

IRIDEX CORP
Form 10-K
March 27, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 28, 2013

or

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the transition period from to .

Commission file number 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	77-0210467
(State or other jurisdiction	(I.R.S. Employer
of incorporation or organization)	Identification Number)

1212 Terra Bella Avenue, Mountain View CA 94043-1824

(Address of principal executive offices)

(Zip Code)

(650) 940-4700

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(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on which Registered
Common	NASDAQ Global Market

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

Common Stock, par value \$0.01 per share

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. 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 Securities Exchange Act of 1934 (the "Exchange 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 Exchange Act 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 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). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) 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.

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

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

The aggregate market value of the voting common equity held by non-affiliates of the Registrant was approximately \$54,494,721 as of June 28, 2013 the last business day of the Registrant's most recently completed second fiscal quarter, based on the closing price reported for such date on the NASDAQ Global Market. The registrant did not have any non-voting common equity outstanding. For purposes of this disclosure, shares of common stock held by each executive officer and director and by each holder of 5% or more of the outstanding shares of common stock have been

excluded from this calculation, because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 11, 2014, Registrant had 9,993,948 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2014 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, such as statements relating to levels of future sales and operating results; gross margins; sales levels generated by our independent sales force and through our distribution partners; future tax rates and availability of certain deferred potential tax benefits; leveraging our core business and increasing recurring revenues; broadening our product lines through product innovation and new treatments; general economic conditions; levels of international sales; market acceptance of our products; expectations for and sources of future revenues; our marketing programs and trends in healthcare; our ability to take advantage of economies-of-scale in product development and manufacturing; our current and future liquidity and capital requirements; efforts to decrease costs and manage cash flows; levels of future investment in research and development efforts; our ability to develop and introduce new products through strategic alliances, OEM relationships and acquisitions; the availability of components from third-party manufacturers; results of clinical studies and the status of our regulatory clearance; the impact of regulatory actions and determinations; and risks associated with bringing new products to market. In some cases, forward-looking statements can be identified by terminology, such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “intends,” “continue,” or the negative of such terms or other comparable terminology. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements. The reader is strongly urged to read the information contained under the captions “Item 1A. Risk Factors - Factors That May Affect Future Results” in this Annual Report on Form 10-K for a more detailed description of these significant risks and uncertainties. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management’s analysis only as of the date of this Form 10-K. We undertake no obligation to update such forward-looking statements to reflect events or circumstances occurring after the date of this report.

As used in this Annual Report on Form 10-K, the terms “Company,” “IRIDEX,” “we,” “us” and “our” refer to IRIDEX Corporation, a Delaware corporation, and when the context so requires, our wholly owned subsidiaries, IRIS Medical Instruments, Inc. and Light Solutions Corporation, both California corporations, and IRIDEX France S.A.

Item 1. Business

General

IRIDEX Corporation is a leading worldwide provider of therapeutic based laser consoles, delivery devices and consumable instrumentation used to treat sight-threatening eye diseases in ophthalmology. In February 2012, we sold our aesthetics business to Cutera, Inc. The sale of the aesthetics business was a significant step forward in our strategy because it allowed us to focus solely on our ophthalmology business which is our core strength. Management believes that this path affords the Company with the best opportunity for long term profitable growth. In accordance with accounting principles generally accepted in the U.S. (“GAAP”), we have recast our financial information disclosed within this Form 10-K to show the results from our ophthalmology business as continuing operations and the results from our aesthetics business as discontinued operations for all periods presented. Our ophthalmology products are sold in the United States predominantly through a direct sales force and internationally through approximately 70 independent distributors in over 100 countries. Revenues from continuing operations in 2013, 2012 and 2011 were \$38.3 million, \$33.9 million and \$33.2 million, respectively, and we generated net income (loss) from continuing operations of \$2.2 million, \$(0.2) million and \$2.1 million, respectively. Total net income including income from discontinued operations for 2013, 2012 and 2011 was \$2.2 million, \$1.4 million and \$2.6 million, respectively.

