DYNATRONICS CORP
Form 10-K
September 28, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)
þ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2012.

¨ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission file number 0-12697

DYNATRONICS CORPORATION
(Exact name of registrant as specified in its charter)

| | |
|---|---|
| Utah<br>(State or other jurisdiction of incorporation or organization) | 87-0398434<br>(I.R.S. Employer Identification No.) |
| 7030 Park Centre Drive, Salt Lake City, Utah<br>(Address of principal executive offices) | 84121-6618<br>(Zip Code) |

Registrant's telephone number, including area code (801) 568-7000

Securities registered under Section 12(b) of the Exchange Act: None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, no par value
(Title of class)

Indicate by checkmark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No þ

Indicate by checkmark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act. Yes ¨ No þ

Indicate by checkmark 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 þ No ¨

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yesþ No¨

Indicate by checkmark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer ¨ |
| Non-accelerated filer ¨ (Do not check if a smaller reporting company) | Smaller reporting company þ |

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of December 30, 2011 (the last day of the registrant's second fiscal quarter) was approximately $7.7 million, based on the average bid and asked price on that date.

As of September 24, 2012, there were 12,688,650 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

The issuer hereby incorporates information required by Part III (Items 10, 11, 12, 13, and 14) of this report by reference to the registrant's definitive proxy statement for the fiscal year ended June 30, 2012 to be filed pursuant to Regulation 14A and provided to stockholders subsequent to the filing of this report.

Transitional Small Business Disclosure Format (Check one): Yes ¨ No þ

TABLE OF CONTENTS

PART I

PART I

Unless the context otherwise requires, all references in this report to "registrant," "we," "us," "our," "Dynatronics" or the "Company" refer to Dynatronics Corporation, a Utah corporation and its wholly owned subsidiary.

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking information. Forward-looking information includes statements relating to future actions, prospective products, future performance or results of current or anticipated products, sales and marketing efforts, costs and expenses, interest rates, outcomes of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management and other matters. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking information in order to encourage companies to provide prospective information about themselves without fear of litigation, so long as that information is identified as forward-looking and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those projected in the information. Forward-looking information may be included in this Annual Report on Form 10-K or may be incorporated by reference from other documents filed by us with the Securities and Exchange Commission. You can find many of these statements by looking for words including, for example, "believes," "expects," "anticipates," "estimates" or similar expressions in this Annual Report on Form 10-K or in documents incorporated by reference in this Annual Report on Form 10-K. Except as otherwise required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information or future events.

We have based the forward-looking statements relating to our operations on management's current expectations, estimates and projections about us and the industry in which we operate. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that we cannot predict. In particular, we have based many of these forward-looking statements on assumptions about future events that may prove to be inaccurate. Accordingly, our actual results may differ materially from those contemplated by these forward-looking statements. Any differences could result from a variety of factors, including, but not limited to the following:

- strategies, outlook and growth prospects;
- future plans and potential for future growth;
- liquidity, capital resources and capital expenditures;
- growth in demand for our products;
- economic outlook and industry trends;
- development of our markets;
- the impact of regulatory initiatives;
§ new state or federal legislation; and
- the strength of our competitors.

Item 1. Business

Our Company

Dynatronics is a Utah corporation formed on April 29, 1983. Our predecessor company, Dynatronics Research Company, was formed in 1979. Our principal business is the distribution and marketing of physical medicine and aesthetic products many of which we design and manufacture. We operate on a fiscal year basis, ending June 30. For example, reference to fiscal year 2012 refers to the fiscal year ended June 30, 2012. All references to financial statements in this report refer to the consolidated financial statements of Dynatronics Corporation and its subsidiary, Dynatronics Distribution Co. LLC.

