Zacks Small-Cap Research

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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com
scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Spring Bank Pharmaceuticals Inc. (SBPH - NASDAQ)

FY:16 Results; Milestones Abound

Based on our DCF model and a 20% discount rate, SBPH is valued at approximately $33.00 per share. Our model applies a 15% probability of SB9200 sales for chronic hepatitis B virus based on historical Phase 2 success ratios. Our valuation includes geographic contributions from the US, Europe and Asia.

Current Price (2/16/2017)	$8.50
Valuation	**$33.00**

OUTLOOK

Spring Bank Pharma is currently conducting a Phase 2 trial for SB 9200, an immunomodulatory agent built on their small molecule nucleic acid hybrid chemistry platform. The drug targets the RIG-I and NOD2 signaling proteins, engaging the body's immune response to potentially address a variety of diseases including HBV, RSV, HIV Latency and HDV.

In June 2016, the company began dosing its first patient in its ACHIEVE trial with initial data expected in 1H:17. Following $33 million in FY:16 fundraising, SBPH has sufficient capital to complete its Phase 2a and STING preclinical development through 2H:18.

At the current price, we view Spring Bank shares as undervalued, with substantial upside given the size of the Hepatitis B market. We maintain our target price of $33.00 per share and believe that expansion into new diseases and the STING program can provide additional upside to our valuation.

SUMMARY DATA

52-Week High	**13.25**
52-Week Low	**6.31**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**13,269**
Shares Outstanding (mil)	**9.42**
Market Capitalization ($mil)	**80.0**
Short Interest Ratio (days)	**2.09**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$0.3 A	$0.3 A	$0.3 A	$0.1 A	$0.9 A
2016	$0.3 A	$0.1 A	$0.0 A	$0.0 A	$0.4 A
2017					$0.0 E
2018					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.37 A	-$0.39 A	-$0.58 A	-$0.67 A	-$2.03 A
2016	-$1.11 A	-$0.62 A	-$0.53 A	-$0.13 A	-$2.39 A
2017					-$1.72 E
2018					-$1.72 E

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WHAT'S NEW

Spring Bank Announces FY:16 Results

Spring Bank Pharmaceuticals Inc. (NASDAQ: SBPH) filed its fiscal year 2016 10-K on February 15, 2017 in conjunction with a press release highlighting the company's achievements over the period. Full-year revenues of $352 thousand were as expected and represent National Institute of Health grants to support the development of SB 9200. No grant revenue was received in the third or fourth quarter.

Operating expenses for the year were $19.4 million, divided between R&D at $14.0 million and G&A at $5.7 million. This was an increase from the prior year's expenses of $11.6 million due to a non-cash charge related to share transactions, higher clinical trial costs and greater public company and employee costs. Interest income totaled $96 thousand, up from $32 thousand in the prior year, and other income was $1.9 million, due to the change in fair value of warrant liabilities.

Fourth quarter expenses were $4.4 million, slightly less than our estimate of $4.5 million. R&D expenses were $2.8 million, matching our estimate and flat with 4Q:15 levels. G&A expenses of $1.6 million were $0.1 million behind our estimate, but higher than the $1.3 million for the same period in 2015.

Cash and equivalents of $25.5 million rose sequentially from $12.8 million due to the November share issuance, providing sufficient capital to support the company's development programs until third quarter 2018.

Recent Highlights

- On December 19, 2016, Spring Bank announced a collaboration between its SB9200 immunomodulator and Arbutus Biopharma's (NASDAQ: ABUS) AB-423, a capsid inhibitor. The collaboration will begin with preclinical combination work that will examine the mechanism of joining a capsid inhibitor and an immune modulator for HBV treatment.

- On October 6, 2016, Spring Bank announced a collaboration with Arrowhead Pharmaceuticals (NASDAQ: ARWR) to use Arrowhead's AR-520, an RNAi gene silencer, and Spring Bank's SB9200. The ARC-520 compound uses a small interfering RNAs (siRNAs) upstream of the reverse transcription process to inhibit HBV cccDNA-derived mRNA and reduce the production of HBV viral proteins. Regulatory agencies raised safety concerns regarding preclinical work in non-human primates employing Arrowhead's proprietary "EX1" liver-targeted, intravenously administered delivery vehicle. Due to these concerns Arrowhead halted all of the HBV-related clinical trials in early December 2016, however, the program may return if the safety concerns are addressed.

