(148)
Principal payments on capital leases	(324)	(132)
Net cash provided by financing activities	<u>5,492</u>	<u>5,240</u>
Effect of exchange rate on cash and cash equivalents	(21)	5
Net decrease in cash and cash equivalents	(6,377)	(7,395)
Cash and cash equivalents, beginning of year	10,066	17,461
Cash and cash equivalents, end of year	<u>\$ 3,689</u>	<u>\$ 10,066</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	<u>\$ 33</u>	<u>\$ 40</u>
Non-cash operating and financing activities:		
Insurance premiums financed	\$ 396	\$ 241

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 is located in Petaluma, California. The Company is a specialty pharmaceutical company dedicated to identifying, developing and commercializing unique, differentiated therapies to patients living with chronic skin conditions. The Company believes its products, which are sold throughout the United States and internationally, have improved patient outcomes by treating and reducing certain skin diseases including acne, atopic dermatitis, scarring, infections, itch, pain and harmful inflammatory responses.

Reverse Stock Split

Effective June 19, 2019 5:00 pm EDT, the Company effected a reverse stock split of its common stock, par value \$0.0001 per share. Every nine shares of common stock were reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Instead, each resulting fractional share of common stock was down to one whole share and each fractional share settled with cash. The reverse stock split reduced the number of shares of the Company’s common stock outstanding from 11,972,328 to 1,328,891. The total number of authorized shares of common stock was not proportionally decreased and the par value per share of the common stock continues to be \$0.0001.

All common shares and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect a 1-for-9 reverse stock split.

NOTE 2 – Liquidity and Financial Condition

The Company reported a net loss of \$11,798,000 for the year ended March 31, 2019. At March 31, 2019 and March 31, 2018, the Company’s accumulated deficit amounted to \$169,238,000 and \$157,440,000, respectively. The Company had working capital of \$8,905,000 and \$12,993,000 as of March 31, 2019 and March 31, 2018, respectively.

On November 16, 2018, the Company entered into a placement agency agreement with Dawson James Securities, Inc. with respect to the issuance and sale of units with each unit consisting of one share of common stock, par value \$0.0001 per share or, in lieu of common stock, if purchasing common stock would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of the outstanding common stock, shares of Series C convertible preferred stock (“Series C”) convertible into shares of common stock, together with warrants to purchase one share of common stock at an exercise price equal to \$9.00 per whole share, in a public offering. The public offering price for each unit was \$9.00. On November 21, 2018, at closing of the offering, the Company sold 507,156 shares of common stock, 9.65 shares of Series C (convertible into 107,222 shares of common stock) and warrants to purchase up to 307,188 shares of common stock for gross proceeds of \$5,530,000 and net proceeds of \$4,743,000 after deducting placement agent commissions and other offering expenses.

On December 8, 2017, the Company entered into an At Market Issuance Sales Agreement with B. Riley FBR, Inc. under which the Company may issue and sell shares of common stock having an aggregate offering price of up to \$5,000,000 from time to time through B. Riley acting as its sales agent. The Company will pay B. Riley a commission rate equal to 3.0% of the gross proceeds from the sale of any shares of common stock sold through B. Riley as agent. For the period of April 1, 2018 through October 3, 2018, the Company sold 29,710 shares of common stock for gross proceeds of \$999,000 and net proceeds of \$957,000 after deducting commissions and other offering expenses.

In addition, on October 4, 2018, the Company sold 12,556 shares of common stock, at a price of \$21.51 per share, through its At Market Issuance Sales Agreement with B. Riley FBR, Inc. for gross proceeds of \$270,000 and net proceeds of \$262,000 after deducting commissions and other offering expenses. This sale exceeded the aggregate market value of the Company's securities sold during the period of twelve calendar months prior to the sale of one-third of the aggregate market value of its common stock held by non-affiliates, and thus, the 12,556 shares of common stock were unregistered. The Company could be liable in the event claims or suits for rescission are brought and successfully concluded for failure to register these securities or for acts or omissions constituting offenses under the Securities Act, the Securities Exchange Act of 1934, or applicable state securities laws. The Company could be liable for damages and penalties assessed by the SEC and state securities regulators.

The Company expects to continue incurring losses for the foreseeable future and may need to raise additional capital to pursue its product development initiatives, to penetrate markets for the sale of its products and continue as a going concern. The Company cannot provide any assurances that it will be able to raise additional capital.

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 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 condensed consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

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.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America 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 and derivative instruments, 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") No. 2014-09, "Revenue from Contracts with Customers Topic 606" ("Topic 606") using the modified retrospective method. There was no 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 to a customer base, including hospitals, medical centers, doctors, pharmacies, distributors and wholesalers. The Company sells products directly to end users and to distributors. The Company also has entered into agreements to license its technology and products. The Company also provides regulatory compliance testing and quality assurance services to medical device and pharmaceutical companies.

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.

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

Disaggregation of Revenue

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

	Year Ended March 31,	
	2019	2018
Product		
Human Skin Care	\$ 15,912,000	\$ 14,277,000
Animal Skin Care	1,969,000	1,386,000
	<u>17,881,000</u>	<u>15,663,000</u>
Service	1,089,000	995,000
Total	<u>\$ 18,970,000</u>	<u>\$ 16,658,000</u>

Sales Tax and Value Added Taxes

The Company accounts for sales taxes and value added taxes imposed on its goods and services on a net basis.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents may be invested in money market funds, commercial paper, variable rate demand instruments, and certificates of deposits.

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, 2019, no customer represented more than 10% of the net accounts receivable balance. For the year ended March 31, 2019, one customer represented 18%, and one customer represented 10% of net revenues. At March 31, 2018, one customer represented 36%, and one customer represented 18% of the net accounts receivable balance. For the year ended March 31, 2018, one customer represented 22%, one customer represented 19%, one customer represented 13%, and one customer represented 12% 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, 2019 and 2018 in the amounts of \$24,000 and \$17,000, respectively. Additionally, at March 31, 2019 and 2018, the Company has allowances of \$443,000 and \$1,275,000, 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 \$184,000 and \$111,000 at March 31, 2019 and 2018, respectively, which is included in cost of product 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, accounts payable and accrued expenses and other liabilities 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, 2019 and 2018, 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, 2019 and 2018, 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, 2019 and 2018, research and development expense amounted to \$1,518,000 and \$1,575,000, respectively.