Recent Developments

In August 2012, we introduced to the market our new Dynatron® Solaris®Plus line of combination therapy devices that are capable of generating seven waveforms of electrotherapy and our patented three-frequency ultrasound, as well as light therapy through a newly designed hand-held light probe or two light pads. These newly-designed light pads and probes are the most powerful and reliable light therapy tools we have ever offered. The light probe includes outputs of up to 1,000 mW of infrared wavelength light, 500 mW of blue wavelength light and 500 mW of red wavelength light. The SolarisPlus product line consists of four new units, the Dynatron SolarisPlus 709, 708, 706, and 705, as well as the new Tri-Wave light probe and light pads. These attractive new units provide our most advanced technology and can be mounted on a customized cart for ease of use. The new cart is expected to be available by October 2012. This new line of products represents the most comprehensive redesign project in our history and updates the Solaris line of products introduced in 2003.

Description of Products

We manufacture and distribute a broad line of medical equipment for physical medicine applications including therapy devices, medical supplies and soft goods, treatment tables and rehabilitation equipment. Our products are used primarily by physical therapists, chiropractors, sports medicine practitioners, podiatrists, physicians and other physical medicine professionals.

We also manufacture and distribute a line of aesthetic equipment including aesthetic massage and microdermabrasion devices, as well as skin care products. These products are used by aestheticians, plastic surgeons, dermatologists and other aesthetic services providers.

The products we manufacture fall into the following categories: Physical Medicine Products and Aesthetic Products.

Physical Medicine Products

Electrotherapy - The therapeutic effects of electrical energy have occupied an important position in physical medicine for over five decades. There has been an evolution through the years to use the most effective and painless waveforms and frequencies to produce patient comfort and successful treatment of pain and related physical ailments. Medium frequency alternating currents, which we use primarily in our electrotherapy devices, are believed to be the most effective and comfortable for patients. Electrotherapy can be effective in treating chronic intractable pain and/or acute post-traumatic pain, increasing local blood circulation, relaxation of muscle spasms, prevention or retardation of disuse atrophy, and muscle re-education.

Therapeutic Ultrasound - Ultrasound therapy provides therapeutic deep heat to soft tissue through the introduction of sound waves into the body. It is one of the most common modalities used in physical therapy for treating pain, muscle spasms and joint contractures.

We market a broad line of devices that include electrotherapy, ultrasound or a combination of both of these modalities in a single device. The Dynatron 125 ultrasound and the Dynatron 525 electrotherapy devices target the low-priced segment of the market. The “50 Series Plus” products offer combinations of electrotherapy and ultrasound modalities at a reasonable cost to the practitioner. The Dynatron SolarisPlus products add tri-wave light therapy capabilities to electrotherapy and ultrasound combination devices. We intend to continue development of our electrotherapy and ultrasound technology and remain a leader in the design, manufacture and sale of therapy devices.

Light Therapy – Light therapy has been popular among physical medicine practitioners for its ability to provide topical heating to increase local blood circulation, provide temporary relief of minor muscle and joint aches, pain and stiffness as well as to treat minor pain and stiffness associated with arthritis. The wavelength of the light determines the depth of penetration – the longer the wavelength the deeper the penetration. The benefits of light therapy have been documented by numerous research studies published over the past four decades.

Our Dynatron SolarisPlus 709, 708, 706, and 705 units, as well as the Dynatron X3 and DX2 devices, all feature light therapy technology. These units are capable of powering either a powerful handheld light probe or the larger light pads. The new Dynatron Tri-wave light pad is capable of treating larger areas of the body via unattended infrared, red and blue wavelength light therapy. This tri-wave light pad is powered by the Dynatron SolarisPlus units.

Thermal Therapy – For many decades, physical therapists and other medical practitioners have relied on cold compression therapy as a primary standard of care for treating patient injuries and for post surgical conditions. In March 2012, we introduced the new Dynatron Quad7 therapy device to the market. The innovative Quad7 incorporates technology designed to deliver thermal therapy (hot or cold) and compression therapy through a variety

of wraps and innovative ThermoStim Probes. The ThermoStim Probes are also designed to provide simultaneous thermal therapy and electrotherapy treatments. The Quad7 has the flexibility to offer seven different treatments as follows:

1) Intermittent compression
2) Cold and compression
3) Heat and compression
4) Cold and stim
5) Heat and stim
6) Cold
7) Heat

The ability to offer such a variety of treatments is unique to the Quad7 and dramatically expands both the variety and location of conditions that can be treated. The Dynatron Quad7 employs state-of-the-art technology providing precise temperature control while moving beyond the current standard by eliminating the need for ice when providing cold therapy.

