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

FORM 8-K

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

October 30, 2023
Date of Report (date of earliest event reported)

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

Delaware	**000-27598**	**77-0210467**
(State or other jurisdiction of Employer incorporation or organization)	**(Commission File Number)**	**(I.R.S. Identification Number)**

1212 Terra Bella Avenue
Mountain View, California 94043
(Address of principal executive offices, including zip code)

(650) 940-4700
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

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

Title of Class	**Trading Symbol**	**Name of Exchange on Which Registered**
Common Stock, par value $0.01 per share	IRIX	Nasdaq Global Market

Item 8.01 Other Events.

On October 26, 2023, WPS Government Health Administrators, ("WPS"), a Medicare Administrative Contractor ("MAC") published "Local Coverage Determination L39620 Micro-Invasive Glaucoma Surgery (MIGS)" (the "LCD"), with a future effective date of December 24, 2023. WPS administers Part B Medicare benefits in Kansas, Nebraska, Missouri, Iowa, Indiana, and Michigan.

Four other MACs, including Palmetto GBA, Celerian Group Company, National Government Services and Noridian Healthcare Solutions participated in a Contractor Advisory Committee Meeting on Micro-Invasive Glaucoma Surgery that was held on January 5, 2023, which meeting is believed to have served as a precursor for the WPS LCD. The Company cannot predict whether or when these additional MACs may issue their own local coverage determinations or the scope, outcome, or impact on Iridex's business of such decisions.

The family of Iridex Laser Systems includes various laser instruments, including the Cyclo G6 Laser System, which have been authorized by the U.S. Food and Drug Administration ("FDA") to deliver laser energy to soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, dermatology, ear, nose and throat (ENT)/otolaryngology, and ophthalmology. With respect to Cyclo G6 Laser System and Probe Delivery Devices for use in ophthalmology, such devices have been cleared by FDA for the intended use of transscleral cyclophotocoagulation of the ciliary processes and for the treatment of glaucoma, including primary open-angle, closed-angle, and refractory.

While Iridex (the "Company") cannot predict how the WPS LCD will be ultimately interpreted and implemented by Medicare and its contractors, on October 30, 2023, Company consulted with expert external reimbursement advisors in an effort to evaluate the potential impact of the LCD on the Company's business. Although the LCD does not deny coverage, it imposes additional requirements for reimbursement. Among the issues examined are (i) the intent of the LCD; (ii) the use and application of definitions within the LCD (e.g., how a determination expressly defined as relating to incisional surgical techniques pulled within its scope non-incisional transscleral cyclophotocoagulation); and (iii) the LCD's failure to recognize any distinctions among (a) endo cyclophotocoagulation and (b) transscleral cyclophotocoagulation, or (x) continuous wave cyclophotocoagulation and (y) micropulse cyclophotocoagulation.

As a result of its consultation with expert external advisors, Iridex currently believes that the LCD will likely be interpreted to materially limit the patient types for which WPS will reimburse cyclophotocoagulation procedures after December 24, 2023 – that is, based the following criteria set forth in the LCD:

" 4. Cyclophotocoagulation will be considered medically reasonable and necessary for patients with refractory glaucoma when:

1. Have failed trabeculectomy or tube shunt procedures AND
2. Minimal useful vision and elevated intraocular pressure AND
3. Have no visual potential and need pain relief"

Refractory Glaucoma is defined within the LCD as "glaucoma that is difficult to treat and poorly controlled on maximally tolerated medical therapy or failed surgical therapy regardless of stage of disease."

Prior to the development and release of Iridex's MicroPulse transscleral laser therapy, the Company marketed and sold its G-Probe Delivery Device, used for continuous-wave transscleral cyclophotocoagulation procedures primarily on refractory glaucoma patients suffering from late-stage symptoms of that disease, including lost vision and pain. Updated versions of the G-Probe are still sold in domestic and international markets and comprise up to 50% of current glaucoma probe sales. In the United States, the updated version of the G-Probe is integrated within the Cyclo G6 Glaucoma Laser System.