Advertising Costs

Advertising costs are charged to operations as incurred. Advertising costs amounted to \$157,000 and \$177,000, for the years ended March 31, 2019 and 2018, 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, 2019 and 2018, the Company recorded revenue related to shipping and handling costs of \$55,000 and \$46,000, 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 \$374,000 and \$203,000 for the years ended March 31, 2019 and 2018, respectively. These amounts were recorded in other comprehensive loss in the accompanying consolidated statements of comprehensive loss for the years ended March 31, 2019 and 2018.

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 \$162,000, and foreign currency transaction losses of \$208,000, for the years ended March 31, 2019 and 2018, respectively. 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 estimate for forfeitures for all stock options.

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, 2019 and 2018 were \$4,349,000 and \$3,975,000, respectively.

Net 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. The computation of basic loss per share for the years ended March 31, 2019 and 2018 excludes the potentially dilutive securities summarized in the table below because their inclusion would be anti-dilutive.

	March 31,	
	2019	2018
Common stock to be issued upon vesting of restricted stock units	4,000	4,000
Common stock to be issued upon exercise of options	165,000	155,000
Common stock to be issued upon exercise of warrants	446,000	153,000
Common stock to be issued upon conversion of Series C	17,000	–
Common stock to be issued upon exercise of common stock units (1)	46,000	–
	<u>678,000</u>	<u>312,000</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.

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.

Adoption of Recent Accounting Standards

Financial Instruments

On April 1, 2018, the Company adopted ASU No. 2016-01, *Financial Instruments-Overall*, which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The Company has determined there was no material impact on the Company's consolidated financial position and results of operations upon adoption of this topic.

Statement of Cash Flows

On April 1, 2018, the Company adopted ASU No. 2016-15, *Statement of Cash Flows (Topic 230)*. This amendment provides guidance on the presentation and classification of specific cash flow items to improve consistency within the statement of cash flows. The Company has determined there was no material impact on the Company's consolidated financial position and results of operations upon adoption of this topic.

On April 1, 2018, the Company adopted ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company has determined there was no material impact on the Company's consolidated financial position and results of operations upon adoption of this topic.

Business Combinations

On April 1, 2018, the Company adopted ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting, including acquisitions, disposals, goodwill, and consolidation. The Company has determined there was no material impact on the Company's consolidated financial position and results of operations upon adoption of this topic.

Stock Compensation

On April 1, 2018, the Company adopted ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, clarifying when a change to the terms or conditions of a share-based payment award must be accounted for as a modification. The new guidance requires modification accounting if the fair value, vesting condition or the classification of the award is not the same immediately before and after a change to the terms and conditions of the award. The Company has determined there was no material impact on the Company's consolidated financial position and results of operations upon adoption of this topic.

Recent Accounting Standards

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases (Topic 842)*, which will require lessees to recognize a right of use asset and lease liability on the balance sheet for leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The amendment will be effective for annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* and ASU No. 2018-11, *Leases - Targeted Improvements*. ASU No. 2018-10 provides certain amendments that affect narrow aspects of the guidance issued in ASU No. 2016-02. ASU No. 2018-11 allows entities the option to prospectively apply the new lease standard at the adoption date instead of recording the cumulative impact of all comparative reporting periods presented within retained earnings. Upon adoption of Topic 842, the Company expects recognition of additional assets and corresponding liabilities pertaining to its operating leases on its consolidated balance sheets. The Company does not expect the adoption of the new standard to have a significant impact on its consolidated statements of operations and cash flows.

Reporting Comprehensive Income

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ("ASU 2018-02"). ASU 2018-02 provides financial statement preparers with an option to reclassify stranded tax effects within accumulated other comprehensive income to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act of 2017 (the "Tax Act") (or portion thereof) is recorded. ASU 2018-02 is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted for any interim period for which financial statements have not been issued. The Company does not believe that the adoption of this guidance will have a material impact on the Company's consolidated financial statements due to the presence of a full valuation allowance. However, the Company is in the process of evaluating the impact of this new guidance on the Company's consolidated financial statements and disclosures.

Stock Compensation

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of ASC Topic 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. This amendment will be effective for annual and interim periods beginning after December 31, 2018. The Company is currently evaluating the impact ASU No. 2018-07 will have on its consolidated financial position, results of operations or financial statement disclosure.

Accounting standards that have been issued or proposed by the FASB, the SEC or other standard setting bodies that do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption.

NOTE 4 – Accounts Receivable

Accounts receivable, net consists of the following:

	March 31,	
	2019	2018
Accounts receivable	\$ 3,948,000	\$ 2,829,000
Less: allowance for doubtful accounts	(24,000)	(17,000)
Less: discounts, rebates, distributor fees and returns	(443,000)	(1,275,000)
	<u>\$ 3,481,000</u>	<u>\$ 1,537,000</u>

NOTE 5 – Inventories

Inventories consist of the following:

	March 31,	
	2019	2018
Raw materials	\$ 1,766,000	\$ 1,619,000
Finished goods	1,643,000	1,246,000
	<u>\$ 3,409,000</u>	<u>\$ 2,865,000</u>

NOTE 6 – Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31,	
	2019	2018
Prepaid insurance	\$ 354,000	\$ 440,000
Prepaid rebates	78,000	270,000
Tax prepaid to Mexican tax authorities	963,000	215,000
Other prepaid expenses and other current assets	299,000	622,000
	<u>\$ 1,694,000</u>	<u>\$ 1,547,000</u>

The long-term portion of the prepayment to the Mexican tax authorities amounted to \$399,000 and is recorded in other assets in the accompanying March 31, 2019 balance sheet.

NOTE 7 – Property and Equipment

Property and equipment consists of the following:

	March 31,	
	2019	2018
Manufacturing, lab, and other equipment	\$ 3,575,000	\$ 3,653,000
Office equipment	380,000	361,000
Furniture and fixtures	110,000	100,000
Leasehold improvements	576,000	592,000
	<u>4,641,000</u>	<u>4,706,000</u>
Less: accumulated depreciation and amortization	(3,914,000)	(3,570,000)
	<u>\$ 727,000</u>	<u>\$ 1,136,000</u>

Depreciation and amortization expense amounted to \$453,000 and \$490,000 for the years ended March 31, 2019 and 2018, respectively.