Oscillation Therapy - Soft tissue oscillation therapy has been used for the treatment of pain in Europe for over 15 years, yet it has been used in the United States market for only approximately eight years. The Dynatron X5 Oscillation Therapy device creates an electrostatic field within the patient, resulting in a highly effective treatment for reducing minor muscle aches and pains.

Iontophoresis - Iontophoresis uses electrical current to transdermally deliver drugs such as lidocaine for localized treatment of inflammation without the use of needles. The Dynatron iBoxTM, our proprietary iontophoresis device, is capable of delivering two treatments simultaneously. We also distribute a line of proprietary iontophoresis electrodes under the brand name of Dynatron Ion electrodes along with other types of iontophoresis electrodes from other manufacturers.

Vibration Therapy - We introduced our V-Force vibration therapy device in June 2010. Originally developed for the Russian space program to compensate for bone and muscle loss resulting from extended periods in space, whole-body vibration therapy provides neuromuscular training to increase strength, improve balance and enhance flexibility. A number of clinical studies have demonstrated its effectiveness in the areas of balance/fall prevention, circulation improvement, knee rehabilitation, low back pain relief, range of motion expansion and many other neuromuscular conditions.

Manufactured Medical Supplies and Soft Goods - We currently manufacture or have manufactured for us over 700 medical supply and soft goods products including hot packs, cold packs, lumbar rolls, exercise balls, wrist splints, ankle weights, cervical collars, slings, cervical pillows, bolsters, positioning wedges, back cushions, weight racks, rehabilitation products, back and wrist braces, mat tables, work tables, training stairs, and parallel bars.

Manufactured Treatment Tables and Rehabilitation Equipment - We manufacture and distribute motorized and manually operated physical therapy treatment tables, rehabilitation parallel bars, and other specialty rehabilitation products.

Distributed Medical Equipment, Supplies and Soft Goods - Over the years, we have significantly expanded the number of products we distribute to include additional exercise equipment, massage therapy products, treatment tables, parallel bars, hand therapy products, hot and cold therapy products, lotions and gels, paper products, athletic tape, canes and crutches, reflex hammers, stethoscopes, splints, elastic wraps, exercise weights, Thera-Band® (a registered mark of Hygenic Corp.) tubing, walkers, treadmills, stair climbers, heating units for hot packs, whirlpools, gloves, electrodes, hydrotherapy and aquatic exercise products, clinical supplies, aids to daily living products, cardio equipment, diagnostic and evaluation products, orthopedic supports, patient positioners, rehabilitation equipment, traction equipment, wound and edema care products, pilates and yoga equipment, nutritional supplements, emergency care products and portable electrotherapy products. Our 400-page full-line catalog was first introduced to the market

in calendar 2008 and updated in 2011, containing over 13,000 rehabilitation products. A new 2013-14 expanded catalog is targeted for release in late 2012.

We market our products through direct sales representatives, independent dealers, our e-commerce website and our product catalog. We continually seek to update our line of manufactured and distributed medical supplies and soft goods.

Aesthetic Products

We manufacture and market a line of aesthetic products under the brand name of Synergie™. The Synergie Elite Aesthetic Massage System ("AMS") applies therapeutic vacuum massage to skin and subcutaneous tissues to achieve a temporary reduction in the appearance of cellulite and reduces the circumferential body measurements of the treated areas.

The results of a Dynatronics-sponsored research study available at our offices show that 91% of Synergie participants experienced a reduction in the appearance of cellulite. In addition, participants on average reported a cumulative reduction of six-inches in girth around the hips, thighs, and waist.

We also manufacture and market the Synergie Elite microdermabrasion device as a companion to the AMS device. The microdermabrasion device gently exfoliates the upper layers of skin, exposing softer, smoother skin. In conjunction with the microdermabrasion devices, we offer a unique line of skin care products under the trademark Calisse™ which is designed to enhance the effects of the microdermabrasion treatments.