Iridex has already been contacted by a number of physicians who communicated concern over the potential limitation in the range of their patients covered for transscleral cyclophotocoagulation laser therapy ("TLT") treatment, particularly with respect to populations that would have difficulty tolerating more invasive and tissue-damaging surgical procedures. Iridex intends to appeal the scope of the WPS LCD and attempt to engage with the MACs to distinguish between non-incisional transscleral cyclophotocoagulation procedures and the alternative incisional surgical MIGS procedures. Among other unintended consequences, Iridex believes that by limiting application of TLT, the LCD has the potential to direct more patients into higher-risk surgical procedures that both increase the potential of complications for patients and increase the total cost of care. Thus, Iridex believes the LCD is likely to increase overall treatment costs while potentially decreasing overall patient welfare.

At this time, Iridex cannot estimate what impact the WPS LCD or any future local coverage determinations by other MACs will have on its glaucoma business. We and other stakeholders plan to challenge the LCD. According to the American Glaucoma Society approximately 60% of U.S glaucoma patients are covered by Medicare. While the states included in WPS's MAC jurisdiction comprise approximately 8% of Iridex's U.S. glaucoma probe sales, if the other MACs adopt similar determinations, this could impact a majority of Iridex's glaucoma revenue in the U.S. In such a scenario, Iridex would expect physicians to continue to use Iridex's probes where there is coverage for the devices and related procedures. Additionally, patients that continue to be covered by medicare advantage or private health insurance and those willing to self-pay may continue to utilize the full range of TLT treatment options where available, particularly when such treatment modalities are preferred by physicians and their patients as a superior option to invasive surgery.

Outside the U.S., where Iridex currently receives approximately 50% of its glaucoma revenue, neither the LCD nor any future local coverage determination are expected to materially impact that business. Reimbursement payments outside the U.S. are generally lower and more restrictive in scope, with TLT's successful and growing penetration within those markets providing further support for the demand for our products and perceived utility and efficacy of Iridex's offerings.

Iridex intends to assess and adjust its domestic glaucoma operations from time-to-time as appropriate in response to any changed reimbursement policies that materially impact its ability to maintain and expand its glaucoma business. For the past several years, sales and marketing expenses relating to the Company's domestic glaucoma efforts have involved significantly larger expenditures compared to the Company's retina and international operations.

Iridex is withdrawing its previously announced annual guidance for 2023. Iridex plans to provide additional information during its third quarter earnings release based on the information available at that time.

Included within the WPS LCD was language addressing the clinical evidence necessary to obtain future coverage support. Much of the criteria aligns well with past clinical studies relating to Iridex's TLT and particularly to the clinical study Iridex has planned to initiate during the current fiscal quarter. Accordingly, Iridex plans to work with its participating physicians to fulfill the stated clinical requirements and thereby continue to demonstrate the value of the MicroPulse technology to patients.

Clinical Criteria from the WPS LCD:

"To be considered reasonable and necessary current and future MIGS procedures/device must meet the following requirements:

1. FDA approved.
2. Demonstrated effectiveness of ≥20% or more reduction of intraocular pressure (IOP) on the same or reduced medication for duration of 24 months or longer demonstrated by moderate-high quality literature.

The literature defines the patient population who may best benefit from the procedure.

3. Literature supports the new technology is at least equivalent to current treatment options.
4. Literature supports low risk of serious adverse events.
5. Literature supports that the surgery/procedure does not interfere with ability to perform definitive surgical management in future if indicated.
6. New devices that offer the same or similar function must demonstrate they are equivalent (or superior) to existing devices with published peer-reviewed literature."

Cautionary Note Regarding Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Act of 1934, as amended, including those statements concerning plans to engage with the MACs, appeal the WPS LCD and pursue clinical studies. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements and includes this statement for purposes of complying with these safe harbor provisions. Any statements made in this Current Report that are not statements of historical fact, including statements about the Company's beliefs and estimates, are forward-looking statements and should be evaluated as such. These statements are not guarantees of future performance and actual results may differ materially from those described in these forward-looking statements as a result of a number of factors. Please see a detailed description of these and other risks contained in Iridex's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 10, 2023. Forward-looking statements contained in this Current Report are made as of this date and will not be updated.

* The information in Item 8.01 of this Current Report shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act or Exchange Act, except as expressly set forth by specific reference in such filing.

MicroPulse® is a registered trademark of Iridex, Inc.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IRIDEX CORPORATION

By: /s/ David I. Bruce
David I. Bruce
President and Chief Executive Officer

Date: October 31, 2023