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IGEN INTERNATIONAL INC /DE

Form 8-K

April 17, 2002

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

Date of Report (Date of earliest event reported) April 15, 2002

Commission File Number 0-23252

IGEN INTERNATIONAL, INC.

(Exact name of registrant)

Delaware

94-2852543

(State of organization)

(I.R.S. Employer Identification No)

16020 Industrial Drive, Gaithersburg Maryland 20877

(Address of principal executive offices and zip code)

(301) 869-9800

(Registrant's telephone Number)

Item 5. OTHER EVENTS

On April 15, 2002, the U.S. District Court for the District of Maryland reaffirmed its final order of judgment in IGEN's case against Roche Diagnostics, a division of F. Hoffmann-La Roche. The judgment, which was entered on February

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15, 2002, awards IGEN \$505 million in damages; confirms the Company's right to terminate the license agreement; and directs and commands Roche to grant to IGEN for use in its retained fields a license to improvements developed by Roche under the agreement, including Roche's Elecsys(R) diagnostics product line.

In upholding the judgment, the district court rejected several motions filed by Roche seeking to reduce by more than \$400 million the monetary damages awarded to IGEN. The district court also rejected Roche's challenge to the jury's finding that Roche materially breached the license agreement in five separate and distinct ways. Finally, the court dismissed Roche's attempts to obtain a new trial on numerous issues, including the amount of punitive damages awarded.

Earlier this year, the Company advised Roche in writing that the license agreement will automatically terminate once the Court of Appeals affirms that portion of the judgment holding that Roche materially breached the license agreement. It is expected that Roche will file an appeal with the Fourth Circuit Court of Appeals within 30 days. Roche has posted a bond in the amount of \$620 million to secure its financial obligations to IGEN under the judgment. The Company anticipates that the decision of the Court of Appeals will be issued in mid-2003.

With the judgment now confirmed by the district court, Roche is barred from marketing, selling, placing or distributing outside of its licensed field any products, including its Elecsys diagnostics product line, that are based on IGEN's ORIGEN(R) technology. Once the license agreement is terminated, Roche will be prohibited from manufacturing, marketing, and selling all ORIGEN-based products, including its Elecsys diagnostics product line in all markets and to all customers. Thereafter, IGEN will be free to sell ORIGEN-based products in all diagnostics markets, including hospitals, blood banks and clinical reference laboratories. Contrary to a recent letter issued by Roche, Roche will not have continuing access to the Company's ORIGEN technology or be able to continue sales or service for its Elecsys product line after the license is terminated.

IGEN has been evaluating various opportunities to exploit its proprietary ORIGEN technology independently of Roche, both for the field currently licensed to Roche as well as for IGEN's retained field, such as physician office laboratories, emergency rooms, intensive care units, among others. This might include, among other things, commercializing the present Elecsys product line and integrating these improvements into a new product line. The Company has been in discussions with third parties regarding the various possibilities.

With respect to all improvements developed by Roche and its subcontractors under the license agreement, the judgment commands and directs that within 30 days of the present court ruling, the following must occur:

>> Roche must grant the Company for use in its retained fields an irrevocable, perpetual, fully-paid (royalty-free), non-exclusive license (with the right to sublicense) to Roche's entire Elecsys 1010 instrument, entire Elecsys 2010 instrument, all aspects of the ORIGEN-based assays (tests) developed by Roche, the ORIGEN-based module of the E170 instrument, the ORIGEN-based DNA probe analyzer developed by Roche, and the nucleic acid amplification

technology called PCR that was used by Roche in connection with the ORIGEN-based DNA probe system.

>> Roche must deliver to the Company all documents, protocols, formulas, system specifications, design drawings, processes, data, controls, materials, regulatory filings, know-how, and show-how in the possession, custody or control of Roche and all of its subcontractors, including

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Hitachi.

- >> Roche must deliver to the Company all other information and materials required or necessary to enable IGEN to design, develop, replicate, manufacture, validate, obtain regulatory approval for and commercialize the improvements.
- >> Roche must timely respond to all of the Company's reasonable requests for information and must make its personnel and its subcontractors (including Hitachi) available to the Company for on-site and other consultations to ensure the full transfer of the improvements.
- >> Roche must bear all costs associated with the transfer to the Company of the improvements.

This report contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, about litigation, including the timing for completion of and prospects for ultimate success on any appeal of the litigation, the commercial viability of the Company's technology and the improvements awarded to the Company, the timeline of the transfer of improvements, the likelihood and affects of a termination of the license to Roche, the timeline for and likelihood of filing an appeal, the prospects for new business arrangements, and future growth prospects. Actual results might differ materially from these statements due to risks and uncertainties, including risks associated with litigation generally including future decisions that may be made by the courts. More complete descriptions of the risks applicable to IGEN appear in the Company's documents filed with the Securities and Exchange Commission and available on request from the Company. IGEN disclaims any intent or obligation to update these forward-looking statements.

Signatures

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

IGEN International, Inc.

By: /s/ Samuel J. Wohlstadter

Samuel J. Wohlstadter
Chairman & Chief Executive Officer

Dated: April 17 , 2002