As part of the aesthetics line of products, we market the Synergie Elite LT device which provides light therapy for aesthetic applications. Light therapy is used in aesthetic applications to improve skin tone and appearance. Combining elements of the AMS vacuum massage techniques with microdermabrasion and Synergie Elite LT for light therapy has provided aestheticians with the ability to provide an enhanced "ultimate facial" available only with the use of Synergie devices.

Allocation of Sales Among Key Products

No product accounted for more than 10% of total revenues in fiscal years 2012 and 2011. Sales of manufactured physical medicine products represented approximately 42% and 41% of total physical medicine product sales in fiscal years 2012 and 2011, respectively. Distribution of products manufactured by other suppliers accounted for the balance of our physical medicine product sales in those years.

Patents and Trademarks

Patents. We hold a United States patent on the multi-frequency ultrasound technology that will remain in effect until June 2013, and a United States patent on the microdermabrasion device that will remain in effect until February 2020. We also hold two United States design patents on the microdermabrasion device that will remain in effect until November 2015. Additionally, we hold a United States patent on the combination of our aesthetic massage and microdermabrasion technologies that will remain in effect until February 2020, a United States patent on our light therapy technology that will remain in effect until August 2025, and have been informed by the United States Patent Office that a patent will be issuing later this year on our combination traction/light therapy technology. An additional patent application relating to our thermoelectric technology has been filed with the United States Patent and Trademark Office and is pending.

Trademarks. We have developed and we use registered trademarks in our business, particularly relating to our corporate and product names. The trademark "Dynatron®" has been registered with the United States Patent and Trademark Office. In addition, United States trademark registrations have been obtained for the trademarks: "Synergie®," "Synergie Peel®," "Dynatron Solaris®," "BodyIce®, and "Sympathetic Therapy®." Company materials are also protected under copyright laws, both in the United States and internationally.

Federal registration of a trademark enables the registered owner of the mark to bar the unauthorized use of the registered mark in connection with a similar product in the same channels of trade by any third-party anywhere in the

United States, regardless of whether the registered owner has ever used the trademark in the area where the unauthorized use occurs. We have filed applications and own trademark registrations, and we may register additional trademarks in countries where our products are or may be sold in the future. Protection of registered trademarks in some jurisdictions may not be as extensive as the protection in the United States.

We also claim ownership and protection of certain product names, unregistered trademarks, and service marks under common law. Common law trademark rights do not provide the same level of protection that is afforded by the registration of a trademark. In addition, common law trademark rights are limited to the geographic area in which the trademark is actually used. We believe these trademarks, whether registered or claimed under common law, constitute valuable assets, adding to recognition of Dynatronics and the effective marketing of Dynatronics products. Trademark registration onceobtained is essentially perpetual, subject to the payment of a renewal fee. We therefore believe that these proprietary rights have been and will continue to be important in enabling us to compete.

Trade Secrets. We own certain intellectual property, including trade secrets that we seek to protect, in part, through confidentiality agreements with key employees and other parties involved in research and development. Even where these agreements exist, there can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known to or independently developed by competitors. Our proprietary product formulations are generally considered trade secrets, but are not otherwise protected under intellectual property laws.

We intend to protect our legal rights concerning intellectual property by all appropriate legal action. Consequently, we may become involved from time to time in litigation to determine the enforceability, scope, and validity of any of the foregoing proprietary rights. Any patent litigation could result in substantial cost and divert the efforts of management and technical personnel.

Warranty Service

We provide a warranty on all products we manufacture for time periods ranging in length from 90 days to five years from the date of sale. We service warranty claims on these products primarily at our Salt Lake City, Utah and Chattanooga, Tennessee facilities depending on the service required. We also have field service in other parts of the United States and Canada. Our warranty policies are comparable to warranties generally available in the industry. Warranty claims were approximately $125,000 and $136,000 in fiscal years 2012 and 2011, respectively. However, with the introduction of many new products in the last year, we expect that warranty expenses may rise in fiscal year 2013.