During the year ended March 31, 2019, the Company did not incur a loss or gain on the disposal of property and equipment. During the year ended March 31, 2018, the Company realized a loss of \$10,000 on the disposal of property and equipment. This amount was recorded within operating expenses in the accompanying consolidated statements of comprehensive loss.

NOTE 8 – Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31,	
	2019	2018
Salaries and related costs	\$ 957,000	\$ 817,000
Professional fees	279,000	206,000
Other	265,000	383,000
	<u>\$ 1,501,000</u>	<u>\$ 1,406,000</u>

NOTE 9 – Common Stock Liability

On October 4, 2018, the Company sold 12,556 shares of common stock, at a price of \$21.51 per share, through its At Market Issuance Sales Agreement with B. Riley FBR, Inc. for gross proceeds of \$270,000 and net proceeds of \$262,000 after deducting commissions and other offering expenses. This sale exceeded the aggregate market value of the Company’s securities sold during the period of twelve calendar months prior to the sale of one-third of the aggregate market value of its common stock held by non-affiliates, and thus, the 12,556 shares of common stock were unregistered. The Company could be liable in the event claims or suits for rescission are brought and successfully concluded for failure to register these securities or for acts or omissions constituting offenses under the Securities Act, the Securities Exchange Act of 1934, or applicable state securities laws. The Company could be liable for damages and penalties assessed by the SEC and state securities regulators. Accordingly, at March 31, 2019, the Company recorded a \$270,000 liability in the accompanying consolidated balance sheet.

NOTE 10 – Long-Term Debt

Financing of Insurance Premiums

On February 1, 2018, the Company entered into a note agreement for \$241,000 with an interest rate of 5.81% per annum with final payment on December 1, 2018. This instrument was issued in connection with financing insurance premiums. The note was payable in monthly installments of \$25,000. During the year ended March 31, 2019, the Company made principal and interest payments in the amounts of \$218,000 and \$3,000, respectively. There is no outstanding balance on this note as of March 31, 2019.

On May 1, 2018, the Company entered into a note agreement for \$48,000 with an interest rate of 9.3% per annum with final payment on December 1, 2018. This instrument was issued in connection with financing insurance premiums. The note was payable in monthly installments of \$6,000. During the year ended March 31, 2019, the Company made principal and interest payments in the amounts of \$47,000 and \$1,000, respectively. There is no outstanding balance on this note as of March 31, 2019.

On February 1, 2019, the Company entered into a note agreement for \$349,000 with an interest rate of 6.06% per annum with final payment on December 1, 2019. This instrument was issued in connection with financing insurance premiums. The note is payable in monthly installments of \$36,000. During the year ended March 31, 2019, the Company made principal and interest payments in the amounts of \$34,000 and \$2,000, respectively. The remaining balance of this note amounted to \$315,000 at March 31, 2019, all of which is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

Financing of Automobiles

On August 10, 2016, the Company entered into a note agreement for \$26,000 with an interest rate of 2.49% per year, and a monthly payment of \$432. This instrument was issued in connection with the financing of an automobile. During the year ended March 31, 2018, the Company made principal and interest payments related to this note in the amounts of \$4,000 and \$350, respectively. During the year ended March 31, 2019, the Company made principal and interest payments related to this note in the amounts of \$17,000 and \$200, respectively. During the year ended March 31, 2019, the note was repaid in full and no balance remained at March 31, 2019.

On September 27, 2016, the Company entered into a note agreement for \$38,000 with an interest rate of 0%, and monthly payment of \$630. This instrument was issued in connection with the financing of an automobile. During the year ended March 31, 2018, the Company made principal payments related to this note in the amount of \$8,000. During the year ended March 31, 2019, the Company made principal payments related to this note in the amount of \$8,000. The remaining balance of this note amounted to \$19,000 at March 31, 2019, of which \$7,000 is included in the current portion of long-term debt in the accompanying consolidated balance sheet.

Principal note payments due in years subsequent to March 31, 2019 are as follows:

For Years Ending March 31,

2020	\$	322,000
2021		8,000
2022		4,000
Total minimum payments	\$	334,000
Less: current portion		(322,000)
Long-term portion	\$	<u>12,000</u>

NOTE 11 – Capital Leases

During March 2017, the Company entered into a fleet capital lease. The Company at various times from March 2017 to March 31, 2019 leased automobiles through the lease agreement. The aggregate cost of the assets financed is \$422,000 and for the year ended March 31, 2019 the Company recorded depreciation expense of \$154,000. The present value of the minimum lease payments was calculated using discount rates of ranging from 9.7% to 10.9%. During the year ended March 31, 2019, the Company made principal and interest payments related to capital leases in the amounts of \$154,000 and \$27,000, respectively. The remaining principal balance on these obligations amounted to \$141,000 at March 31, 2019, all of which is included in the current portion of capital lease obligations in the accompanying consolidated balance sheet.

The Company recorded interest expense in connection with these lease agreements in the amount of \$27,000 for the year ended March 31, 2019.

Minimum capital lease payments due in years subsequent to March 31, 2019 are as follows:

For Years Ending March 31,

Total minimum lease payments in 2020	\$	147,000
Less: amounts representing interest		(6,000)
Present value of minimum lease payments		141,000
Less: current portion		(141,000)
Long-term portion	\$	—

NOTE 12 – Commitments and Contingencies***Lease Commitments***

On June 23, 2016, the Company entered into Amendment No. 8 to its property lease agreement, extending the lease on its Petaluma, California facility to September 30, 2024. The lease contains an early termination right for the Company effective October 31, 2019, if the landlord is unable to accommodate the Company's growth. Pursuant to the amendment, the Company agreed to increase the lease payment from \$11,072 to \$11,764 per month, commencing on October 1, 2017, with annual increases thereafter through the lease term.

The Company also shares certain office and laboratory space, as well as certain laboratory equipment, in a building located at 454 North 34th Street, Seattle, Washington. The space is rented for \$2,700 per month and requires a ninety-day notice for cancellation.

