

**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): November 15, 2017**

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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 November 15, 2017, the Registrant issued a press release announcing top-line results from the inarigivir (50mg) monotherapy dosing cohort 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued November 15, 2017.</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: November 16, 2017

**SPRING BANK PHARMACEUTICALS, INC.**

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



**Spring Bank Pharmaceuticals Announces Positive Top-Line Results from the Second Cohort of Part A of the Phase 2 ACHIEVE Trial**

*Low Dose of Inarigivir Soproxil (50mg) Monotherapy Demonstrates a Favorable Safety Profile and Significant Dose-Dependent Antiviral Activity, Meeting Both Primary Endpoints*

*Conference Call Scheduled for Tomorrow, Nov. 16 at 8:00 a.m. EST*

**HOPKINTON, MA, Nov. 15, 2017**– Spring Bank Pharmaceuticals, Inc. (Nasdaq: SBPH) today announced top-line results from the second cohort (50mg monotherapy) of Part A of the ongoing Phase 2 ACHIEVE trial. Spring Bank is developing inarigivir, an orally-administered selective immunomodulator, as a potential backbone in a combinatorial treatment for chronic hepatitis B virus (HBV), with the goal of substantially increasing functional cure rates in a simple, safe and selective manner. The primary endpoints for Part A of the Phase 2 ACHIEVE trial are safety and antiviral activity, as measured by the change in HBV DNA at week 12 from baseline, with multiple exploratory secondary endpoints. All patients in this cohort have transitioned to tenofovir disoproxil fumarate (marketed by Gilead Sciences, Inc. as Viread®) 300mg daily for an additional 12 weeks.

“We are happy to report that inarigivir 50mg daily for 12 weeks met both primary endpoints of safety and efficacy in the second cohort of the ACHIEVE trial,” stated Nezam Afdhal, M.D., D.Sc., chief medical officer of Spring Bank. “The anti-viral dose response in both HBV DNA and HBV RNA at a dose not yet associated with full immune activation is encouraging and supports further development as we move towards combination therapies with inarigivir serving as a potential backbone treatment, with the ultimate goal of achieving elevated functional cure rates for HBV patients.”

The second cohort of the trial consisted of 18 evaluable patients, with 14 in the inarigivir 50mg treatment group (10 HBeAg-positive, 4 HBeAg-negative) and 4 on placebo. Two patients in cohort 2 dropped out due to patient choice at day 1 and week 2, respectively, and are not included in the analysis. Within the inarigivir treatment group, inarigivir was well tolerated, with no serious adverse events observed. Overall, treatment-emergent adverse events ranged from mild to moderate in severity, with no interferon-like side effects, and no clinical or biochemical events above Grade 3 were observed. Alanine aminotransferase (ALT) flares, defined as an increase in ALT above 200 IU/ml, were observed in 2 patients in the inarigivir treatment group, both of whom were HBeAg-positive, and each of whom had a reduction in viral markers consistent with a beneficial immune flare.

Overall, inarigivir demonstrated a statistically significant reduction in HBV DNA at week 12 compared to the combined placebo group (n=8), with a mean reduction of 0.74 log<sub>10</sub> in the inarigivir treatment group (unpaired t-test, p=0.0008). HBV DNA reductions were greater in HBeAg-negative patients, with a mean reduction of 1.05 log<sub>10</sub> (unpaired t-test, p=0.01) and a mean reduction of 0.61 log<sub>10</sub> in HBeAg-positive patients (unpaired t-test, p=0.006), when compared to placebo.



For the secondary endpoint of quantitative reduction in HBV RNA, the inarigivir treatment group (mean reduction of 0.95 log<sub>10</sub>; unpaired t-test, p=0.03) performed significantly better than placebo (mean increase of 0.48 log<sub>10</sub>), with the effect more pronounced in HBeAg-negative patients. Additionally, when comparing the HBV DNA and HBV RNA response between the first cohort (25mg) and the second cohort (50mg), the second cohort showed a dose-dependent doubling of the mean decline. For the secondary endpoint of quantitative reduction in HBV surface antigen (HBsAg), one HBeAg-positive patient in the inarigivir treatment group had a sustained greater than 0.5 log<sub>10</sub> reduction in HBsAg. All 4 HBeAg-negative patients had undetectable HBV RNA at week 12, but no major reduction in HBsAg, suggesting that the patients' HBsAg may have come from predominantly integrated HBV DNA.