- Spring Bank's collaboration with Gilead Sciences (NASDAQ: GILD) continues as the partner contributes Viread (tenofovir) to combination studies performed in the phased trials. Gilead has recently launched an improved version of tenofovir which demonstrates ten times the efficacy of its precursor as well as improved renal and bone safety. The new drug named Vemlidy is expected to replace the currently used Viread in the next stage of trials.

- Spring Bank raised $15 million in gross proceeds with the sale of 1.64 million shares of common stock and warrants in November 2016. The securities were sold at a price of $9.12 per share and the warrants have a strike price of $10.79 and a five year duration. The proceeds from the financing, along with the $15.6 million on the balance sheet as of the end of 3Q:16 are expected to provide sufficient funding to support the operations and development programs through 3Q:18.

- The company continues to enroll the first cohort of its Phase 2a dose finding study and expects to report top-line results by 2Q:17. We remind investors that expectations for the initial dose of 25 mg are minimal given the objective of developing a dose response curve. The second, third and fourth cohorts will double the dose of SB9200 each iteration to 50 mg, 100 mg and 200 mg respectively and are where we should expect to see the highest rate of response.

Anticipated Milestones

- 1H:17 - Report top-line results from first dosing cohort from SB 9200 Phase 2a ACHIEVE study
- 2H:17 - Preclinical proof-of principle results for SB 11285 in certain cancer in vivo models
- Late 2H:17 - Report top-line results from 50mg & 100mg monotherapy cohorts from Phase 2a ACHIEVE study in 2H 2017 & 1H 2018 respectively
- Mid-2018 - Report results from last monotherapy dosing cohort from Phase 2a ACHIEVE study
- Mid-2018 - Potential IND submission for SB 11285
- 2H:18 - Potential preclinical proof-of-principle results for SB 9200 / HBV antivirals fixed-dosed combination
- Initiate Phase 2b portion of ACHIEVE study (subject to 2a results & additional funding)

Review of Spring Bank Thesis

As a reminder, we currently have a $33.00 price target based on our estimates of a 2022 worldwide launch of SB 9200 either alone or with a global pharmaceutical partner. SB 9200 is a small dinucleotide developed as a prodrug using the company's small molecule nucleic acid hybrid (SMNH) platform technology. The product is designed to activate specific intracellular sensor proteins including RIG-I, NOD 2 and STING which activate the body's immune system to fight viral infections including hepatitis B (HBV).

The company's lead product is in Phase 2a trials for chronic HBV. SB 9200 is pan-viral and could be a future treatment option in addressing certain viral respiratory diseases, HIV latency, hepatitis D (HDV) and potentially other diseases caused by RNA viruses. The compound functions by selectively modulating the antiviral signaling proteins, RIG-I and NOD2, in virally-infected cells. This selective immune-modulation has the capability to up-regulate the host immune response and potentially destroy the virally-infected cell. Subject to additional funding, Spring Bank may pursue these indications.

SBPH also has a very exciting immuno-oncology drug in the pre-clinical phase that targets the STING (STimulator of INterferon Genes) protein. Initial work performed by Spring Bank and others pursuing this pathway have engendered a lot of interest and investment given the promising early-stage preclinical data.