The Company currently rents approximately 800 square feet of sales office space in Herten, the Netherlands. The office space is rented on a month to month basis at \$1,700 per month and requires a sixty-day notice for cancellation.

On May 12, 2016, the Company entered into a property lease agreement, on its Woodstock, Georgia sales office space. The initial term of the agreement was from June 1, 2016 expiring on May 31, 2018, with an option to extend for a one-year period. On May 1, 2018, the Company amended the lease term to run from June 1, 2018 to August 31, 2018. The payment is \$1,300 per month. The lease was extended for two months and terminated on October 30, 2018.

On August 1, 2016, the Company entered into Amendment No. 1 to its property lease agreement in Jamison, Pennsylvania. Pursuant to the amendment, the Company extended the term of the lease to July 31, 2019. Additionally, the Company agreed to lease payments of \$2,369 per month for year one, \$2,431 per month for year two and \$2,493 per month for year three.

On June 15, 2017, the Company entered into its property lease agreement, on its Fairfield, California office space. The initial term of the agreement is from June 15, 2017 expiring on October 31, 2019. The payment is \$4,103 per month.

On October 1, 2018, the Company entered into a property lease agreement, on its Woodstock, Georgia sales office space. The initial term of the agreement was from October 1, 2018 expiring on November 30, 2023. The payment is \$5,672 per month.

Minimum lease payments for non-cancelable operating leases are as follows:

For Years Ending March 31,

2019	\$	438,000
2020		245,000
2021		7,000
Total minimum lease payments	<u>\$</u>	<u>690,000</u>

Rental expense amounted to \$556,000 and \$507,000 for the years ended March 31, 2019 and 2018, respectively.

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 Matters

Potential Severance Payments

As of March 31, 2019, the Company had employment agreements in place with three of its key executives. Two of the agreements provide, among other things, for the payment of up to twelve months of severance compensation for terminations under certain circumstances. At March 31, 2019, potential severance payments to key executives would be \$454,000, if triggered.

Appointment of Chief Executive Officer and Interim Financial Officer

On December 11, 2018, the Company's Board appointed Mr. Frederick (Bubba) Sandford as its Chief Executive Officer and Interim Chief Financial Officer for an initial term of nine months, subject to a mutual extension of an additional three months. Mr. Sandford was appointed as a Class III director of the Board on December 14, 2018.

In connection with Mr. Sandford's appointment as the Company's Chief Executive Officer and Interim Chief Financial Officer, the Company entered into an employment agreement with him, in which the Company agreed to pay him a base annual salary of \$350,000 per year. The Company also agreed to pay him a performance bonus of a maximum of 60% of his base annual salary for achieving certain agreed upon targets.

In addition, pursuant to the agreement, Mr. Sandford was granted 50,000 stock options to purchase the Company's common stock, of which 44,445 stock options were treated as an inducement grant and 5,555 stock options were from the Company's equity incentive plan. The Company granted the options on January 10, 2019 with an exercise price of \$6.453 per share, and will become 100% exercisable nine months after date of grant and have a maximum term of ten years. Upon termination, the options are exercisable for up to twelve months from the termination date and in no event later than ten years from the grant date.

The Resignation of Chief Executive Officer, President and Director and Chief Financial Officer and Secretary

On December 12, 2018, Jim Schutz and Robert Miller resigned from their positions as the Company's Chief Executive Officer and President and Chief Financial Officer and Secretary, respectively. On the same date, Mr. Schutz also resigned from the Board.

In connection with Mr. Schutz's resignation, the Company entered into a separation and mutual release agreement with Mr. Schutz on December 13, 2018, in which the Company agreed to pay him severance, consisting of \$250,000, paid in two equal installments with the first half paid on December 14, 2018 and the second half paid on the next payroll after three months, \$38,461 to compensate him for his unused paid time off, and continuation of dental, vision and health insurance until December 31, 2018. Mr. Schutz's outstanding equity awards were accelerated to December 12, 2018 and remained exercisable until January 14, 2019. Mr. Schutz also agreed to aid with the transition for 30 calendar days. The options expired unexercised on January 14, 2019.

In connection with Mr. Miller's resignation, the Company entered into a separation and mutual release agreement with Mr. Miller on December 13, 2018, in which the Company agreed to pay him severance, consisting of \$225,000, paid in two equal installments with the first half paid on December 14, 2018 and the second half paid on the next payroll after three months, \$38,461 to compensate him for his unused paid time off, and continuation of dental, vision and health insurance until December 31, 2018. Mr. Miller's outstanding equity awards were accelerated to December 12, 2018 and remained exercisable until January 14, 2019. The options expired unexercised on January 14, 2019.

Release of Chief Operating Officer

On March 5, 2019, Marc Umscheid was released from his position as the Company's Chief Operating Officer.

In connection with Mr. Umscheid's release, the Company entered into a separation and mutual release agreement with Mr. Umscheid, in which the Company agreed to pay him severance, consisting of \$250,000, to be paid on April 4, 2019, \$14,373 to compensate him for his unused paid time off, and continuation of dental, vision and health insurance to be paid over twelve months. Mr. Umscheid has since declined the continued dental, vision and health insurance coverage. Additionally, Mr. Umscheid's outstanding equity awards were accelerated to March 5, 2019 and will remain exercisable through the contractual term.

Other Matters

Nasdaq Listing

On January 4, 2019, the Company received a letter from the Listing Qualifications staff of The Nasdaq Stock Market LLC, notifying the Company that, for the previous 30 consecutive business days, the Company failed to comply with Nasdaq Listing Rule 5550(a)(2), which requires the Company to maintain a minimum bid price of \$1.00 per share for its common stock.

In accordance with Listing Rule 5810(c)(3)(C), Nasdaq has granted the Company a period of 180 calendar days, or until July 3, 2019, to regain compliance with the Rule. The Company may regain compliance with the Rule at any time during this compliance period if the minimum bid price for its common stock is at least \$1.00 for a minimum of ten consecutive business days.

The Company effected a 1-for-9 reverse stock split of its outstanding common stock effective June 19, 2019, 5:00 pm EDT in order to regain compliance with the Rule. As of June 27, 2019, Nasdaq has not made a final determination or informed the Company whether it meets the requirements under the Rule.