Products we distribute carry warranties provided by the manufacturers of those products. We do not generally supplement these warranties or provide unreimbursed warranty services for distributed products. We also sell accessory items for our manufactured products that are supplied by other manufacturers. These accessory products carry warranties from their original manufacturers without supplement from us.

Customers and Markets

We sell our products primarily to licensed practitioners such as physical therapists, chiropractors, podiatrists, sports medicine specialists, medical doctors, hospitals and clinics, plastic surgeons, dermatologists and aestheticians. We currently have 53 direct sales representatives. We also utilize a network of over 150 independent dealers throughout the United States and internationally. These dealers purchase and take title to the products, which they then sell to licensed practitioners.

We have entered into contractural relationships with several Group Purchasing Organizations (“GPOs”) and regional/national chains of physical therapy clinics and hospitals. We sell our products directly to these clinics and hospitals pursuant to preferred pricing arrangements. We also have preferred pricing arrangements with key dealers who commit to purchase certain volumes and varieties of products. No single dealer or national account or group of related accounts was responsible for 10% or more of total sales in fiscal years 2012 and 2011.

We export products to approximately 30 different countries. Sales outside North America totaled approximately $897,000, or 2.8% of net sales, in fiscal year 2012, compared to approximately $679,000, or 2.1% of net sales, in fiscal year 2011. We are working to establish effective distribution for our products in international markets. Our Utah facility is certified to the ISO 13485 quality standard for medical device manufacturing. This ISO designation enables us to qualify for the CE Mark, a designation required for marketing products in the European community, and signifies the device or product was manufactured pursuant to a certified quality system. We have no foreign manufacturing operations. However, we purchase certain products and components from foreign manufacturers.

Competition

We believe our key products are distinguished competitively by our use of the latest technology. Many of our products are protected by patents. We believe that the integration of advanced technology in the design of each product has distinguished Dynatronics branded products in a very competitive market. For example, we were the first company to integrate infrared light therapy as part of a combination therapy device. By manufacturing a portion of the products that we sell, we can focus on quality engineered products at competitive prices. We believe these factors

give us an edge over many competitors who are solely distributors of competing products. Furthermore, the addition of direct sales representatives over the course of the last five years has provided us with expanded direct distribution of our products. This new distribution channel allows us to exercise better control over the sale and distribution of our manufactured products as well as products of other manufacturers that we distribute, including products from competitors such as Mettler Electronics, manufacturer of the Sonicator brand of electrotherapy and ultrasound therapy products and DJO, manufacturer of the Chattanooga brand of electrotherapy products, and many manufacturers of treatment tables, medical supplies and soft goods. Generally, since the migration from being primarily a manufacturer to being a manufacturer and distributor, the competitive landscape takes on different dimensions as outlined below. Dynatronics is one of only two companies in the physical medicine industry that has a direct sales force; the other is Patterson Medical (Sammons Preston), a division of Patterson Companies.

Information necessary to determine or reasonably estimate our market share or that of any competitor in any of these markets is not readily available.

Electrotherapy/Ultrasound

We compete in the clinical market for electrotherapy and ultrasound devices with both domestic and foreign companies. Approximately 12 companies produce electrotherapy and/or ultrasound devices. Some of these competitors are larger and better established, and have greater resources than us. Other than Dynatronics, few companies, domestic or foreign, provide multiple-modality devices, which is one important distinction between us and our competition. Furthermore, we believe no competitor offers three frequencies on multiple-sized soundheads for which we hold a patent or provides the proprietary electrotherapy features offered in the Dynatronics electrotherapy devices. We believe that our primary domestic competitors that manufacture competitive clinical electrotherapy and ultrasound equipment include DJO (Chattanooga Brand), Rich-Mar, Mettler Electronics, and the Metron Division of Patterson Medical.

Light Therapy

Competitors that manufacture and market light therapy devices include DJO (Chattanooga Brand), Rich-Mar, Erchonia, Apollo, Multi Radiance and MedX. We are aware of only two competitors, DJO and Rich-Mar, that offer a device that includes light therapy along with electrotherapy and ultrasound capabilities.