When analyzing the combination of patients in both cohorts 1 and 2 of the ACHIEVE trial, the primary endpoint of HBV DNA reduction stratified for baseline viral load (< or > 6 log<sub>10</sub>) or HBsAg level (< or > 4 log<sub>10</sub>) demonstrated a significant positive correlation between HBV DNA reduction and lower initial viral burden, independent of HBeAg status.

Professor Stephen Locarnini, the Principal Investigator of the Virology Core for the ACHIEVE trial and the Head, Research & Molecular Development, Victorian Infectious Diseases Reference Laboratory, stated, "We are continuing to see a dose dependent antiviral effect on HBV DNA and HBV RNA induced by a low dose of inarigivir, which is consistent with possible inhibition of pgRNA encapsidation, without yet seeing the full immunological effect of inarigivir."

Spring Bank has commenced randomization of patients in the third cohort (100mg) of Part A of the Phase 2 ACHIEVE trial and anticipates that it will release top-line results from this cohort in the second quarter of 2018. Detailed results from the second cohort (50mg) of Part A of the Phase 2 ACHIEVE trial will be presented at a future medical conference.

As previously reported, Spring Bank has also entered into a clinical trial collaboration with Gilead Sciences, Inc., under which Gilead will fund and conduct a Phase 2 trial examining the co-administration of inarigivir and tenofovir alafenamide (marketed by Gilead as Vemlidy®) in patients infected with chronic HBV. Similar to Part A of the Phase 2 ACHIEVE trial, the protocol for this Phase 2 clinical trial provides that treatment will consist of 12 weeks of combination therapy with inarigivir (50mg) and Vemlidy®. Following treatment, all patients will receive Vemlidy® as a monotherapy for 12 weeks. Spring Bank anticipates that Gilead will initiate this clinical trial in the first quarter of 2018.

#### **Conference Call**

Spring Bank will host a conference call and webcast at 8:00 a.m. EST tomorrow, Thursday, November 16, 2017, to discuss the results. The conference call may be accessed by dialing (800) 239-9838 for U.S. callers and (323) 794-2551 for international callers and providing the conference ID 3449739. Additionally, the live, listen-only webcast of the conference call can be accessed by visiting the Investors & Media section of the company's website at [www.springbankpharm.com](http://www.springbankpharm.com). A replay of the conference call will be available following the call until November 30, 2017, or by dialing (844) 512-2921 for U.S. callers and (412) 317-6671 for international callers five minutes prior to the start of the call and providing the conference ID 3449739. A replay of the call may be accessed by visiting Spring Bank's website.



### **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 chronic 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 (formerly SB 9200) 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 **G**enes, 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 plans to disclose additional results from the second inarigivir monotherapy dosing cohort at a future medical conference, (ii) the Company's anticipated timeline for initiating Part B of the Phase 2 ACHIEVE trial, (iii) the Company's anticipated timeline for reporting top-line data from the third cohort of Part A of the Phase 2 ACHIEVE trial, and (iv) the Company's expectations for when Gilead will initiate the Phase 2 co-administration trial examining inarigivir and Vemlidy®.

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, including the top-line results from the 50mg cohort of Part A of the ACHIEVE Phase 2 trial; whether the top-line data Spring Bank has reported in this press



release, which is a preliminary analysis of key efficacy and safety data, 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, 2016, which was filed with the Securities and Exchange Commission (SEC) on February 14, 2017, Spring Bank's Quarterly Reports on Form 10-Q that have been filed with the SEC, 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 subsequent to the date hereof.

## **Contacts**

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