Our ophthalmology products consist of laser consoles, delivery devices and consumable instrumentation including laser probes, and are used in the treatment of serious eye diseases, including the three leading causes of irreversible blindness: diabetic retinopathy, glaucoma and age-related macular degeneration (“AMD”). In addition, our ophthalmology products are often used in vitrectomy procedures (used to treat proliferative diabetic retinopathy, macular holes, retinal tears and detachments) which are generally performed in the operating room and require a consumable single use intraocular laser probe (“EndoProbe”) to deliver light to the back of the eye together with other instrumentation. Our ophthalmology business includes (i) a recurring revenue component, consisting of sales of consumable products, predominantly single use laser probe devices and other instrumentation, combined with the repair, servicing and extended service contracts for our laser systems; and (ii) a capital component, consisting of the laser consoles combined with durable delivery devices (laser systems).

Our laser consoles consist of our IQ products which include IQ 532, IQ 577 and IQ 810 laser photocoagulation systems; and our OcuLight products including OcuLight TX, OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. Certain of our laser consoles are capable of performing traditional continuous wavelength photocoagulation and our patented Fovea-Friendly MicroPulse laser photocoagulation. Towards the end of 2012 we introduced the TxCell Scanning Laser Delivery System, a delivery device which saves significant time in a variety of laser photocoagulation procedures by allowing physicians to deliver the laser in a multi-spot scanning mode, a more efficient method for these procedures than the traditional single spot mode. Our current family of laser probes includes a wide variety of products in 20, 23 and 25 gauge for vitreoretinal surgery and glaucoma surgery.

Ophthalmologists typically use our laser systems in hospital operating rooms (“OR”) and ambulatory surgical centers, as well as their offices and clinics. In the OR and ambulatory surgical centers, ophthalmologists use our laser systems with either an indirect laser ophthalmoscope or a consumable, single use EndoProbe. Since our first shipment in 1990, more than 10,000 medical laser systems manufactured by IRIDEX have been sold worldwide.

IRIDEX Corporation was incorporated in California in February 1989 as IRIS Medical Instruments, Inc. In November 1995, we changed our name to IRIDEX Corporation and reincorporated in Delaware. Our executive offices are located at 1212 Terra Bella Avenue, Mountain View, California 94043-1824, and our telephone number is (650) 940-4700. We can also be reached at our website at www.IRIDEX.com, however, the information on, or that can be accessed through, our website is not part of this report. As used in this Annual Report on Form 10-K, the terms “Company,” “IRIDEX,” “we,” “us” and “our” refer to IRIDEX Corporation, a Delaware corporation, and when the context so requires, our wholly owned subsidiaries, IRIS Medical Instruments, Inc. and Light Solutions Corporation, both California corporations, and IRIDEX France S.A.

Market

Ophthalmology is a large and growing global market. Growth is driven by the aging world population and the onset of diabetes, which is occurring at an epidemic rate, the introduction of new treatment approaches, and the realities of constrained health care system spending.

Diabetic retinopathy is a common complication of diabetes which impairs vision over time and if left untreated can lead to blindness. According to the International Diabetes Federation in an article published in November 2010 – at least 300 million people worldwide have diabetes, and this figure is likely to reach 438 million by the year 2030. According to the World Health Organization in their 2007 report – Vision 2020 The Right to Sight, after 20 years duration more than 75% of patients will have some form of diabetic retinopathy. Laser photocoagulation is currently the standard treatment for this disease, although there has been increased use of pharmaceuticals in recent years. A single treatment of continuous wavelength laser photocoagulation has been shown to stabilize the patient’s vision over the long term. Continuous wavelength laser photocoagulation treatments typically take several months to be fully effective and have been demonstrated to last for many years. This treatment presents a very cost efficient model, and presents a risk of varying degrees of vision loss to the patient. Pharmaceuticals can stabilize vision in the near term, as treatments typically take a few days to be fully effective and have been demonstrated to last for weeks. However, patients receiving pharmaceutical treatment for diabetic retinopathy require repeated injections. The injections are painful and the patients may experience side effects including increased risk of eye infections. Furthermore, a regimen of repeated injections is very costly to both the physician, in terms of time, and to the healthcare system, in terms of dollars spent on treatment. The short comings in treating this disease have led to a renewed interest in alternative approaches that may provide better patient outcomes.

