IR BIOSCIENCES HOLDINGS INC

Form 8-K June 09, 2009

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

Date of Report (Date of earliest event reported): June 4, 2009

IR BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant specified in charter)

Delaware (State of Incorporation)

033-05384 (Commission File Number) 13-3301899 (IRS Employer Identification No.)

8777 E. Via De Ventura, Suite 280 Scottsdale, AZ 85258 (Address of principal executive offices) (Zip Code)

(480) 922-3926

(Registrant's telephone number, including area code)

N/A

(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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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

On June 4, 2009, IR BioSciences Holdings, Inc. (the "Company"), a Delaware corporation, received acknowledgement from YA Global Investments, L.P. ("YA Global") that YA Global has reviewed and accepted the Company's recent submission of an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA). This submission makes for successful completion by the Company of the third, and final, milestone obligation under provisions of the convertible debentures issued by the Company to YA Global. As per the term of the convertible debentures, successful completion of the final milestone is defined as submission of an IND for the use of Homspera in humans which IND was required to be submitted to the FDA for at least one clinical trial (Phase I) in humans by June 30, 2009.

On May 28, 2009, ImmuneRegen BioSciences, Inc., a wholly owned subsidiary of IR BioSciences Holdings, Inc. submitted the IND to the FDA to begin human clinical testing of Homspera, an analog of the endogenous neurokinin Substance P, as a treatment for Idiopathic Pulmonary Fibrosis, a condition for which there are no consistently effective drugs approved for human use in the U.S.

The convertible debentures were sold pursuant to a securities purchase agreement dated as of January 3, 2008 (the "Agreement") providing for the issuance of (i) convertible debentures in an aggregate principal amount up to \$3,000,000 (collectively, the "Convertible Debentures") which are convertible into shares (the "Conversion Shares") of the Company's common stock, par value \$.001 per share (the "Common Stock"), and (ii) warrants (the "Warrants") to purchase 7,500,000 shares of Common Stock (the "Warrant Shares"). The initial closing of the Agreement occurred on January 3, 2008, at which time the Company sold to YA Global \$2 million of the Debentures and the Warrants, and on June 12, 2008 the Company exercised its option to sell and issue to YA Global an additional \$1 million of the Debentures.

This summary is qualified in its entirety by reference to the full text of the Convertible Debenture attached as Exhibit 4.1, the Common Stock Purchase Warrant attached as Exhibit 4.2, the Agreement attached as Exhibit 10.1, the Guaranty Agreement attached as Exhibit 10.2, the Security Agreement attached as Exhibit 10.3 and the Patent Security Agreement attached as Exhibit 10.4, all to the report on Form 8-K filed on January 9, 2008 and all of which is incorporated herein by this reference.

The information in this Report on Form 8-K is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section. This Report will not be deemed an admission as to the materiality of any information in the Report that is required to be disclosed solely by Regulation FD.

The Company does not have, and expressly disclaims, any obligation to release publicly any updates or any changes in the Company's expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

THIS CURRENT REPORT IS NOT AN OFFER OF SECURITIES FOR SALE. ANY SECURITIES SOLD IN AS DESCRIBED ABOVE HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE OFFERED OR SOLD IN THE UNITED STATES UNLESS REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR PURSUANT TO AN EXEMPTION FROM SUCH REGISTRATION.

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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.

IR BIOSCIENCES HOLDINGS, INC.

Dated: June 9, 2009 By: /s/ Michael K Wilhelm

Michael K Wilhelm President and CEO

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