

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 14, 2018**

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**SPRING BANK PHARMACEUTICALS, INC.**

(Exact Name of Company as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction of Incorporation)

**001-37718**  
(Commission File Number)

**52-2386345**  
(IRS Employer Identification No.)

**86 South Street  
Hopkinton, MA 01748**  
(Address of Principal Executive Offices) (Zip Code)

**Company's telephone number, including area code: (508) 473-5993**

(Former Name or Former Address, if Changed Since Last Report)

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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):

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 8.01. Other Events.**

On March 14, 2018, the Registrant issued a press release announcing additional results from the first two cohorts (25mg and 50mg) of Part A of the Registrant's Phase 2 ACHIEVE clinical trial of patients infected with chronic hepatitis B virus. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued March 14, 2018.</a>

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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.

Date: March 14, 2018

**SPRING BANK PHARMACEUTICALS, INC.**

By: \_\_\_\_\_ /s/ Martin Driscoll  
**Martin Driscoll**  
**President and Chief Executive Officer**



**Spring Bank Announces Presentation of Combined Inarigivir 25mg and 50mg 12 and 24 Week ACHIEVE Results Demonstrating Enhanced Anti-Viral Efficacy in HBeAg-Negative Patients**

*Data from the combined first two low dose inarigivir cohorts at weeks 12 and 24 with sequential Viread dosing demonstrate significant reductions in HBV DNA, HBV RNA and HBsAg*

*Data to be presented at the APASL 2018 Annual Meeting*

**HOPKINTON, MA, Mar. 14, 2018** – Spring Bank Pharmaceuticals, Inc. (Nasdaq: SBPH) today announced that Nezam Afdhal, M.D., D.Sc., chief medical officer of Spring Bank, will make an oral presentation at the Asian Pacific Association for the Study of the Liver (APASL) 2018 Annual Meeting (March 14-18, 2018) in New Delhi, India. The presentation will highlight combined results from both the 25mg and 50mg cohorts of Part A of the ongoing Phase 2 ACHIEVE trial examining the use of inarigivir soproxil for treatment of chronic hepatitis B virus (HBV). Spring Bank is developing inarigivir, an orally-administered selective immunomodulator, as a potential backbone in a combinatorial treatment for HBV, with the goal of substantially increasing functional cure rates in a simple, safe and selective manner. All patients in the two low dose cohorts have completed sequential dosing of tenofovir disoproxil fumarate (marketed by Gilead Sciences, Inc. as Viread®) 300mg daily for an additional 12 weeks.

“Data from the combined first two inarigivir monotherapy cohorts at weeks 12 and 24 demonstrate significant reductions in viral markers, including HBV DNA, HBV RNA and HBsAg, with a favorable safety and tolerability profile,” stated Dr. Afdhal.

The data presented at APASL includes 30 patients treated with inarigivir and 8 placebo patients from the first two low dose cohorts. Potent antiviral response, defined as  $> 1 \log_{10}$  reduction in HBV DNA and  $> 3 \log_{10}$  reduction (or to undetectable) in HBV RNA at the end of 12 weeks of inarigivir monotherapy treatment, was seen in 8 patients. Additionally, an enhanced anti-viral effect was observed in patients with baseline low viral burden, as measured by HBsAg ( $< 10^4$ ) and HBV DNA ( $< 10^6$ ). A dose relationship was observed between the pK and anti-viral efficacy at these initial low doses of inarigivir. Furthermore, the switch at week 12 to tenofovir disoproxil fumarate 300mg was associated with significant reduction in HBV DNA but, as expected, showed little effect on further reductions in HBV RNA, potentially indicating the important dual mechanism of action of inarigivir as a direct acting anti-viral preventing HBV RNA encapsidation and an immuno-modulator stimulating immune-mediated clearance of cccDNA.

“When we examine the 11 HBeAg-negative patients who received inarigivir 25mg or 50mg monotherapy, we see a better response rate than in HBeAg-positive patients, with 55% of patients having a  $> 1 \log_{10}$  reduction in HBV DNA and an associated  $> 3 \log_{10}$  reduction in HBV RNA at the end of 12 weeks treatment. Additionally, 9 of the 30 (30%) patients had a  $> 0.5 \log_{10}$  reduction in HBsAg at either week 12 or week 24 after transitioning to tenofovir disoproxil fumarate, a predictor of HBsAg loss with immune therapies such



as interferon, highlighting the potential for inarigivir as a backbone treatment for HBV functional cure,” stated Dr. Afdhal.

