EPIRUS BIOPHARMACEUTICALS, INC.

FORM 8-K
(Current report filing)

Filed 05/10/13 for the Period Ending 05/10/13

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CIK 0001135906
Symbol EPRSQ
SIC Code 2834 - Pharmaceutical Preparations
Industry Biotechnology & Medical Research
Sector Healthcare
Fiscal Year 12/31
ZALICUS INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

245 First Street
Third Floor
Cambridge, MA 02142
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (617) 301-7000

None
(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 8.01. Other Events.
On May 10, 2013, Zalicus Inc. ("Zalicus") issued a press release announcing that Zalicus presented preclinical data on Z160, an N-type calcium channel blocker, and Z944, a T-type calcium channel blocker, at the American Pain Society 2013 Annual Meeting. The full text of Zalicus’s press release regarding the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

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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.

Zalicus Inc.
By: /s/ Jason F. Cole
Name: Jason F. Cole
Title: EVP, Corporate Development and General Counsel

Dated: May 10, 2013

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CAMBRIDGE, Mass. – May 10, 2013 – Zalicus Inc. (Nasdaq Capital Market: ZLCS) today announced that preclinical data highlighting its novel, oral ion channel programs for the treatment of pain including Z160, an N-type calcium channel blocker and Z944, a T-type calcium channel blocker were presented at the 32nd Annual Scientific Meeting of the American Pain Society taking place May 8-11, 2013 in New Orleans, LA.

“These data demonstrate the significant progress we have made in validating the activity of our two most advanced novel, oral calcium channel blockers in preclinical models of pain,” commented Mark H.N. Corrigan, MD, President and CEO of Zalicus. “Our primary focus is on advancing the development of our ion channel programs, including Z160, our first-in-class, oral N-type calcium channel blocker for the treatment of chronic neuropathic pain that is currently actively enrolling two Phase 2 clinical trials, and Z944, a novel oral T-type calcium channel blocker that is continuing to progress in the clinic.” In a poster presentation entitled “Z160: A potent and state-dependent, small molecule blocker of N-type calcium channels effective in nonclinical models of neuropathic pain,” Margaret S. Lee, PhD, Vice President of Research & Translational Medicine at Zalicus, presented preclinical pharmacology data demonstrating that Z160:

- Potently and selectively blocked N-type channel activity
- Provided greater potency at elevated stimulus frequencies, similar to those typical of neurons processing pain signals
- Preferentially enhanced the inactivated state, a mechanism distinct from that of other neuropathic pain drugs or N-type blockers
- Performed with robust activity across a wide range of preclinical pain models with efficacy similar to currently marketed neuropathic pain drugs and no sedative effects.

In a poster presentation entitled “Z944: A first in-class T-type calcium channel blocker effective in nonclinical models of acute and inflammatory pain,” Glenn F. Short III, PhD, Senior Director of Research at Zalicus, presented preclinical data demonstrating that Z944:

- Potently and selectively blocked T-type channel activity
- Exhibited selectivity for the inactivated state and was more active during higher frequency signaling
- Displayed potent activity in preclinical models of pain, particularly inflammatory pain, with efficacy exceeding naproxen

About Z160 and N-type Calcium Channel Blockers

Z160 is a first-in-class, oral, state-dependent, selective N-type calcium channel (Cav2.2) blocker, designed to selectively target neuronal pain signaling by modulating neurons that are undergoing high-frequency firing. Z160 has demonstrated efficacy in multiple animal models of neuropathic and inflammatory pain, suggesting that it has the potential to treat a broad range of chronic pain conditions. Additionally, clinical trials in over 200 subjects have
established Z160 as a safe and well tolerated drug candidate. N-type calcium channels have been recognized as crucial targets in controlling pain because of their key role in transmitting pain through the spinal nerves to the brain. Zalicus has advanced Z160 into two Phase 2 proof-of-concept clinical studies in chronic neuropathic pain and plans to report top-line data in late 2013.

About Z944 and T-type Calcium Channel Blockers

Z944 is a novel, oral, state-dependent, selective T-type calcium channel blocker that has demonstrated preclinical efficacy in multiple inflammatory pain models. T-type calcium channels have been recognized as key targets for therapeutic intervention in a broad range of cell functions and have been implicated in pain signaling. Zalicus completed Phase 1 single and multiple ascending dose clinical studies evaluating the safety and tolerability of Z944 in late 2012 and plans to continue further clinical development during 2013.

About Zalicus

Zalicus Inc. (Nasdaq Capital Market: ZLCS) is a biopharmaceutical company that discovers and develops novel treatments for patients suffering from pain. Zalicus has a portfolio of proprietary clinical-stage product candidates targeting pain such as Z160 and Z944 and has entered into multiple revenue-generating collaborations with large pharmaceutical companies relating to other products, product candidates and drug discovery technologies. Zalicus applies its expertise in the discovery and development of selective ion channel modulators and its combination high throughput screening capabilities to discover innovative therapeutics for itself and its collaborators in the areas of pain, inflammation, oncology and infectious disease. To learn more about Zalicus, please visit www.zalicus.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning Zalicus, its product candidates, their potential and the plans for their clinical and preclinical development, the Zalicus selective ion channel modulation technology and related preclinical product candidates and its other business plans. These forward-looking statements about future expectations, plans, objectives and prospects of Zalicus and its product candidates may be identified by words like “believe,” “expect,” “may,” “will,” “should,” “seek,” “plan” or “could” and similar expressions and involve significant risks, uncertainties and assumptions, including risks related to the development and regulatory approval of Zalicus’ product candidates, including risks relating to formulation and clinical development of Z160 and Z944, the unproven nature of the Zalicus drug discovery technologies, the Company’s ability to obtain additional financing or funding for its research and development, and those other risks that can be found in the “Risk Factors” section of Zalicus’ annual report on Form 10-K on file with the Securities and Exchange Commission and the other reports that Zalicus periodically files with the Securities and Exchange Commission. Actual results may differ materially from those Zalicus contemplated by these forward-looking statements. These forward-looking statements reflect management’s current views and Zalicus does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.