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

November 14, 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 incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer 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 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 2.02. Results of Operations and Financial Condition.

On November 14, 2023, IRIDEX Corporation issued a press release discussing its financial results for its third fiscal quarter of fiscal year 2023, which ended on September 30, 2023. The press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 14, 2023.
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: November 14, 2023

Exhibit 99.1

Iridex Reports Third Quarter 2023 Financial Results and Business Update

MOUNTAIN VIEW, Calif., November 14, 2023 -- Iridex Corporation (Nasdaq: IRIX), a worldwide leader providing innovative and versatile laser-based medical systems, delivery devices, and procedure probes for the treatment of glaucoma and retinal diseases, today reported financial results for the third quarter ended September 30, 2023 and provided a business update.

Recent Business Updates

- Generated total revenue of $12.9 million, representing flat sequential quarter revenue and a decrease of 12% year-over-year
- Cyclo G6® product family revenue in the third quarter of $3.0 million, representing a decrease 12% year-over-year due to reduced systems sales
    - Sold 13,200 Cyclo G6 probes, representing a 3% revenue increase and 3% unit decrease year-over-year
    - Sold 27 Cyclo G6 Glaucoma Laser Systems, compared to 41 in the second quarter of 2023 and 54 in the prior year period
- Retina product revenue was $7.9 million, representing sequential growth of 15% and a decrease of 10% year-over-year
- Cash and cash equivalents totaled approximately $8.0 million as of September 30, 2023
- Announced in late August that the Company is undertaking a review and evaluation of strategic alternatives to unlock shareholder value
- Subsequent to the quarter end, five of seven U.S. Medicare Administrative Contractors (MACs) issued Local Coverage Determinations that impose additional clinical requirements for reimbursement of minimally invasive glaucoma surgery (MIGS) device procedures and for cyclophotocoagulation procedures performed by the Company's G6 laser system and probes

"Our third quarter results reflected a seasonally strong rebound in retina revenue from softness in the first half, but came in below last year's third quarter results, reflecting continued softer environment for capital equipment and the conclusion of a long-running royalty contract earlier this year," said David Bruce, Iridex President and CEO. "While we remain confident in our market position and continuing opportunities based on our differentiated retina laser platforms and unique glaucoma products supported by strong clinical evidence and global user base of thousands of ophthalmologists, subsequent to the quarter end new restrictions to parts of US glaucoma Medicare reimbursement were announced, injecting new challenges in our U.S. glaucoma business. We strongly disagree with the method used by these MACs in determining these changes and in the specific coverage criteria that resulted. We are challenging these restrictions on multiple fronts."

Third Quarter 2023 Financial Results

Revenue for the three months ended September 30, 2023 was $12.9 million compared to $14.6 million during the same period of the prior year and flat versus the second quarter. Retina product revenue

decreased 10% compared to the prior year period to $7.9 million, primarily driven by continued softness in capital equipment demand, and represents an increase of 15% sequentially compared to the second quarter of 2023. Total product revenue from the Cyclo G6 glaucoma product group was $3.0 million, a decrease of 12% compared to the third quarter of 2022 driven entirely by reduced laser systems, while Cyclo G6 probe revenue grew 3%. Other revenue decreased to $1.9 million in the third quarter of 2023 compared to the prior year period of $2.4 million, primarily driven by decreased royalties due to expiration of licensed patents and lower service revenue.

Gross profit for the third quarter of 2023 was $5.6 million or a 43.7% gross margin, a decrease compared to $6.5 million, or a 44.1% gross margin, in the same period of the prior year, and represents sequential growth of 200 basis points compared to the second quarter of 2023.

Operating expenses for the third quarter of 2023 decreased to $7.3 million for the third quarter of 2023 compared to $8.2 million in the same period of the prior year and $8.3 million in the second quarter of 2023. The decrease is the result of cost optimization efforts that began in the second quarter of 2023.
Net loss for the third quarter of 2023 was $1.8 million, or $0.11 per share, compared to a net loss of $1.8 million, or $0.11 per share, in the same period of the prior year and $2.8 million, or $0.17 per share in the second quarter of 2023.