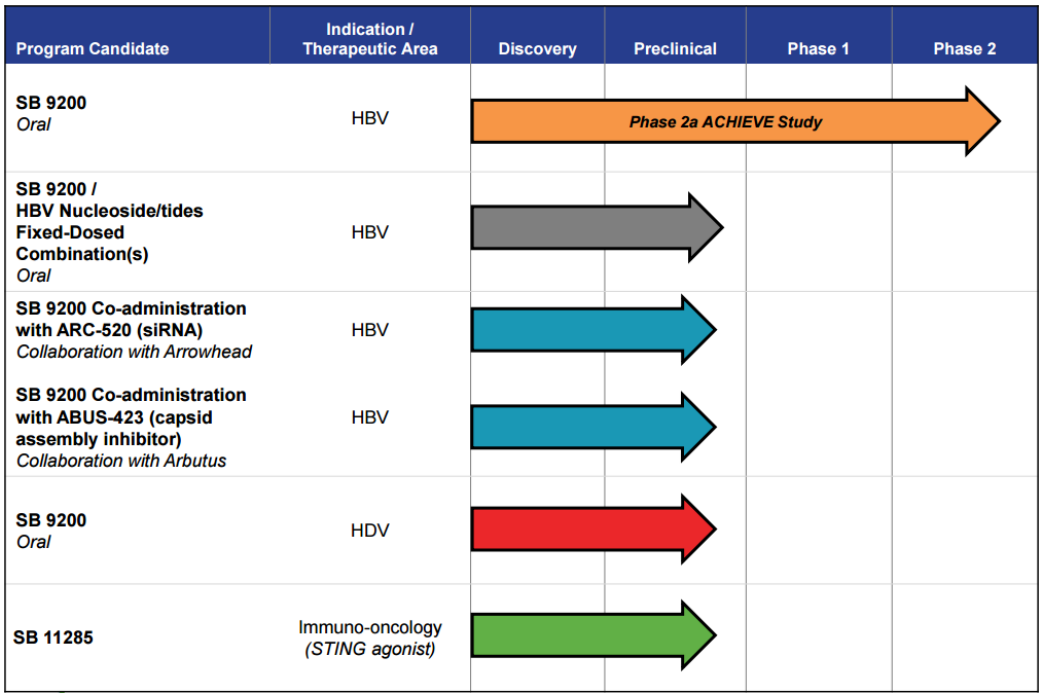
Below we summarize the key elements of our thesis:

- **Positive public health environment for the development CHB functional cure**
- **Potential addressable market size of near 4 million patients in the U.S. and EU alone**
- **Lack of other effective immunomodulators available in the market**
- **Promising proof of concept data in important animal models for chronic HBV**
- **Well tolerated lead compound with no dose limiting toxicities and promising antiviral activity**
- **Proprietary technology platform that can be broadly applied in multiple therapeutic indications**

SB 9200

Using the SMNH technology, Spring Bank has developed SB 9200, which is designed to bind to RIG-I and NOD2, two cytosolic antiviral signaling proteins. SB 9200 is composed of two chemically modified nucleotides linked together. The compound is a prodrug that is rapidly absorbed and converted into its active moiety. It is taken up by the liver where it seeks out RIG-I and NOD2 and binds to them. The HBV virus is able to downregulate the natural antiviral functions of RIG-I and NOD2, thereby preventing the body's natural immune defense from activating and killing the virus. When SB 9200 enters the cell, it restores interferon production by interacting with RIG-I and NOD2.

Exhibit I – Summary of Spring Bank Pharmaceutical Pipeline[1]



Phase 2a Trial for SB 9200

The Phase 2a trial is a proof of principle, dose finding study entitled: "A Study Evaluating the Safety, Pharmaco-kinetics, and Antiviral Efficacy of SB 9200 in Subjects Infected with Chronic HBV (ACHIEVE)." The principle objectives for the trial are to evaluate the safety and antiviral effect of SB 9200 following 12 weeks of monotherapy. Following the initial 12 weeks of treatment, all patients will then be placed on tenofovir 300mg daily for an additional 12 weeks to see if sequential therapy can improve response. The study will establish the optimal dose for SB 9200 for HBV and define the pharmacokinetics of SB 9200 in CHB patients. Patients selected for the trial will have documented evidence of chronic HBV, must not be taking any anti-viral medications, have appropriate levels of HBV DNA and ALT, no evidence of hepatocellular carcinoma, and negative pregnancy test with no plans to conceive during the study.

The double-blind, placebo-controlled Phase 2a study involves the administration of SB 9200 or placebo once daily for 12 weeks followed by the use of the antiviral, tenofovir 300mg, monotherapy for a total of 24 weeks of treatment in each patient cohort. The study has a sequential cohort design with each cohort representing an escalating dose of SB 9200. The study will consist of 80 patients and will be randomized with 20 patients per cohort; 16 of which will be on the active drug and 4 who will be given a placebo. Patients will be treated for 12 weeks on SB 9200 then all patients, including those administered placebo in the first 12 weeks will be given tenofovir for the following twelve weeks. Dosing will start at 25 mg and move up to 50 mg, 100 mg and 200 mg in subsequent cohorts.

