
**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)

December 13, 2004

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

0-27598

(Commission File Number)

77-0210467

(IRS Employer
Identification No.)

**1212 Terra Bella Avenue
Mountain View, California 94043**

(Address of principal executive offices, including zip code)

(408) 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))
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Item 7.01. Regulation FD Disclosure.

The Registrant is making the attached excerpt from its December 2004 Customer Update available to its investors. A copy of the excerpt is furnished 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.

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	IRIDEX TTT Customer Update (Excerpt) dated December 2004.

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/ LARRY TANNENBAUM

Larry Tannenbaum

Chief Financial Officer, Secretary and Senior Vice

President of Finance and Administration

Date: **December 13, 2004**

EXHIBIT INDEX

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99.1	IRIDEX TTT Customer Update (Excerpt) dated December 2004.

IRIDEX TTT Customer Update (Excerpt)

December 2004

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*What's New***TTT4CNV Clinical Trial – Preliminary Results**

On October 22, 2004, Dr. Elias Reichel presented preliminary study results at the Retina Subspecialty Day Program during the AAO meeting:

- Preliminary results presented covered all eyes enrolled (intent-to-treat [ITT]). Some 18- and 24-month follow-up data were not yet available for inclusion. No sub-group or per-protocol analyses were presented.
- A total of 303 eyes were enrolled in the TTT4CNV study according to the following criteria: occult CNV (with less than or equal to 10% classic) due to AMD, CNV lesions less than or equal to 3 mm diameter and ETDRS visual acuity (VA) 20/50 to 20/400. Eyes were randomized 2:1 to TTT treatment or sham treatment. All eyes randomized to treatment received the same TTT dose of 800 mW for 60 seconds and a 3 mm spot. Only one re-treatment was allowed at physician discretion at 3 months.
- At 24 months follow-up: Preliminary results showed 47% of TTT treated eyes lost less than 3 lines of VA compared to 43% of sham treated eyes. This difference was not statistically significant.
- At 18 and 24 months follow-up: Preliminary results showed an advantage of approximately 4 letters in TTT treated eyes, though this trend was not statistically significant.
- At 12 months follow-up: Preliminary results showed 11% of TTT treated patients improved 2 or more lines in VA from baseline compared to 3% of patients who received sham treatment. This secondary outcome **was statistically significant**.
- Safety results were also presented. Some patients, both in the treatment and sham groups, showed greater than or equal to 6 lines of VA loss at the one-month follow-up visit. This occurred in 5% of TTT treated eyes compared to 1% of sham eyes. This finding was not statistically significant.

*IRIDEX' Comments:***Observations on Preliminary Trial Results:**

- This study demonstrates that TTT creates a biological effect and can improve vision in certain patients. Though trends showed a benefit for TTT, the sample size was too small to demonstrate a statistically significant difference in an ITT analysis.
- The acute vision loss safety profile appears comparable to PDT for occult CNV [Verteporfin in Photodynamic Therapy (VIP)].
- About 45% of TTT4CNV lesions were found by reading center specialists to be larger than the 3 mm spot size of the laser. A per protocol analysis is being performed to evaluate the impact of this observation.
- Sub-group analyses are being performed to identify the common baseline characteristics of patients who experienced vision improvement/stabilization and those who experienced vision loss.
- Sub-group & per-protocol analyses will not change the primary ITT outcome, but may reveal statistically and clinically significant findings.
- Definitive conclusions about TTT should be deferred until these data analyses are completed.

- These preliminary results are more closely associated with the specific TTT4CNV study protocol as implemented rather than TTT as a general treatment. With this in mind, it is very likely that different treatment parameters and patient selection criteria may have had different results.
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Comparison to the occult with no classic arm of the VIP trial:

- Eyes treated in the TTT4CNV trial had similar results to the VIP trial in preserving vision but the sham eyes lost less vision in the TTT4CNV Trial vs. the VIP Trial.
 - VIP required that eyes have recent progression of disease. TTT4CNV did not have this requirement.
 - A higher percentage of sham patients dropped out of the TTT4CNV study than treated patients (differential dropout) possibly due to availability of PDT or other treatments during the follow-up period. This differential dropout rate may have moderated the differences measured between treated and sham groups although there can be no assurance that this moderated the effect.
- VIP required detailed sub-group analyses to identify the sub-group (occult with no classic with small lesions and worse vision) that demonstrated a statistically significant benefit from Visudyne PDT.

Comparison to Results from Other TTT Studies using the IRIS Medical OcuLight 810 nm Photocoagulator and Large Spot Slit Lamp Adapter:

Outside of the trial, ophthalmologists around the world are successfully utilizing TTT to treat AMD as reported in 29 non-randomized studies (10 peer-reviewed) that treated more than 1,000 eyes with occult CNV with follow-up ranging from 6 to 29 months. In these studies in general:

- Approximately 75% of eyes treated with TTT avoided 3 lines of vision loss.
- Dosing protocols were tailored for specific patient pigmentation/lesion characteristics while TTT4CNV used a single 800 mW power setting independent of individual patient characteristics such as pigmentation and degree of sub-retinal fluid; and TTT4CNV used a single 3 mm spot size regardless of lesion size.
- Patient baseline characteristics (lesion size, VA, etc.) may have been different than TTT4CNV.

Concluding Comments:

- Occult wet AMD is a difficult disease to treat. No available treatment has shown a substantially improved benefit over others.
- Most other treatment options available today are drug-based, very expensive and offer modest benefit to patients' vision. Everyone prefers lower cost alternatives and will carefully evaluate the incremental benefit to incremental cost.
- IRIDEX encourages physicians to remain open-minded about TTT as a treatment option for occult CNV until further data analyses from the TTT4CNV trial can be completed and presented (anticipated during the first quarter of 2005).

IRIDEX is encouraged that a number of patients experienced a significant improvement in vision and looks forward to a more thorough analysis of the study data, which may provide insights into the patients who responded best to TTT. We will share further results and ideas with you as they develop.



For More Information Call: 1-800-388-4747 (USA); 650-962-8100 (Int'l)