Vibration Therapy

The primary competitors that manufacture and market vibration therapy devices include PowerPlate and Wave Manufacturing. These competitors offer units that are more expensive than our unit. In addition, we offer a better warranty and believe that we provide better training and customer service than these competitors.

Medical Supplies and Soft Goods

We compete against various manufacturers and distributors of medical supplies and soft goods, some of which are larger, more established and have greater resources than us. Excellent customer service, along with providing online ordering capability and value to customers is of key importance for us to remain competitive in this market. While there are many specialized manufacturers in this area such as DJO, Hausmann Industries and Fabrication Enterprises, most of our competitors are primarily distributors such as Patterson Medical, North Coast Medical and Meyer Distributing. It is not common for manufacturers of products in this category to have any direct distribution of their products. They typically rely on distribution companies like Dynatronics or the competitors mentioned in this section for sale of their products. We enjoy cost advantages on the products we manufacture and distribute directly to end users compared to companies that only distribute similar products. Dynatronics and Patterson Medical are the only two companies with a direct sales force. All other competitors are primarily catalog or internet sales companies. In addition to our proprietary products, we also distribute products manufactured by many of our competitors.

Iontophoresis

Our competitors in the iontophoresis market include DJO (EMPI and Iomed divisions) Rich-Mar, Travanti Pharma and ActivaTek Inc. We believe that DJO enjoys the largest market share of the iontophoresis market. We also believe that our strong distribution network is important to our continued ability to compete in this increasingly competitive market. In addition, our products target a lower selling price than the products of DJO. Our Dynatron iBox iontophoresis device is helping expand our presence in this market.

Treatment Tables

Our primary competition in the treatment table market is from domestic manufacturers including Hill Laboratories Company, Hausmann Industries, Patterson Medical, Bailey Manufacturing, Tri-W-G, DJO, Armedica, and Clinton Industries. We believe we compete based on our industry experience and product quality. In addition, certain components of the treatment tables are manufactured overseas, which we believe allows for pricing advantages over competitors.

Aesthetic Products

Our two primary competitors in the therapeutic massage industry are LPG Systems and Silhouette Tone. Other competitors include Cynosure, Inc., Palomar Medical, and Syneron. The Synergie Elite AMS device utilizes proprietary technology that has been proven effective in a research study and in ten years of use by doctors and spas. In addition, we provide a comprehensive training and certification program for aestheticians and medical practitioners. Our aesthetic massage equipment is priced lower than competitors' units, providing a significant advantage in the marketplace. There are a number of competitors in the microdermabrasion market including Mega Peel, Diamond Peel, DermaGenesis, DermaMed, E-Med, Integremed, Medical Alliance, Palomar, Slimtone USA and Soundskin Corp. The Synergie microdermabrasion device incorporates a patented anti-clogging design for the crystals, which sets it apart from competitors' units. In addition, the system has an innovative disposable system for the abrasive material, which prevents unwanted contact with the spent crystals following treatment. Powered by the Synergie Elite AMS device, the Synergie Elite microdermabrasion device is one of the most powerful and easy to control units on the market.

Competitors in the light therapy segment of the aesthetic market include Revitalite, Silhouette Tone, Photo Actif, and DermaPulse. We believe the Synergie Elite LT device is the most powerful of all the units on the market. It features a computerized dosage calculation system and is competitively priced.

Manufacturing and Quality Assurance

We manufacture therapy devices, soft goods and other medical products at our facilities in Salt Lake City, Utah and Chattanooga, Tennessee. We purchase some components for our manufactured products from third-party suppliers. All parts and components purchased from these suppliers meet specifications we have established. Trained staff performs all sub-assembly, final assembly and quality assurance procedures. Every effort is made to design Dynatronics products to incorporate component parts and raw materials that are readily available from suppliers.