Glaucoma is a leading cause of blindness in the world. WHO estimates that approximately 60.5 million people had glaucoma in 2010 and given the aging of the world’s population, this number is anticipated to increase to nearly 80 million by 2020. Currently, glaucoma is not curable, and vision loss resulting from glaucoma currently cannot be regained. Often, glaucoma is chronic and must be monitored for the duration of the patient’s life. Most cases of glaucoma can be controlled and vision loss slowed or halted by treatment. Pharmaceuticals are typically the first treatment method prescribed for glaucoma. These pharmaceutical treatments are commonly self-administered in drop form by the patients. Patients often have difficulties applying the pharmaceutical drops properly and may fail to appropriately or timely apply the medication, which may significantly reduce the effectiveness of the pharmaceutical. Even when administered correctly, pharmaceuticals have demonstrated reduced efficacy over time. When pharmaceuticals lose their effectiveness, laser treatment is often performed, and ultimately surgery may be required. The short comings in treating this disease have led to a renewed interest in surgical approaches that may allow treatment earlier and may result in better patient outcomes.

AMD is a disease that affects the aged. WHO indicates that, in 2006, 3 million people had lost their sight due to AMD and that the number affected is expected to double by the year 2020. Unfortunately, although pharmaceuticals are used to delay vision loss there is currently no cure for AMD. Pharmaceuticals require repeated injections in the eye every six to eight weeks, which are painful, increase the risk of adverse side effects, are costly, and their long term viability is unproven. Continuous wavelength laser photocoagulation can also be used to treat AMD, although it is used less frequently because the disease often requires the laser to be applied to the area of the retina responsible for central vision and the likelihood of significant loss of visual function is too high. The shortcomings in treating this disease has led to a renewed interest in investigating alternative approaches that might allow treatment earlier which would result in better patient outcomes.

Laser Photocoagulation

We produce laser photocoagulator systems. Laser photocoagulation is the standard-of-care for the treatment of many sight-threatening eye diseases, the majority of which are diseases of the retina and glaucoma. Photocoagulation delivers laser light to carefully targeted eye tissue and generates a local healing response. Laser photocoagulation has been demonstrated to be a safe and effective therapy with long-term benefits.

The traditional method of performing laser photocoagulation uses a mode which delivers continuously-on laser light, which is referred to as continuous wave (“CW”) mode. Use of this mode typically leads to local tissue damage under the belief that tissue damage was necessary to generate the beneficial response associated with laser photocoagulation and can cause loss of visual function.

MicroPulse

MicroPulse is a method of delivering laser energy using a mode which chops the CW beam into short, microsecond long, laser pulses, which we have developed. There is a growing body of clinical evidence that demonstrates that MicroPulse therapy can generate the beneficial response associated with CW laser photocoagulation with no detectible tissue damage for the treatment of Diabetic Retinopathy, Glaucoma and AMD. When used to treat Diabetic Retinopathy we refer to this as Fovea-Friendly because the laser can be used to treat the fovea without any loss of visual function typically associated with CW laser photocoagulation. Our IQ products are capable of MicroPulse as well as CW laser photocoagulation.

The IRIDEX Strategy

We are one of the worldwide leaders in developing, manufacturing, marketing, selling and servicing innovative medical laser systems and associated instrumentation for the treatment of the sight-threatening eye diseases mentioned above. With the sale of our aesthetics business we are now focused exclusively on our ophthalmology business. At the end of 2013, the Company had \$13.4 million in cash and no debt. Other than in 2012, when we incurred a net loss of \$0.2 million from our ophthalmology operations, we generated net income from our ophthalmology operations in each of the past five years. It is our goal to continue to operate our business profitably.