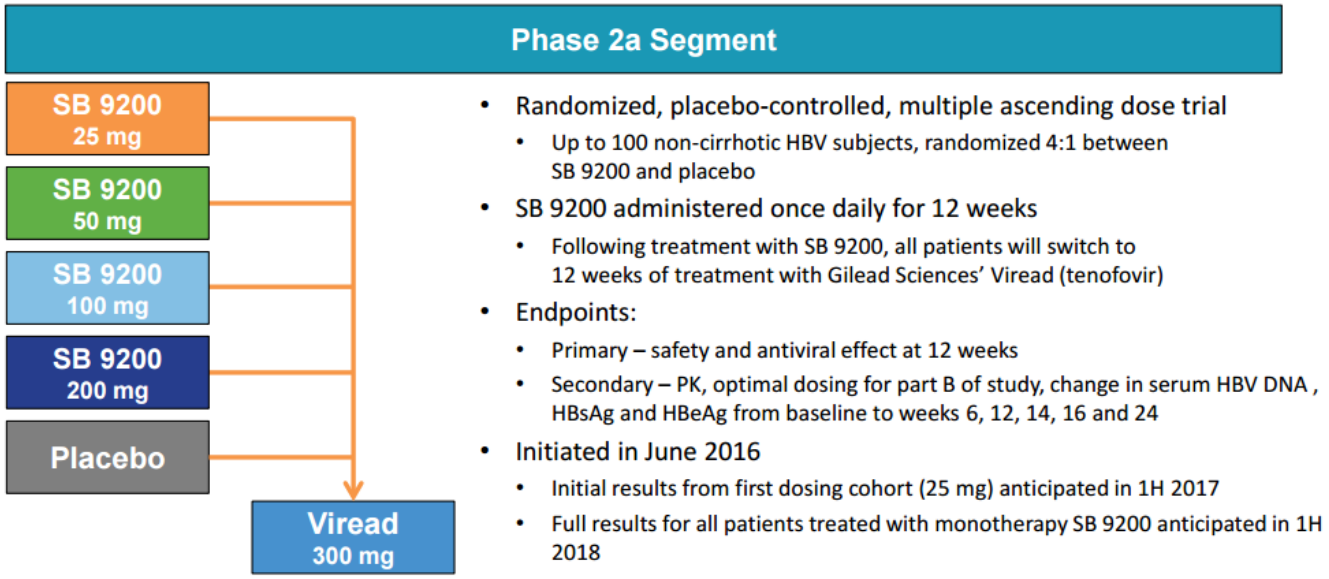
The primary endpoint will be safety and >1log reduction in HBV DNA. The secondary endpoints will be a reduction in HBeAg and HBsAg. We believe that a a 0.5 log reduction in HBsAg in 30% or greater patients will indicate a successful trial because this exceeds the efficacy of interferon and the side effect profile is substantially better and administration is by tablet rather than an injection. Extensive virology and immunology substudies will be generated from this Phase 2a trial to ascertain additional information on relevant biomarkers, immune responses and other key factors.

In June 2016, Spring Bank dosed its first patient in the CHB Phase 2a trial and we expect top-line data from the first cohort in 1H:17. Studies are currently taking place in Canada, Korea and Hong Kong with Taiwan coming on when the study begins to recruit for the second cohort. Based on the sequential dosing design for the Phase 2a trial in CHB patients, the potential exists for multiple data readouts from the study in 2017 and the first half of 2018 as the various cohorts are completed. Management may provide updates on the trial as each cohort is completed and the data are fully analyzed.

[1] Source: February 2017 Corporate Presentation

Results from this Phase 2a trial in CHB patients will be the near-term driver for the stock. We assume, similar to interferon, that a marked reduction in surface antigen after the first 12 weeks will be a strong indicator of the patient's ability to eventually clear the virus. This is supported, among other evidence, by data presented in late 2015 by Gilead using Viread alone and in combination with interferon showing HBsAg levels at a 12-week threshold strongly predicting patient response to therapy.

Exhibit II – Phase 2a Trial Design[2]



Phase 2b Trial

The company's current plans for a potential Phase 2b trial in CHB patients forecasts a larger trial with 200 patients. This trial will compare the combination therapy of SB 9200 with a nucleoside/nucleotide analog and SB 9200 alone. The two most effective doses will be employed in the five arms of 40 patients each and since effective doses will already have been determined, the arms can run in parallel, reducing trial duration. We also note that despite engaging over twice the number of patients as the 2a study, the trial cost is only expected to be slightly greater than the 2a cost as Phase 2b will not perform in-depth virological and immunological studies. Following the initial investigatory therapy, patients will be given tenofovir[3] for one year for long term follow-up.