The development and manufacture of our products is subject to rigorous and extensive regulation by the United States Food and Drug Administration, or FDA, and other regulatory agencies and authorities in the United States and abroad. In compliance with the FDA's Good Manufacturing Practices, or GMP, we have developed a comprehensive program for processing customer feedback and analyzing product performance trends. By ensuring prompt processing of timely information, we are better able to respond to customer needs and ensure proper operation of the products.

Our Salt Lake City facility is certified to ISO 13485:2003 standards for medical products. ISO 13485 is an internationally recognized quality management system standard adopted by over 90 countries. The ISO 13485 certification also allows us to qualify for CE Mark certification. With the CE Mark certification, we are able to market qualified products throughout the European Union and in other countries where CE Mark certification and ISO 13485 certification are recognized.

Products manufactured at our facility in Tennessee are subject to our own internal quality system which mimics the quality system implemented at our facility in Utah. While we have not sought ISO certification for the Tennessee facility, we believe our quality system is rigorous and adequate for producing the type of quality product to which our customers have become accustomed.

Research and Development

Total research and development ("R&D") expenses in fiscal year 2012 were $1,410,406, compared to $1,383,712 in fiscal year 2011. The increase in R&D expenditures in fiscal year 2012 reflects the increased expenditure levels

begun in fiscal year 2011 to develop the new Dynatron Quad7 and Dynatron SolarisPlus product lines. The Dynatron Quad7 was introduced in March 2012 and the new Dynatron SolarisPlus product line was introduced in August 2012. R&D expenses represented approximately 4.5% and 4.2% of our net sales in fiscal years 2012 and 2011, respectively. R&D expenditures are expected to decrease to more traditional levels in fiscal year 2013. The SolarisPlus and Quad 7 research and development projects collectively represent the most significant research and development undertakings in the history of the Company resulting in the higher R&D expenditures of the past two years.

Regulatory Matters

The manufacture, packaging, labeling, advertising, promotion, distribution and sale of our products are subject to regulation by numerous national and local governmental agencies in the United States and other countries. In the United States, the FDA regulates our products pursuant to the Medical Device Amendment of the Food, Drug, and Cosmetic Act, or FDC Act, and regulations promulgated thereunder. Advertising and other forms of promotion and methods of marketing of the products are subject to regulation by the Federal Trade Commission, or FTC, under the Federal Trade Commission Act.

As a device manufacturer, we are required to register with the FDA and once registered we are subject to inspection for compliance with the FDA's Quality Systems regulations. These regulations require us to manufacture our products and maintain our documents in a prescribed manner with respect to manufacturing, testing, and control activities. Further, we are required to comply with various FDA requirements for reporting. The FDC Act and medical device reporting regulations require us to provide information to the FDA on deaths or serious injuries alleged to have been caused or contributed to by the use of our products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to occur. The FDA also prohibits an approved device from being marketed for unapproved uses. All of our therapeutic and aesthetic treatment devices as currently designed are cleared for marketing under section 510(k) of the Medical Device Amendment to the FDC Act or are considered 510(k) exempt. If a device is subject to section 510(k) approval requirements, the FDA must receive premarket notification from the manufacturer of its intent to market the device. The FDA must find that the device is substantially equivalent to a legally marketed predicate device before the agency will clear the new device for marketing. We intend to continuously improve our products after they have been introduced to the market. Certain modifications to our marketed devices may require a premarket notification and clearance under section 510(k) before the changed device may be marketed, if the change or modification could significantly affect safety or effectiveness. As appropriate, we may therefore submit future 510(k) notifications, Pre-Market Approval ("PMA") or PMA supplement applications to the FDA. No assurance can be given that clearance or approval of such new applications will be granted by the FDA on a timely basis, or at all. Furthermore, we may be required to submit extensive preclinical and clinical data depending on the nature of the product changes. All of our devices, unless specifically exempted by regulation, are subject to the FDC Act's general controls, which include, among other things, registration and listing, adherence to the Quality System Regulation requirements for manufacturing, medical device reporting and the potential for voluntary and mandatory recalls described above.