Our strategy is to leverage our existing brand and distribution channel in the ophthalmology market promote the adoption of MicroPulse as a viable treatment alternative for Diabetic Retinopathy, Glaucoma and AMD and consequently to introduce a broad array of products that:

1. Improve therapeutic outcomes for patients suffering from sight-threatening eye diseases.
2. Improve the efficiency of physicians and reduce their costs, and
3. Provide economic benefits to healthcare systems.

To achieve these goals we are pursuing a number of organic initiatives which we anticipate will be supplemented from time to time by acquisitions. We anticipate that the successful execution of this strategy will lead to profitable growth and enhanced shareholder value. See Item 1A. Risk Factors – Factors That May Affect Future Results – “Our future success depends on our ability to develop and successfully introduce new products and new applications.” and “Efforts to acquire additional companies or product lines may divert our managerial resources away from our business operations, and if we complete additional acquisitions, we may incur or assume additional liabilities or experience integration problems.”

Ophthalmic Products

We utilize a systems approach to product design. Each system includes a console, which generates the laser energy, and a number of interchangeable peripheral delivery devices for use in specific clinical applications. This approach allows our customers to purchase a basic console system and add additional delivery devices as their needs expand or as new applications develop. We believe that this systems approach is our distinguishing characteristic and also brings economies-of-scale to our product development and manufacturing efforts because individual applications do not require the design and manufacture of complete stand-alone products. Our primary capital equipment products range in price from \$1,000 to \$60,000 and consist of laser consoles and specialized durable delivery devices. Our line of consumable products range in price from \$10 to \$250 and consist primarily of cannulas and laser probes.

Consoles

Our laser consoles, which are identified below, incorporate the economic and technical benefits of solid state and semiconductor laser technology.

Visible (Yellow) Photocoagulator Console. Our IQ 577 delivers visible (Yellow – 577nm) laser light. This product utilizes state of the art user interface technology and delivers a 577 wavelength which is at the peak of oxyhemoglobin absorption and allows ophthalmologists to obtain optimal results with lower power (more tissue sparing) compared with green wavelengths. The IQ 577 console weighs 18 pounds, has dimensions of 7.5”H x 12”W x 14”D, draws a maximum of 250 Watts of wall power, requires no water cooling, and has a remote control and wireless footswitch.

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Visible (Green) Photocoagulator Console. Our IQ 532 delivers visible (Green – 532nm) laser light. This product utilizes a user interface and product platform based on the IQ 577, as more fully described above, as well as our OcuLight TX, OcuLight GL and OcuLight GLx Photocoagulators. The OcuLight TX/GL/GLx have dimensions of 6”H x 12”W x 12”D, draw a maximum of 300 Watts of wall power and require no water cooling.

Infrared Photocoagulator Consoles. The OcuLight and IQ 810 photocoagulator consoles used by ophthalmologists are available in two infrared (810nm) output power ranges: the OcuLight SL at 2 Watts and the IQ 810 and OcuLight SLx at 3 Watts. The OcuLight consoles weigh 14 pounds and have dimensions of 4”H x 12”W x 12”D. The IQ 810 console weighs 11 pounds and has dimensions of 7”H x 12”W x 12”D. Neither requires external air nor water cooling.

MicroPulse Enabled Consoles. MicroPulse mode is offered as an option on some of our infrared and visible laser photocoagulator systems.

Multi-wavelength Laser System Configurations. When used in conjunction with specific IRIDEX laser consoles, our Symphony slit lamp adapters can deliver multiple laser wavelengths from a single slit lamp installation. Our laser consoles, together with our Symphony slit lamp adapters, combine the clinical versatility and convenience of multiple wavelength delivery into one delivery device for retinal and glaucoma procedures. Currently, our compatible consoles are the OcuLight GLx and the OcuLight TX green laser consoles and the OcuLight SLx and the IQ 810 infrared laser consoles and the IQ 577 yellow laser console.