Spring Bank also announced that it will soon complete the initial 12 weeks of patient dosing for the monotherapy treatment in the third cohort (100mg) of Part A of the Phase 2 ACHIEVE trial. Subject to approval by the Data Safety Monitoring Board, Spring Bank anticipates starting recruitment of the fourth cohort (200mg) in the first half of 2018.

As previously reported, Spring Bank has also entered into a clinical trial collaboration with Gilead Sciences, Inc., under which Gilead is funding and conducting a Phase 2 trial examining the co-administration of inarigivir and tenofovir alafenamide (marketed by Gilead as Vemlidy®) in patients with HBV. Similar to the protocol of Part B of the Spring Bank Phase 2 ACHIEVE trial, the protocol for this Phase 2 clinical trial involves 12 weeks concomitant administration of inarigivir (50mg) and Vemlidy®. Following treatment, all patients will receive Vemlidy as a monotherapy for a further 36 weeks. Gilead recently initiated the inarigivir 50mg + Vemlidy cohort of this clinical trial and it is expected that results from this study will be available in the second half of 2018.

#### **About Inarigivir and the ACHIEVE Trial**

Spring Bank’s lead product candidate, inarigivir, is a novel small molecule nucleic acid hybrid (SMNH) compound being developed as both monotherapy and combination therapy for the treatment of HBV. Part A of the Phase 2 clinical trial is designed to enable Spring Bank to select one or two doses to move forward into Part B of the Phase 2 clinical trial and to obtain the necessary dosing and safety data to study the combined use of inarigivir and a direct-acting antiviral. Part A of the Phase 2 ACHIEVE trial is a placebo-controlled, sequential-cohort, double-blind trial to evaluate increasing doses of inarigivir as monotherapy for 12 weeks followed by Viread® 300 mg for an additional 12 weeks. Part A of the ACHIEVE trial has an adaptive trial design that will enroll 80 chronically-infected HBV patients between 18 and 70 years of age, who have been or will be assigned to one of four dosing cohorts, 25 mg, 50 mg, 100 mg or 200 mg of inarigivir, or placebo, once daily for 12 weeks. All subjects then receive Viread® 300 mg once daily for an additional 12 weeks of treatment. Part B of the Phase 2 ACHIEVE trial is planned to examine the concomitant use of inarigivir and Viread® in approximately 200 HBV patients. Spring Bank plans to initiate Part B of the Phase 2 ACHIEVE trial in the second half of 2018.

#### **About Spring Bank Pharmaceuticals**

Spring Bank Pharmaceuticals is a clinical-stage biopharmaceutical company engaged in the discovery and development of a novel class of therapeutics using its proprietary small molecule nucleic acid hybrid (SMNH) chemistry platform. SMNH compounds are small segments of nucleic acids that the company designs to selectively target and modulate the activity of specific proteins implicated in various disease states. The company is developing its most advanced SMNH product candidate, inarigivir soproxil for the treatment of viral diseases, including hepatitis B virus (HBV). Spring Bank Pharmaceuticals is also developing other SMNH product candidates, including SB 11285, the company’s lead immunotherapeutic agent for the treatment of selected cancers through the activation of the **ST**imulator of **IN**terferon **Genes**, or STING, pathway. For more information, please visit [www.springbankpharm.com](http://www.springbankpharm.com)



## **Forward-Looking Statements**

Statements in this press release about Spring Bank's future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements about (i) the Company's expectations relating to the completion of the third cohort (100mg) and beginning the fourth cohort (200mg) of Part A of the Phase 2 ACHIEVE trial, (ii) the Company expectations for the release of data from the inarigivir 50mg + Vemlidy study being conducted by Gilead, and (iii) the Company's anticipated timeline for initiating Part B of the Phase 2 ACHIEVE trial.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether preliminary data that Spring Bank reports changes following a more comprehensive review of the data related to the clinical trial and as more patient data become available or as additional analyses are conducted; whether Spring Bank's product candidates will advance through the clinical trial process on a timely basis, or at all; whether Spring Bank's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Spring Bank's product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of Spring Bank's Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission (SEC) on February 20, 2018 and in other filings Spring Bank makes with the SEC from time to time.

In addition, the forward-looking statements included in this press release represent Spring Bank's views as of the date hereof. Spring Bank anticipates that subsequent events and developments will cause Spring Bank's views to change. However, while Spring Bank may elect to update these forward-looking statements at some point in the future, Spring Bank specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Spring Bank's views as of any date after the date hereof.

## **Contacts**

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