Cash and cash equivalents totaled $8.0 million as of September 30, 2023. Cash use of $1.8 million in the third quarter increased compared to $1.2 million in the second quarter of 2023. Balance sheet shifts affected cash usage in the quarter as previously announced operating cost reductions and inventory reductions to reduce cash usage were offset by a $1.7 million reduction in accounts payable. We expect to continue making progress with inventory reductions and expect fourth quarter cash usage to be significantly less than the third quarter.

Glaucoma Reimbursement Developments
Between October 24th and November 9th, five of the seven Medicare Administrative Contractors (“MACs”) that manage part of US Medicare coverage in the U.S. published “Local Coverage Determination” (the “LCDs”), that become effective December 24, 2023. The new LCDs primarily targeted Minimally Invasive Glaucoma Surgery (MIGS) procedures and devices, however also significantly restricted the criteria for coverage of cyclophotocoagulation reimbursement, the procedures which utilize Iridex’s G6 laser system and probes, for glaucoma patients.

After consultation with expert external advisors, Iridex believes that the LCDs will likely be interpreted to materially limit the patient types for which the respective MACs will reimburse cyclophotocoagulation procedures.

Iridex has been in contact with a number of societies and individual physicians who communicated concern over the potential limitation in the range of their patients covered for transscleral cyclophotocoagulation laser treatment. Iridex intends to appeal the restrictive criteria of the LCDs and to engage with the MACs to distinguish the clinical justification between non-incisional transscleral cyclophotocoagulation procedures and the alternative incisional surgical MIGS procedures.

At this time, Iridex cannot accurately predict the impact these LCDs coverage changes will have on its glaucoma business. Approximately two-thirds of our total U.S. glaucoma procedure volume is performed in regions covered by the five MACs that issued LCDs. The American Glaucoma Society estimates 60% of

U.S. glaucoma patients are covered by Medicare, and among Medicare patients, approximately half are covered by MACs, with the other half enrolled in Medicare Advantage plans who have not restricted the coverage criteria for cyclophotocoagulation. This implies about 20% of U.S. procedures fall directly under the coverage restrictions, with our glaucoma procedures for the most severe patients least affected and those for more moderate stage most affected. At this time, it is uncertain how physicians will react to coverage reductions and their decisions to offer our treatments to patients. Iridex is working to educate physicians about specific patient coverage ratios in their practice area and to support continued use and further expand adoption of our procedures where coverage for the devices and related procedures is maintained. Outside the U.S., which accounts for approximately 50% of Iridex glaucoma revenue, no material impact to the business is expected.

“Our top priority is maintaining fair market access to the procedures performed by the G6 laser platform following the recently issued LCDs. We disagree with the restrictive criteria defined to deem the procedures medically necessary and are collaborating with industry stakeholders to have the coverage policies appealed to reflect the extensive clinical evidence in support of cyclophotocoagulation procedures. We have submitted an appeal for correction based on inconsistency between the conclusions of the referenced studies and the final coverage restrictions. Among other unintended consequences, we believe that by limiting coverage of our MicroPulse and continuous-wave procedures, the LCDs have the potential to direct more patients into higher risk surgical procedures that both increase the potential for complications in patients, increase the total cost of care and decrease overall patient welfare,” said David Bruce, Iridex President and CEO. “As we work to retain full coverage of CPC in the affected MAC regions, we remain focused on our initiatives to accelerate G6 probe adoption in the covered population, including advancing our large multicenter prospective trial to further validate the safety and effectiveness of MPTLT procedures. We have high confidence that the efficacy and safety of or procedures will prevail, and the increased clinician awareness generated through this process can provide increased exposure to position MPTLT solidly as a key non-incisional procedure in the glaucoma continuum of care.”

Guidance Withdrawn for Full Year 2023
Iridex cannot accurately predict the impact to our glaucoma probes and system sales that will result from the reimbursement changes of the five LCDs as our customers and prospects evaluate their usage of probes and system purchases. Given this uncertainty, guidance has been withdrawn as the impact to Cyclo G6 system and probe sales is evaluated further.

Strategic Review to Unlock Shareholder Value
In August 2023, the Iridex board of directors announced it is conducting, in consultation with its financial and legal advisors, a review and evaluation of strategic alternatives that may be available to the Company to unlock shareholder value. Iridex has engaged Piper Sandler to act as financial advisor in connection with the strategic review process.

