

ACHILLION PHARMACEUTICALS INC

Form 8-K

September 27, 2013

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): September 27, 2013

Achillion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

**Delaware
(State or other jurisdiction**

of incorporation)

300 George Street

**001-33095
(Commission**

File Number)

**52-2113479
(IRS Employer**

Identification No.)

06511

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New Haven, CT

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (203) 624-7000

N/A

(Former name or former address, if changed since last report)

Check the appropriate box if the Form 8-K 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 8.01. Other Events

Achillion Pharmaceuticals, Inc. (the Company) announced today that the Company received a response from the U. S. Food and Drug Administration (the FDA), on the clinical hold related to sovalprevir, the Company's NS3 protease inhibitor. The FDA response indicated that, while the Company's submission addressed all issues noted in the FDA's June 29, 2013 letter, the FDA concluded that the removal of the clinical hold is not warranted.

The Company also announced interim data from the ongoing -007 Phase 2a clinical trial evaluating two doses of sovalprevir, either 200 mg or 400 mg once daily, in combination with 50 mg once daily of ACH-3102 and ribavirin twice daily for 12 weeks in patients with treatment-naïve GT 1a or 1b hepatitis HCV.

The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current report on Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 8.01 shall be deemed to be furnished, and not filed:

99.1 Press Release dated September 27, 2013

SIGNATURE

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

ACHILLION PHARMACEUTICALS, INC.

Date: September 27, 2013

By: /s/ Mary Kay Fenton
Mary Kay Fenton

Chief Financial Officer

Exhibit Index

99.1 Press Release dated September 27, 2013