The letter has no effect on the listing or trading of the Company's common stock at this time. However, there can be no assurances that the Company will be able to regain compliance with Listing Rule 5550(a)(2). In the event the Company does not regain compliance with the Listing Rule prior to the expiration of the compliance period, the Company may be eligible for additional time. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse split, if necessary. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to the Staff of Nasdaq that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting.

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 effect 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.

Sale of Common and Series C Preferred Stock Units

On November 16, 2018, the Company entered into a placement agency agreement with Dawson James Securities, Inc. with respect to the issuance and sale of units, each unit consisting of one share of common stock, par value \$0.0001 per share or, in lieu of common stock, if purchasing common stock would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of the outstanding common stock, shares of Series C convertible into shares of common stock, together with warrants to purchase one share of common stock at an exercise price equal to \$9.00 per whole share, in a public offering. The public offering price for each unit was \$9.00. The warrants offered in the public offering are Series C warrants and will terminate on the fifth anniversary of the date of issuance. Each full warrant will entitle the holder to purchase one share of common stock at an initial exercise price of \$9.00 per share.

The closing of the offering occurred on November 21, 2018 and at such closing the Company sold 507,156 shares of common stock, 9.65 shares of Series C (convertible into 107,222 shares of common stock) and warrants to purchase up to 307,188 shares of common stock for gross proceeds of \$5,530,000. The net proceeds to the Company from the sale of the shares of common stock, or preferred stock, and the warrants was \$4,743,000, after deducting placement agent commissions and other estimated offering expenses payable by the Company.

Pursuant to the placement agency agreement, the Company agreed to pay Dawson James Securities, Inc. a cash fee equal to 8% of the aggregate gross proceeds raised in this offering. The Company also agreed to pay fees and expenses of the placement agent, not to exceed \$167,500, and to issue to Dawson James Securities, Inc., on the closing date, a unit purchase option for the purchase of up to 276,470 units to purchase up to 46,000 shares of common stock, equal to 5% of the aggregate number of units sold in the public offering, with an exercise price of \$11.25, or 125% of the price per unit. The Benchmark Company, LLC provided certain financial advisory services. As compensation for services provided, the Company made a cash payment of \$74,000 and on November 16, 2018 issued common stock purchase warrants to purchase up to 7,639 shares of common stock. The common stock purchase warrants have an exercise price of \$9.00 per share, become exercisable on the 180th day after the date of issuance and expire on November 16, 2023.

During the year ended March 31, 2019, investors who participated in the transaction converted 8.10 shares of Series C into 90,000 shares of common stock.

At-the-Market Offering

On December 8, 2017, the Company entered into an At Market Issuance Sales Agreement, with B. Riley FBR, Inc. (“B. Riley”) under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$5,000,000 from time to time through B. Riley acting as its sales agent. The Company will pay B. Riley a commission rate equal to 3.0% of the gross proceeds from the sale of any shares of common stock sold through B. Riley as agent. For the year ended March 31, 2019, the Company sold 29,710 shares of common stock for gross proceeds of \$999,000 and net proceeds of \$957,000 after deducting commissions and other offering expenses. For the year ended March 31, 2018, the Company sold 25,333 shares of common stock for gross proceeds of \$1,034,000 and net proceeds of \$968,000 after deducting commissions and other offering expenses.

Registered Direct Offering

On March 2, 2018, the Company entered into a placement agency agreement with Dawson James Securities, Inc. Dawson James Securities, Inc. acted as the lead placement agent and The Benchmark Company, LLC acted as a co-placement agent in the public offering. On March 6, 2018, the Company sold 158,730 shares of its common stock at a public offering price of \$31.50 per share, for gross proceeds of \$5,000,000 and net proceeds of \$4,500,000 after deducting commissions and other offering expenses. Additionally, pursuant to the placement agency agreement, the Company agreed to pay the placement agents a cash fee equal to 8% of the aggregate gross proceeds raised in the public offering, excluding any proceeds from the sale of shares to Montreux Equity Partners. The Company also issued the placement agents warrants to purchase up to 4,762 shares of its common stock. The placement agent warrants will be exercisable beginning on August 28, 2018 and ending on March 1, 2023 and have an exercise price of \$39.38 per share. The Company also agreed to pay certain expenses of the placement agents, including legal and diligence fees, in any case not to exceed \$65,000.

Common Stock Issued to Services Providers

During the year ended March 31, 2018, the Company entered into an agreement with Actual, Inc., a firm that provides marketing and branding consulting services. On July 27, 2017, the Company issued 285 shares of restricted common stock valued at \$60.66 per share and on August 22, 2017, the Company issued 343 shares of restricted common stock valued at \$49.77 per share. The aggregate fair market value of the common stock issued in July 2017 and August 2017 was \$35,000. On December 1, 2017, the Company issued 609 shares of restricted common stock valued at \$45.18 per share. On January 2, 2018, the Company issued 526 shares of restricted common stock valued at \$52.29 per share. On July 12, 2018, the Company issued 1,971 shares of restricted common stock valued at \$22.32 per share. The Company has determined that the fair value of the common stock was more readily determinable than the fair value of the services rendered. Accordingly, during year ended March 31, 2019 and 2018, the Company recorded \$44,000 and \$90,000 of expense related to common stock issued. The expense was recorded as selling, general and administrative expense in the accompanying consolidated statement of comprehensive loss for year ended March 31, 2019 and 2018, respectively.

During the year ended March 31, 2018, the Company entered into an agreement with Benchmark Securities., a firm that provides financial consulting services. On July 31, 2018, the Company issued 765 shares of restricted common stock valued at \$19.62 per share. The Company has determined that the fair value of the common stock was more readily determinable than the fair value of the services rendered. Accordingly, during year ended March 31, 2019, the Company recorded \$15,000 of expense related to common stock issued. The expense was recorded as selling, general and administrative expense in the accompanying consolidated statement of comprehensive loss for year ended March 31, 2019.

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.

During the year ended March 31, 2017, the 2006 Plan expired. No additional equity will be granted from the 2006 Plan. All outstanding options will remain outstanding until exercised, forfeited or expired.

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, 2018, the board of directors approved an increase of 69,945 shares authorized for issuance. During the year ended March 31, 2019, the board of directors approved an increase of 102,863 shares authorized for 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, 2018, the board of directors approved an increase of 38,127 shares authorized for issuance. During the year ended March 31, 2019, the board of directors approved an increase of 4,860 shares authorized for issuance.

