ALIMERA SCIENCES INC
Form 8-K
March 27, 2012

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): March 27, 2012

ALIMERA SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-34703**	**20-0028718**
(State or other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

6120 Windward Parkway

Suite 290

Alpharetta, Georgia **30005**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant s telephone number, including area code: (678) 990-5740

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:

¨ 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))

Item 7.01. Regulation FD.

Alimera Sciences, Inc. (Alimera) is furnishing the following disclosure under Regulation FD to update certain statements made during its fourth quarter 2011 conference call, held on March 8, 2012, as well as certain statements made in press releases issued by Alimera on February 28, 2012 and March 8, 2012.

Based on recent discussions with European regulatory authorities and Alimera s regulatory consultants in Europe, Alimera believes that it will take longer than originally anticipated to obtain marketing authorizations for ILUVIEN® from the seven countries in which Alimera filed for such authorization (Austria, France, Germany, Italy, Portugal, Spain and the United Kingdom). As indicated in the Final Assessment Report (FAR) received by Alimera on February 27, 2012, each of these countries has reached a consensus that ILUVIEN is approvable. However, although the Decentralized Procedure Members States Standard Operating Procedure provides that each country shall adopt a national decision within 30 days after the Reference Member State closes the procedure (i.e., the issuance of the FAR), given the amount of time regulatory authorities in these countries have taken recently with respect to other drugs between the issuance of a FAR and the issuance of formal marketing authorizations, Alimera now believes that these authorizations likely will be issued in the second and third quarters of 2012, although one or more countries could take longer. Alimera does not anticipate, however, that the projected timing of these formal marketing authorizations will delay the availability of ILUVIEN in Europe, which Alimera expects to be by the end of 2012.

Various statements made in this Current Report on Form 8-K are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, regarding, among other things, Alimera s future results of operations and financial position, business strategy and plans and objectives of management for Alimera s future operations. Words such as anticipate, believe, estimate, expect, intend, may, p contemplate, predict, project, target, likely, potential, continue, will, would, should, could, or the negative of these terms a are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The events and circumstances reflected in Alimera s forward-looking statements may not occur and actual results could differ materially from those projected in its forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to, delay in or failure to obtain regulatory approval of Alimera s product candidates, uncertainty as to Alimera s ability to commercialize (alone or with others), and market acceptance of, ILUVIEN in Europe, the extent of government regulations, uncertainty as to relationship between the benefits of Alimera s product candidates and the risks of their side-effect profiles, dependence on third-party manufacturers to manufacture Alimera s product candidates in sufficient quantities and quality, uncertainty of clinical trial results, limited sales and marketing infrastructure, inability of Alimera s outside sales force to successfully sell and market ILUVIEN in the U.S. following regulatory approval and Alimera s ability to operate its business in compliance with the covenants and restrictions that it is subject to under its credit facility, as well as other factors discussed in the Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations sections of Alimera s Annual Report on Form 10-K for the year ended December 31, 2010, and Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC s website at www.sec.gov. Additional factors may also be set forth in those sections of Alimera s Annual Report on Form 10-K for the year ended December 31, 2011 to be filed with the SEC. In addition to the risks described above and in Alimera s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Alimera s results. There can be no assurance that the actual results or developments anticipated by Alimera will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Alimera. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All forward-looking statements made in this Current Report on Form 8-K are expressly qualified by the cautionary statements contained or referred to herein. Alimera cautions investors not to rely too heavily on the forward-looking statements Alimera makes or that are made on its behalf. These forward-looking statements speak only as of the date on which they are made (unless another date is indicated). Alimera undertakes no obligation, and specifically declines any obligation, to publicly update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

The information in Item 7.01 of this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURE

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.

ALIMERA SCIENCES, INC.

By: /s/ RICHARD S. EISWIRTH, JR.
Name: Richard S. Eiswirth, Jr.
Title: Chief Operating Officer and Chief Financial Officer

Dated: March 27, 2012