UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) February 23, 2018

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

Delaware	**0-27598**	**77-0210467**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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)

Not Applicable
(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. ☐

Item 2.02. Results of Operations and Financial Condition.

The information provided under Item 7.01 of this Current Report on Form 8-K is incorporated into this Item 2.02 (Results of Operations and Financial Condition) by reference.

Item 7.01. Regulation FD Disclosure.

On February 23, 2018, IRIDEX Corporation ("Iridex") announced a voluntary recall of one of its laser accessories called the TruFocus LIO Premiere™. In connection with this announcement, Iridex revised its preliminary revenues for its fourth fiscal quarter and full fiscal year 2017. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 23, 2018.

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/ William M. Moore
William M. Moore
President and Chief Executive Officer

Date: February 23, 2018

Exhibit 99.1

IRIDEX Issues Voluntary Recall of TruFocus LIO Premiere™ Laser Indirect Ophthalmoscope

Updates Preliminary Financial Results for 2017 Fourth Quarter and Full Year

FOR IMMEDIATE RELEASE: February 23, 2018
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043
888.725.8115

On February 23, 2018**,** IRIDEX Corporation ("Company") initiated a voluntary recall of a specific laser accessory called the TruFocus LIO Premiere™. The LIO is a headmounted indirect ophthalmoscope that connects to an IRIDEX laser console and is used to view and perform laser treatments on a patient's eye. There are 104 TruFocus LIO Premiere units at customer sites worldwide. The Company has received reports of three adverse events occurring during procedures in which the TruFocus LIO Premiere was used. These reports stated that the procedures resulted in patients experiencing permanent damage to the eye, including focal cataracts and iris burns.

Customers who have the TruFocus LIO Premiere should stop using it. IRIDEX is notifying its distributors and customers via FedEx and is arranging for return of all recalled products.

Recalled products were manufactured from May 26, 2017 to November 6, 2017 and distributed from June 5, 2017 to January 29, 2018.

The following part numbers have been recalled: 87300, 87301, 87302, 87303, and 87304.

IRIDEX has notified the U.S. Food and Drug Administration (FDA) of this action.

Customers with questions may contact the Company at 1-844-357-9485 in the US and 1-650-962-8100 outside the US between the hours of 8:00 a.m. and 5:00 p.m. PT. Customers may also contact the Company via e-mail at techsupport@iridex.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

As a consequence of this recall program, the Company has revised its preliminary financial results for the fourth quarter and full year ended December 30, 2017 to the following:

- Total revenue for the fourth quarter of 2017 is expected to be $10.2 to $10.3 million
- Total revenue for 2017 is expected to be $41.5 to $41.6 million

IRIDEX expects to release its complete fourth quarter and full year 2017 results on Thursday, March 8, 2018 and will host a corresponding conference call beginning at 2:00 p.m. PT / 5:00 p.m. ET, at which time, the Company plans to provide additional details regarding the financial impact of this recall program.

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, 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 http://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 the Company's recall of its TruFocus LIO Premiere product, the company's anticipated revenue for the fourth quarter and fiscal year 2017 and the timing of the Company's release of its complete fourth quarter and full fiscal year 2017 results. 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, including adjustments in connection with the Company's audit of fiscal year 2017. Please see a detailed description of these and other risks contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and Quarterly Reports on Form 10-Q for subsequent fiscal quarters, each of which was filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date and will not be updated.

Investor Relations Contact
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