In September 2016, the FDA, the European Medicines Agency (EMA), American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) will meet in Virginia along with many of the key stakeholders working in the field of HBV to devleop standards for biotechnology and large pharmaceutical companies on trial design and desired endponts for potential HBV therapies. The results of this meeting will help the regulatory agencies develop guidance on how to proceed with HBV drug development, what is needed from Phase 2 and later trials and what endpoints are critical for validating potential Phase 3 studies.

Based on the trial design, and following additional funding, we anticipate Phase 2b trials will begin in 2018. Based on the trial size and objectives, we believe the 2b program should last for about a year and provide results in 2019.

SB 9200 Use in Combination Therapy

As we mentioned in our initiation, the concurrent use of multiple therapies is believed necessary to clear HBV from the liver. This potentially includes an immunomodulator, a disease modifying agent and an antiviral suppressant. Many companies are working on combination therapies in disease modifying agents and antivirals and have publicly indicated the need for an immunomodulator in the treatment regimens in their studies. Interferon is the only approved immunomodulator therapy available, however, the side effects are difficult for patients to tolerate resulting in low compliance by study subjects and potential additional costs for a trial using this as part of the combination.

[2] Source: February 2017 Corporate Presentation
[3] The study may use tenofovir alafenamide fumarate (TAF or Vemlidy) instead of the closely related tenofovir disoproxil (Viread) used in the prior studies.

Therefore, Spring Bank's SB 9200 is a natural alternative given the promising data from the animal studies and the Phase 1 trial. Spring Bank has publicly stated a desire to study SB 9200 in CHB patients in combination use with other treatment modalities either currently marketed or in clinical development. On October 6, 2016, Spring Bank and Arrowhead Pharmaceuticals announced a collaboration to use SB 9200 in conjunction with Arrowhead's ARC-520 in HBV therapy in its MONARCH trial.

The combination therapy will join SB 9200's immunomodulatory features with the gene silencing qualities of ARC-520. A direct-acting antiviral will also be used, such as tenofovir or entecavir. If successful, the trial will show increased cure rates for HBV, with improved tolerability and shorter duration of treatment compared to standard therapy. The MONARCH trial is expected to be completed by first half 2019.

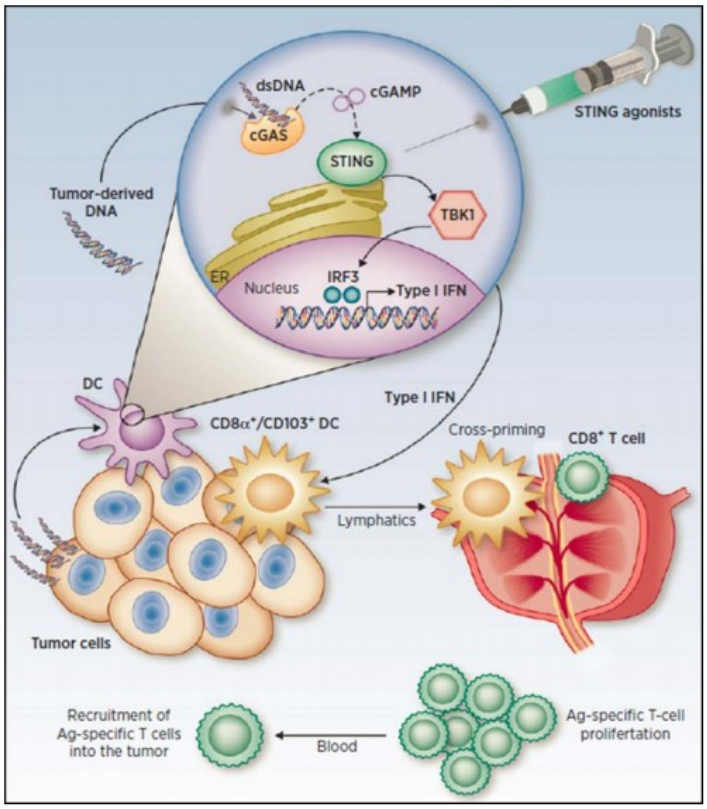
SB 11285 Development Program

Spring Bank first publicly announced its STING program in early September 2016 with a release noting that poster presentations would be made at AACR the following month. On October 20, the company presented scientific data on its novel proprietary STING agonist program, as a potential immunotherapeutic agent for the treatment of selected cancers called SB 11285. The data illustrated that the activation of the STING pathway can induce cellular interferons and cytokines and promote an aggressive and strong anti-tumor response. The agent also stimulates multiple pattern recognition receptors and interferon stimulated genes. SB 11285 has potent immune-modulating and anti-tumor activities and acts through recruiting T-cells, facilitating T-cell trafficking into tumors and facilitating cancer cell apoptosis within the metastasized tumor.