Stock-Based Compensation

On April 1, 2017, the Company adopted ASU 2016-09 and, as a result, made a Company-wide accounting policy change with respect to accounting for forfeitures. The Company applied a modified retrospective approach for adoption of the new policy and accordingly recorded an \$11,000 increase to opening accumulated deficit at April 1, 2017. In accordance with the adoption of the accounting policy, the Company no longer estimates forfeitures based on historical experience and no longer reduces compensation expense based on the expected forfeitures. Beginning April 1, 2017, the Company will record forfeitures as they occur and will reduce compensation cost at the time of forfeiture.

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 an estimate for forfeitures for all stock options.

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,	
	2019	2018
Fair value of the Company's common stock on date of grant	\$ 10.71	\$ 61.02
Expected term	5.38 yrs	6.42 yrs
Risk-free interest rate	2.61%	2.04%
Dividend yield	0.00%	0.00%
Volatility	121.5%	120.8%
Fair value of options granted	\$ 9.00	\$ 53.73

Share-based awards compensation expense is as follows:

	Year Ended March 31,	
	2019	2018
Cost of revenues	\$ 90,000	\$ 169,000
Research and development	107,000	159,000
Selling, general and administrative	1,379,000	2,082,000
Total stock-based compensation	<u>\$ 1,576,000</u>	<u>\$ 2,410,000</u>

At March 31, 2019, there were unrecognized compensation costs of \$826,000 related to stock options which is expected to be recognized over a weighted-average amortization period of 1.01 years.

At March 31, 2019, there were unrecognized compensation costs of \$55,000 related to restricted stock which is expected to be recognized over a weighted-average amortization period of 1.50 years.

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options.

Stock-Based Award Activity

Stock-based awards outstanding at March 31, 2019 under the various plans are as follows:

Plan	Stock Options	Unvested Restricted Stock	Total
2006 Plan	10,000	–	10,000
2011 Plan	92,000	1,000	93,000
2016 Plan	19,000	3,000	22,000
Granted outside shareholder approved plans	44,000	–	44,000
	<u>165,000</u>	<u>4,000</u>	<u>169,000</u>
Stock-based awards available for grant as of March 31, 2019			<u>343,000</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, 2018	155,000	\$ 114.30		
Options granted	73,000	10.71		
Options exercised	–	–		
Options forfeited	(7,000)	60.48		
Options expired	(56,000)	108.00		
Outstanding at March 31, 2019	<u>165,000</u>	<u>\$ 72.81</u>	<u>7.48</u>	<u>\$ 107,000</u>
Exercisable at March 31, 2019	<u>80,000</u>	<u>\$ 124.02</u>	<u>5.68</u>	<u>\$ –</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 \$8.46 per share at March 31, 2019.

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, 2018	4,000	\$ 58.14
Restricted stock awards granted	2,000	17.10
Restricted stock awards vested	(2,000)	53.46
Restricted stock awards forfeited	-	62.73
Unvested restricted stock awards outstanding at March 31, 2019	4,000	\$ 27.99

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,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	\$ 28,118,000	\$ 25,487,000
Research and development tax credit carryforwards	1,850,000	1,789,000
Stock-based compensation	3,795,000	3,697,000
Allowances and accruals	1,142,000	1,118,000
Other deferred tax assets	252,000	284,000
State income taxes	1,000	1,000
Basis difference in assets	14,000	(3,000)
Total deferred tax assets	\$ 35,172,000	\$ 32,373,000
Deferred tax assets	35,172,000	32,373,000
Valuation allowance	(35,172,000)	(32,373,000)
Deferred tax assets	\$ -	\$ -

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,	
	2019	2018
Domestic	\$ 10,088,000	\$ 12,607,000
Foreign	1,252,000	1,671,000
	\$ 11,340,000	\$ 14,278,000

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

	Year Ended March 31,	
	2019	2018
Current:		
State	\$ 2,000	\$ 37,000
Foreign	456,000	13,000
	<u>458,000</u>	<u>50,000</u>
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
	<u>\$ 458,000</u>	<u>\$ 50,000</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,	
	2019	2018
Expected federal statutory rate	21.0%	30.8%
State income taxes, net of federal benefit	4.5%	0.5%
Research and development credit	0.6%	0.3%
Foreign earnings taxed at different rates	1.3%	(0.3%)
Effect of state net operating loss expiration	(3.0%)	(0.9%)
Effect of permanent differences	(4.3%)	(4.2%)
Effect of other foreign permanent differences	(4.0%)	-
True-up of state deferred assets	1.5%	7.7%
Tax cuts and Jobs Act impact	-	(103.7%)
	<u>17.6%</u>	<u>(69.8%)</u>
Change in valuation allowance	21.6%	68.5%
Totals	<u>(4.0%)</u>	<u>(1.3%)</u>

As of March 31, 2019, the Company had net operating loss carryforwards for Federal, California and Foreign income tax purposes of approximately \$107,000,000, \$40,500,000 and \$3,200,000, respectively. Of the Federal net operating loss carryforwards at March 31, 2018, \$100,000,000 begin to expire in 2024 and \$7,000,000 will carryforward indefinitely, subject to an annual limitation of 80% of taxable income. The California net operating loss carryforwards and foreign net operating loss carryforwards, begin to expire in 2029 and 2028, respectively. As of March 31, 2019, the Company had Federal and California research credit carryforward of approximately \$1,000,000 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 credit of \$50,000, which begin to expire in the fiscal year ending March 31, 2023 if not utilized.

The Company has completed a study to assess whether a change in control has occurred or whether there have been multiple changes of control since the Company's formation through March 31, 2019. The Company determined, based on the results of the study, no change in control occurred for purposes of Internal Revenue Code section 382. The Company, after considering all available evidence, fully reserved for these and its other deferred tax assets since it is more likely than not such benefits will not be realized in future periods. The Company has incurred losses for both financial reporting and income tax purposes for the year ended March 31, 2019. Accordingly, the Company is continuing to fully reserve for its deferred tax assets. 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. If it is determined in future periods that portions of the Company's deferred income tax assets satisfy the realization standards, the valuation allowance will be reduced accordingly.