Ophthalmic Delivery Devices and Other Products

Our versatile family of consoles and delivery devices has been designed to accommodate the addition of new capabilities with a minimal incremental investment. Typically users of our consoles can add capabilities by simply purchasing new interchangeable delivery devices and utilizing them with their existing console. We have developed both consumable and durable delivery devices and expect to continue to develop additional delivery devices.

TxCeLL Scanning Laser Delivery System (“TxCell”). TxCell was introduced in the second half of 2012. It allows the physician to perform multi-spot pattern scanning for efficient retinal photocoagulation, confluent laser patterns for tissue-sparing MicroPulse protocols and allows for standard single spot photocoagulation. A second version was introduced at the end of 2013 that worked with a wider variety of slit lamps existing in the market and included a number of enhanced features.

TruFocus Laser Indirect Ophthalmoscope (“LIO”). The indirect ophthalmoscope is designed to be worn on the physician’s head and to be used in procedures to treat peripheral retinal disorders, particularly in infants or adults requiring treatment in the supine position. This product can be used in both diagnosis and treatment procedures at the point-of-care. The IRIDEX LIO is recognized as the “standard of the ophthalmic industry”.

Slit Lamp Adapter (“SLA”). These adapters allow the physician to utilize a standard slit lamp in both diagnosis and treatment procedures. Physicians can install an SLA in a few minutes and convert standard diagnostic slit lamps into a therapeutic photocoagulator delivery system. SLAs are used in treatment procedures for both retinal diseases and glaucoma. These devices are available in a wide variety of spot diameters. Our standard SLAs have a single fiber and deliver laser light from a single laser console. Our Symphony SLA has multiple fibers and can deliver laser light from two compatible laser consoles.

Operating Microscope Adapter (“OMA”). These adapters allow the physician to utilize a standard operating microscope in both diagnosis and laser treatment procedures. These devices are similar to SLAs, except that they are oriented horizontally and therefore can be used to deliver retinal photocoagulation to a supine patient.

EndoProbe. Our EndoProbe fiber optic delivery devices are used for endophotocoagulation, a retinal treatment procedure performed in the hospital operating room or surgery center during a vitrectomy procedure. These sterile disposable probes are available in tapered, angled, stepped, aspirating, illuminating, and adjustable styles. The EndoProbe is offered in a wide variety of gauges.

G-Probe. The G-Probe is used in procedures to treat medically and surgically uncontrolled glaucoma, in many instances replacing cyclocryotherapy, or freezing of eye tissues. The G-Probe's non-invasive procedure takes approximately ten minutes, is performed on an anesthetized eye in the doctor's office, and results in less pain and fewer adverse side effects than cyclocryotherapy. The G-Probe is a sterile consumable multi-use product.

DioPexy Probe. The DioPexy Probe is a hand-held instrument which is used in procedures to treat retinal tears, and breaks non-invasively through the sclera, as an alternative method of attaching the retina. Our DioPexy Probe results in increased precision, less pain and less inflammation than traditional cryotherapy.

GreenTip™ Soft Tip Cannula. The GreenTip cannula allows surgeons to effectively visualize and access the proximity of the retina while performing a fluid air exchange during a vitrectomy procedure. Benefits include optimal contrast against the retina, maximized visualization and greater protection of the retina with its unique atraumatic silicone tip. The GreenTip cannula is a sterile disposable single-use product.

MoistAir™ In-Line Air Humidifier. The MoistAir Humidifying Chamber connects to the air line and provides humidified air to the eye during fluid air exchange. Studies have shown that the use of humidified air can substantially reduce the dehydrating effects, delay lens feathering, protect corneal endothelium, and may prevent visual field loss defects after macular hole surgery. The MoistAir Humidifying Chamber is a sterile disposable single use product.

Ophthalmology Treatments

The following chart lists the procedures for treating ophthalmic diseases that can be addressed by utilizing our ophthalmic laser systems. These procedures typically are performed in an OR, ambulatory surgical centers or clinic/outpatient settings and are non-elective and covered by insurance.

	Procedure	Console	Delivery Devices and Other Product	Mode
Age-related Macular Degeneration	Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter	CW

Diabetic Retinopathy

Macular Edema
