

**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): April 10, 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 April 10, 2018, the Registrant issued a press release announcing expanded results from 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued April 10, 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: April 10, 2018

**SPRING BANK PHARMACEUTICALS, INC.**

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



**Spring Bank Announces Expanded Inarigivir Data from the ACHIEVE Trial to Be Presented at The International Liver Congress™**

*\*Results from full 24 weeks of dosing from the first two cohorts of Part A in the ongoing Phase 2 ACHIEVE trial in hepatitis B to be highlighted in oral and poster presentations*

*\*30% of patients in first two cohorts achieved  $>0.5\log_{10}$  reduction in HBsAg*

*\*Additional benefit of  $>0.5\log_{10}$  reduction in HBsAg observed in HBeAg high viral load patients when sequentially-dosed with tenofovir disoproxil fumarate*

*\*Dose and exposure-dependent effect of inarigivir on HBV DNA and HBV RNA demonstrated*

**HOPKINTON, Mass., Apr. 10, 2018**– Spring Bank Pharmaceuticals, Inc. (Nasdaq: SBPH), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of viral infections, inflammatory diseases and certain cancers, today announced that the principal investigators for the ongoing Phase 2 ACHIEVE trial examining the use of inarigivir soproxil for the treatment of chronic hepatitis B virus (HBV) will present expanded results from both the 25mg and 50mg cohorts of Part A of the study in two presentations, one oral and one poster, at The International Liver Congress™, the Annual Meeting of the European Association for the Study of the Liver (EASL) being held April 11-15, 2018, in Paris.

In the poster presentation, Professor M.F. Yuen, Chief of Gastroenterology and Hepatology, University of Hong Kong, and Principal Investigator for the ACHIEVE trial, will show the full 24-week clinical and virological data from the 25mg and 50mg cohorts of inarigivir monotherapy, including sequential dosing data following the switch from inarigivir, a selective immunomodulator, to tenofovir disoproxil fumarate (Viread®). The data demonstrate the potent anti-viral effect of inarigivir on HBV DNA and HBV RNA, which was highly significant in HBeAg-negative patients. Professor Yuen's presentation will also highlight the improved benefit in HBeAg high viral load patients, evidenced by  $>0.5\log_{10}$  reduction in HBsAg in five patients during the sequential 12 weeks of tenofovir disoproxil fumarate dosing. This important finding supports the rationale for the further study of inarigivir co-administered with tenofovir disoproxil fumarate, particularly in the HBeAg high viral load population. The EASL scientific programme committee has selected Professor Yuen's poster presentation as part of a special oral poster tour, indicating the importance of these expanded findings from the full 24 weeks of dosing in the first two cohorts of Part A of the ACHIEVE trial.

"The first two cohorts have demonstrated a dose and exposure-dependent effect of inarigivir on HBV DNA and HBV RNA, which is enhanced in HBeAg-negative patients and those with initial low baseline levels of HBsAg and HBV DNA," said Professor Yuen. "Of further interest, 9 of the 30 patients (30%) had reductions in HBsAg of  $>0.5 \log_{10}$ , an effect not seen with nucleotides or other oral agents currently under development and that is indicative of the potential for functional cure."

In the oral presentation, Professor Stephen Locarnini, Head of Research & Molecular Development at the Victorian Infectious Diseases Reference Laboratory and Principal Investigator of the Virology Core for the



ACHIEVE trial, will present data on the HBsAb responses, which are important for viral clearance in patients receiving inarigivir. Utilizing novel assays that measure both HBsAb clearance response and complexed anti-HBs (masked HBs), Professor Locarnini will present data showing that these responses are enhanced in a dose dependent fashion by inarigivir and associated with anti-viral reductions in HBV DNA and HBV RNA. Masked anti-HBs responses were seen in 9 patients, of which 2 patients (11%) received 25mg inarigivir and 7 patients (50%) received 50mg inarigivir. An HBsAb clearance profile was seen in 10 of the 30 patients (33%) receiving inarigivir.

Professor Locarnini stated, "An HBsAb antibody response is needed for immunological viral cure. These findings at low doses of inarigivir are rarely seen (<2%) with nucleotide/nucleosides and reflect the novel direct acting anti-viral activity of inarigivir and the potential for RIG-I activation to drive T follicular helper (TFH) cell formation and development of an anti-viral antibody response. We look forward to the future examination of the data from the ongoing dose escalation and combination studies."

#### **Presentation Details:**

##### Poster Presentation

Reference: FRI 327  
Session: Viral hepatitis B/D: Therapy  
Title: **Dose response and safety of the daily, oral RIG-I agonist Inarigivir (SB 9200) in treatment naïve patients with chronic hepatitis B – results from the 25mg and 50mg cohorts in the ACHIEVE trial**  
Date/Time: Friday, April 13, 2018 from 9:00 a.m. to 5:00 p.m. CET  
Authors: M.F. Yuen, *et al.*

##### Oral Presentation

Reference: PS-160  
Session: Parallel session: HBV and HDV Current and Emerging Treatments (Hall: South 4)  
Title: **Effects of SB9200 (Inarigivir) therapy on immune responses in patients with chronic hepatitis B**  
Date/Time: Saturday, April 14, 2018 at 9:00 a.m. CET  
Authors: Renae Walsh, Stephen Locarnini, *et al.*

Additional details, including presentation abstracts, can be found on the ILC website at <https://ilc-congress.eu/>. A copy of the presentation materials can be accessed by visiting the [Presentations](#) and [Publications](#) section of the Spring Bank Pharmaceuticals website after the presentations conclude.

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 monotherapy, as well as sequential dosing of tenofovir disoproxil fumarate 300mg (marketed by Gilead Sciences, Inc. as Viread®) daily for an additional 12 weeks. As previously announced, Spring Bank 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. In



addition, as previously announced, Gilead has initiated a Phase 2 trial examining the co-administration of inarigivir 50mg with tenofovir alafenamide 25mg (marketed by Gilead Sciences, Inc. as Vemlidy®) in the treatment of chronic HBV patients.

#### **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 ACHIEVE clinical trial is designed to enable Spring Bank to select one or two doses to move forward into Part B of the 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 Phase 2 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, and (ii) 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**

### **For investor and media inquiries:**

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