On April 1, 2017, the Company adopted ASU No. 2016-09. As a result of adopting ASU No. 2016-09, the Company has made an accounting policy election to account for forfeitures as they occur. This change has been applied on a modified retrospective basis, with no material impacts on the Company's financial statements. The adoption of ASU No. 2016-09 also requires excess tax benefits and tax deficiencies be recorded in the income statement as opposed to additional paid-in capital when the awards vest or are settled and recognize all previously unrecognized excess tax benefits and tax deficiencies upon adoption as a cumulative-effect adjustment to retained earnings. As of April 1, 2017, the Company recognized excess tax benefit of approximately \$533,000 as an increase to deferred tax assets. However, the entire amount was offset by a full valuation allowance. Accordingly, an \$11,000 cumulative-effect adjustment to retained earnings was recorded as of March 31, 2018.

The Company only recognizes tax benefits from an uncertain tax position 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 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. To date, the Company has not recognized such tax benefits in its consolidated financial statements.

The Company has identified its federal tax return and its state tax return in California as major tax jurisdictions. The Company also filed tax returns in foreign jurisdictions, principally Mexico and the Netherlands. The Company's evaluation of uncertain tax matters was performed for tax years ended through March 31, 2019. Generally, the Company is subject to audit for the years ended March 31, 2018, 2017 and 2016 and may be subject to audit for amounts relating to net operating loss carryforwards generated in periods prior to March 31, 2018. 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, other than those identified above that would result in a material change to its financial position.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act reduced the federal corporate income tax rate from 35% to 21% effective January 1, 2018, which the Company expects will positively impact its future effective tax rate and after-tax earnings in the United States. The Company recognized a one time decrease related to its federal deferred tax assets and deferred tax liabilities, before the valuation allowance at March 31, 2018. As the change in the valuation allowance completely offset the change in deferred taxes, therefore there was no impact on the consolidated financial statements at March 31, 2018 related to the rate change.

In accordance with SEC Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, the Company made a reasonable estimate of the Tax Act's impact and provisionally recorded this estimate in our 2017 results. As of March 31, 2019, the Company completed our accounting for the impacts of the Tax Act, resulting in no material changes to previously recorded provisional amounts.

The Company does not have any tax positions for which it is reasonably possible the total amount of gross unrecognized tax benefits will increase or decrease within 12 months of March 31, 2019. The unrecognized tax benefits may increase or change during the next year for items that arise in the ordinary course of business.

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 \$275,000 and \$281,000 for the years ended March 31, 2019 and 2018, respectively.

NOTE 17– Geographic Information

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 shows the Company's product revenues by geographic region:

	Year Ended March 31,	
	2019	2018
United States	\$ 9,040,000	\$ 8,372,000
Latin America	3,962,000	3,007,000
Europe and Rest of the World	4,879,000	4,284,000
Total	<u>\$ 17,881,000</u>	<u>\$ 15,663,000</u>

The Company's service revenues amounted to \$1,089,000 and \$995,000 for the years ended March 31, 2019 and 2018, respectively.

NOTE 18 – Subsequent Events***Sale of Certain Animal Health Product Rights***

On May 20, 2019, the Company closed on an asset purchase agreement for the sale of certain animal health product rights and assets for the Asian and European markets to Petagon, Limited, an international importer and distributor of quality pet food and products. The purchase price for the assets is \$2,700,000. The Company agreed that it will continue to supply products to Petagon for five years at certain agreed upon transfer prices. The sale involves certain Asian patents and trademarks and the exclusive right to distribute animal health care products in Asia and Europe.

Reverse Stock Split

Effective June 19, 2019 5:00 pm EDT, the Company effected a reverse stock split of its common stock, par value \$0.0001 per share. Every nine shares of common stock were reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Instead, each resulting fractional share of common stock was down to one whole share and each fractional share settled with cash. The reverse stock split reduced the number of shares of the Company's common stock outstanding from 11,972,328 to 1,328,891. The total number of authorized shares of common stock was not proportionally decreased and the par value per share of the common stock continues to be \$0.0001.

All common shares and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect a 1 for 9 reverse stock split.

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 effective as of March 31, 2019.

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). 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 effective as of March 31, 2019.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 2019 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, 2019 (the “2019 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 2019 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, 1129 N. McDowell Blvd., Petaluma, California 94954.

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, 1129 N. McDowell Blvd., Petaluma, California 94954. 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 2019 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 2019 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 2019 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 2019 Proxy Statement.

ITEM 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference to the 2019 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	Form of Series A Common Stock Purchase Warrant for February 2014 offering (included as exhibit 4.1 to the Company's Current Report on Form 8-K filed February 26, 2014 and incorporated herein by reference).

- 4.3 [Warrant Agreement, including Form of Warrant entered into by and between Oculus Innovative Sciences, Inc. and Computershare, Inc. and Computershare Trust Company, N.A., dated January 20, 2015](#) (included as exhibit 4.1 to the Company's Current Report on Form 8-K filed January 26, 2015 and incorporated herein by reference).
- 4.4 [Underwriters Warrant issued to Maxim Partners LLC on January 26, 2015](#) (included as exhibit 4.2 to the Company's Current Report on Form 8-K filed January 26, 2015 and incorporated herein by reference).
- 4.5 [Underwriters Warrant issued to Robert D. Keyser, Jr. on January 26, 2015](#) (included as exhibit 4.3 to the Company's Current Report on Form 8-K filed January 26, 2015 and incorporated herein by reference).
- 4.6 [Underwriters Warrant issued to R. Douglas Armstrong on January 26, 2015](#) (included as exhibit 4.4 to the Company's Current Report on Form 8-K filed January 26, 2015 and incorporated herein by reference).
- 4.7 [Underwriters Warrant issued to Dawson James Securities, Inc. on January 26, 2015](#) (included as exhibit 4.5 to the Company's Current Report on Form 8-K filed January 26, 2015 and incorporated herein by reference).
- 4.8 [Underwriters Warrant issued to Dawson James Securities, Inc. on January 26, 2015](#) (included as exhibit 4.6 to the Company's Current Report on Form 8-K filed January 26, 2015 and incorporated herein by reference).
- 4.9 [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).
- 4.10 [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).
- 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 October 26, 1999, between Oculus Innovative Sciences, Inc. and RNM Lakeville, L.P.](#) (included as exhibit 10.7 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 [Amendment No. 1 to Office Lease Agreement, dated September 15, 2000, between Oculus Innovative Sciences, Inc. and RNM Lakeville L.P.](#) (included as exhibit 10.8 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 [Amendment No. 2 to Office Lease Agreement, dated July 29, 2005, between Oculus Innovative Sciences, Inc. and RNM Lakeville L.P.](#) (included as exhibit 10.9 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 [Amendment No. 3 to Office Lease Agreement, dated August 23, 2006, between Oculus Innovative Sciences, Inc. and RNM Lakeville L.P.](#) (included as exhibit 10.23 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).
- 10.6 [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).
- 10.7 [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).
- 10.8 [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).
- 10.9 [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).