Scott Shuda, Chairman of the board of directors, commented on the strategic review process, “As a public company, Iridex must always seek to maximize shareholder value. Iridex’s product offerings today are stronger than they have ever been, and the board believes this is an appropriate time to explore strategic options for the future of each of our product lines.”

Webcast and Conference Call Information
Iridex's management team will host a conference call today beginning at 2:00 p.m. PT / 5:00 p.m. ET. Investors interested in listening to the conference call may do so by accessing the live and recorded webcast on the "Event Calendar" page of the "Investors" section of the Company's website at www.iridex.com.

About Iridex
Iridex Corporation is a worldwide leader in developing, manufacturing, and marketing innovative and versatile laser-based medical systems, delivery devices and consumable instrumentation for the ophthalmology market. The Company's proprietary MicroPulse® technology delivers a differentiated treatment that provides safe, effective, and proven treatment for targeted sight-threatening eye conditions. Iridex's current product line is used for the treatment of glaucoma and diabetic macular edema (DME) and other retinal diseases. Iridex products are sold in the United States through a direct sales force and internationally primarily through a network of independent distributors into more than 100 countries. For further information, visit the Iridex website at www.iridex.com.

Safe Harbor Statement
This announcement 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 clinical expectations and commercial trends, market adoption and expansion, demand for and utilization of the Company's products and results and expected sales volumes. 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 our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 10, 2023. Forward-looking statements contained in this announcement are made as of this date and will not be updated.

Investor Relations Contact
Philip Taylor
Gilmartin Group
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IRIDEX Corporation
Condensed Consolidated Statements of Operations
(In thousands, except per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2023	**October 1, 2022**	**September 30, 2023**	**October 1, 2022**
Total revenues	$ 12,850	$ 14,635	$ 39,411	$ 41,777
Cost of revenues	7,229	8,175	22,489	23,073
Gross profit	5,621	6,460	16,922	18,704
Operating expenses:				
Research and development	1,541	1,687	5,135	5,725
Sales and marketing	3,823	4,445	12,370	13,352
General and administrative	1,945	2,023	6,343	5,759
Total operating expenses	7,309	8,155	23,848	24,836
Loss from operations	(1,688)	(1,695)	(6,926)	(6,132)
Other income (expense), net	(58)	(58)	346	(216)
Loss from operations before provision for income taxes	(1,746)	(1,753)	(6,580)	(6,348)
Provision for income taxes	8	14	30	51
Net loss	$ (1,754)	$ (1,767)	$ (6,610)	$ (6,399)
Net loss per share:				
Basic	$ (0.11)	$ (0.11)	$ (0.41)	$ (0.40)
Diluted	$ (0.11)	$ (0.11)	$ (0.41)	$ (0.40)
Weighted average shares used in computing net loss per share:				
Basic	16,231	15,986	16,089	15,921
Diluted	16,231	15,986	16,089	15,921

IRIDEX Corporation
Condensed Consolidated Balance Sheets
(In thousands and unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,981	$ 13,922
Accounts receivable, net	8,114	9,768
Inventories	10,118	10,608
Prepaid expenses and other current assets	1,129	1,468
Total current assets	27,342	35,766
Property and equipment, net	524	462
Intangible assets, net	1,726	1,977
Goodwill	965	965
Operating lease right-of-use assets, net	2,789	1,665
Other long-term assets	1,603	1,455
Total assets	$ 34,949	$ 42,290
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,613	$ 3,873
Accrued compensation	2,197	2,448
Accrued expenses	1,171	1,548
Other current liabilities	886	968
Accrued warranty	247	168
Deferred revenue	2,239	2,411
Operating lease liabilities	995	1,037
Total current liabilities	10,348	12,453
Long-term liabilities:		
Deferred revenue	10,472	11,742
Other long-term liabilities	2,065	864
Total liabilities	22,885	25,059
Stockholders' equity:		
Common stock	172	169
Additional paid-in capital	87,993	86,802
Accumulated other comprehensive loss	(19)	(24)
Accumulated deficit	(76,082)	(69,716)
Total stockholders' equity	12,064	17,231
Total liabilities and stockholders' equity	$ 34,949	$ 42,290