The FDA is currently evaluating the classification of iontophoresis products. Since the passage of the Medical Device Amendment in 1975, these products have been listed as Class III products. However, the FDA has never required these products be subjected to a Pre-Market Approval ("PMA") process like other Class III devices. Instead, it has allowed iontophoresis products to proceed to market as though they were Class II. Three years ago, FDA indicated they intend to make a final decision to either call for a PMA for iontophoresis products or reclassify them to Class II. We submitted to FDA the required information to allow continued marketing of our proprietary iontophoresis products until the final FDA decision is made. In our submission we urged that the products be reclassified to Class II. If the FDA does not change the classification of iontophoresis products and requires a PMA, we will be required to provide a PMA or, in the alternative, cease distributing our proprietary line and distribute competitor products that comply with the FDA requirements.

During fiscal year 2003, Congress enacted the Medical Device User Fee and Modernization Act (MDUFMA). Among other things, this act imposes for the first time a user fee on medical device manufacturers. Under the provisions of MDUFMA and its subsequent re-authorizations, manufacturers seeking clearance to market a new device must pay a fee to the FDA in order to have their applications reviewed. We submit new products for clearance primarily under section 510(k) of the Medical Device Amendment of the FDC Act. Renewal of MDUFMA was passed this year setting fees for the next five years that are cumulatively double what they have been the prior five years. However, the increase is not considered to have a material effect on operations.

Failure to comply with applicable FDA regulatory requirements may result in, among other things, injunctions, product withdrawals, recalls, product seizures, fines, and criminal prosecutions. Any such action by the FDA could materially adversely affect our ability to successfully market our products. Our Utah and Tennessee facilities are inspected periodically by the FDA for compliance with the FDA's GMP and other requirements, including appropriate reporting regulations and various requirements for labeling and promotion. The FDA Quality Systems Regulations are similar to the ISO 13485 Quality Standard. The GMP regulation requires, among other things, that (i) the

manufacturing process be regulated and controlled by the use of written procedures, and (ii) the ability to produce devices that meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process.

Advertising of our products is subject to regulation by the FTC under the FTC Act. Section 5 of the FTC Act prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. Section 12 of the FTC Act provides that the dissemination or the causing to be disseminated of any false advertisement pertaining to, among other things, drugs, cosmetics, devices or foods, is an unfair or deceptive act or practice. Pursuant to this FTC requirement, we are required to have adequate substantiation for all advertising claims made about its products. The type of substantiation required depends upon the product claims made.

If the FTC has reason to believe the law is being violated (e.g., the manufacturer or distributor does not possess adequate substantiation for product claims), it can initiate an enforcement action. The FTC has a variety of processes and remedies available to it for enforcement, both administratively and judicially, including compulsory process authority, cease and desist orders, and injunctions. FTC enforcement could result in orders requiring, among other things, limits on advertising, consumer redress, divestiture of assets, rescission of contracts, and such other relief as may be deemed necessary. Violation of such orders could result in substantial financial or other penalties. Any such action by the FTC could materially adversely affect the Company's ability to successfully market its products.

From time to time, legislation is introduced in the Congress of the United States or in state legislatures that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of medical devices and products like those we manufacture. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance, or interpretations will be changed, and what the impact of such changes, if any, may be on our business and our results of operations. We cannot predict the nature of any future laws, regulations, interpretations, or applications, nor can we determine what effect additional governmental regulations or administrative orders, when and if promulgated, domestically or internationally, would have on our business in the future. They could include, however, the requirement for the reformulation of certain products to meet new standards, the recall or discontinuance of certain products, additional record keeping, expanded documentation of the properties of certain products, expanded or different labeling, and additional scientific substantiation. Any or all such requirements could have a material adverse effect on our business, results of operations or financial condition.

In addition to compliance with FDA rules and regulations, we are also required to comply with international regulatory laws including Health Canada, CE Mark, or other regulatory schemes used by other countries. We believe all of our present products are in compliance in all material respects with all applicable performance standards in countries where the products are sold. We also believe that our products comply with GMP, record keeping and reporting requirements in the production and distribution of the products in the United States.

Environment