- 10.10 [Amendment No. 4 to Office Lease Agreement, dated September 13, 2007, by and between Oculus Innovative Sciences, Inc. and RNM Lakeville L.P.](#) (included as exhibit 10.43 to the Company's Annual Report on Form 10-K filed June 13, 2008, and incorporated herein by reference).
- 10.11 [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).
- 10.12 [Amendment No. 5 to Office Lease Agreement by and between Oculus Innovative Sciences, Inc. and RNM Lakeville, LLC, dated May 18, 2009](#) (included as exhibit 10.54 to the Company's Annual Report on Form 10-K filed June 11, 2009, and incorporated herein by reference).
- 10.13 [Amendment No. 6 to Office Lease Agreement by and between Oculus Innovative Sciences, Inc. and RNM Lakeville, L.P., dated April 26, 2011](#) (included as exhibit 10.52 to the Company's Annual Report on Form 10-K filed June 3, 2011, and incorporated herein by reference).
- 10.14 [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).
- 10.15 [Amendment No. 7 to Office Lease Agreement by and between Oculus Innovative Sciences, Inc. and 1125-1137 North McDowell, LLC, dated October 10, 2012](#) (included as exhibit 10.58 to the Company's Quarterly Report on Form 10-Q filed November 8, 2012, and incorporated herein by reference).
- 10.16 [Underwriting Agreement entered into by and between Oculus Innovative Sciences, Inc. and Maxim Group LLC as representative of the underwriters named on Schedule A thereto, dated January 20, 2015](#) (included as exhibit 1.1 to the Company's Current Report on Form 8-K filed January 26, 2015 and incorporated herein by reference).
- 10.17† [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).
- 10.18† [Asset Purchase Agreement dated October 27, 2016, between Oculus Innovative Sciences, Inc. and Invekra, 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).
- 10.19† [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).
- 10.20 [Employment Agreement by and between Oculus Innovative Sciences, Inc. and Bruce Thornton, dated November 30, 2016](#) (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 1, 2016, and incorporated herein by reference).
- 10.21 [Employment Agreement by and between Oculus Innovative Sciences, Inc. and Robert Northey, dated November 30, 2016](#) (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed December 1, 2016, and incorporated herein by reference).
- 10.22† [Distribution Agreement by and between Sonoma Pharmaceuticals, Inc. and G. Pohl-Boskamp GmbH & Co. KG, dated April 13, 2016](#) (included as Exhibit 10.33 to the Company's Annual Report on Form 10-K filed on June 28, 2017, and incorporated herein by reference).
- 10.23 [Amendment No. 8 to Office Lease Agreement by the between Oculus Innovative Sciences, Inc. and SSCOP Properties LLC, dated June 23, 2016](#) (included as Exhibit 10.34 to the Company's Annual Report on Form 10-K filed on June 28, 2017, and incorporated herein by reference).
- 10.24 [At Market Issuance Sales Agreement, dated December 8, 2017, by and between Sonoma Pharmaceuticals, Inc. and B. Riley FBR, Inc.](#) (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 8, 2017, and incorporated herein by reference).
- 10.25 [Placement Agency Agreement entered into by and between Sonoma Pharmaceuticals, Inc. and Dawson James Securities, Inc. as representative of the placement agents, dated March 2, 2018](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 6, 2018, and incorporated herein by reference).
- 10.26 [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).
- 10.27† [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).
- 10.28 [Commercial Lease \(Georgia office\) by and between Sonoma Pharmaceuticals, Inc. and PMR Holdings, LLC, dated May 1, 2018](#) (included as exhibit 10.39 to the Company's annual report on Form 10-K filed on June 26, 2018, and incorporated herein by reference).
- 10.29 [Placement Agency Agreement entered into by and between Sonoma Pharmaceuticals, Inc. and Dawson James Securities, Inc., dated November 16, 2018](#) (included as exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 21, 2018, and incorporated herein by reference).
- 10.30 [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).

- 10.31 [Employment Agreement entered into by and between Sonoma Pharmaceuticals, Inc. and Frederick Sandford, dated December 11, 2018](#)(included as exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 14, 2018, and incorporated herein by reference).
- 10.32□+ [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).
- 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 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., 1129 N. McDowell Blvd., Petaluma, California 94954.

(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 (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) and Form S-8 (File No. 333-163988) of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated July 1, 2019 with respect to our audits of the consolidated financial statements of Sonoma Pharmaceuticals, Inc. and Subsidiaries as of March 31, 2019 and 2018, and for the two years in the period ended March 31, 2019, which report is included in this Annual Report on Form 10-K of Sonoma Pharmaceuticals, Inc. for the year ended March 31, 2019.

/s/ Marcum llp

Marcum llp
New York, NY
July 1, 2019

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

I, Frederick Sandford, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sonoma Pharmaceuticals, Inc. for the year ended March 31, 2019;
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 1, 2019

By: /s/ Frederick Sandford
Frederick Sandford
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, Frederick Sandford, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sonoma Pharmaceuticals, Inc. for the year ended March 31, 2019;
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:
 - (e) 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;
 - (f) 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;
 - (g) 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
 - (h) 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):
 - (c) 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
 - (d) 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 1, 2019

By: /s/ Frederick Sandford
Frederick Sandford
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 officer of Sonoma Pharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended March 31, 2019 (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 1, 2019

By: /s/ Frederick Sandford
Frederick Sandford
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)