The SB 11285 program is still in the preclinical testing stage and we anticipate preclinical proof of principle results later this year. Assuming the program remains on track and sufficient funding is obtained, we further anticipate an IND filing by second half 2018.

The exhibit below highlights the method of action for STING. Spring Bank's SB 11285 dinucleotide is able to turn on the STING pathway and signal interferon production. In turn, T-cells are activated to recognize the antigens that are expressed on the tumor cells. The T-cells then migrate to the tumor from the lymph nodes through the bloodstream. When the the T-cells reach the cancer cells, they produce enzymes that induce lysis in the cancer cells and the tumor is essentially disolved.

Exhibit III – Activation of STING and Interferon



ESTIMATES

Our model forecasts a $40,000 course of treatment cost in the United States. We assume a 55% discount of price on average in the EU to $18,000 per treatment and a reduction to $15,000 and $10,000 per course of treatment in Asia and the rest of the world respectively.

We forecast gross margins of 90% on SB 9200. Cost of the active pharmaceutical ingredient and its manufacture are very low and there is a mid-single digit royalty that must be paid to BioHEP that is included in cost of goods sold.

Following Phase 2b trials, Spring Bank is expected to seek a deal structure that includes an upfront amount, an equity or debt investment in the company, milestone payments and royalties. If data are strong emerging from the Phase 2b trials, and the foundation is set for a rapid and smooth Phase 3 launch, we anticipate a deal to transfer from 35% to 40% of total value from the partner to Spring Bank. This will include a combination of the three aforementioned components. For simplicity, we apply a fixed 35% rate to net revenues to represent this value.

Operating expenses will grow from an anticipated $19 million in 2016 to $29 million in 2022. The increase in costs, especially following the hand off of SB 9200 to a partner, will represent research and development costs and other operational costs of developing the other compounds in the company's pipeline. Cash burn over the next four quarters and over the duration of the Phase 2a trial are expected to range from $4.0 million to $4.5 million per quarter. Taxes will be a combination of federal and state income taxes and will be approximately 40% of pre-tax income following the use of available net operating losses.

Our model recognizes the higher risk of a Phase 2 compound and applies a discount rate of 20%. We apply a 15% probability of eventual sales in US, European and Asian markets.

We anticipate that Spring Bank will raise an additional $16 million in late 2017 or early 2018, most likely following positive results from the SB 9200 Phase 2a trial. Our model forecasts the sale of 1.5 million shares at $12 apiece with proceeds after fees and commissions of approximately $16 million.

Based on the assumptions above, our DCF model generates a target price of $33.00 per share.

CONCLUSION

HBV is a global disease that chronically affects 240 million persons in the world and 14 million in the United States and Europe. Currently, there is no cure for HBV and the only currently approved therapies either have very low success rates or merely suppress the virus and require that the patient take the drug indefinitely. SB 9200 has a favorable side effect profile compared to the only other approved immunomodulator and may also offer much higher levels of viral clearance than peginterferon alfa-2a therapy. Based on data in Phase 1 studies, side effects are minimal and no dose limiting toxicities were found.

SB 9200 may show substantially higher efficacy when used as part of a combination therapy with antivirals or a disease modifying agent and we anticipate that the drug will eventually be used in conjunction with these complements when potentially approved in 2022.

The company's lead compound has also shown promise in other RNA viruses such as RSV, rhinoviruses and HIV latency as it is able to upregulate RIG-I and NOD2 proteins which are key players in initiating the immune response. Currently, the technology is focused on stimulating the body's immune response, addressing cancer and reducing inflammation, however, SMNH can target other proteins that can improve a multitude of other disease states.

A functional cure for HBV is extremely valuable as it replaces the current lifetime of therapy for those with chronic HBV and also will prevent many of the long-term consequences of HBV including cirrhosis, liver failure and liver cancer. There is a dramatic need for a cure due to the substantial size of the HBV population that is suffering from the chronic form of the disease, and the high level of morbidity and mortality that arise from cirrhosis and hepatocellular carcinoma. Given that there are currently no other functional cures on the market or any that are in an advanced stage of development, SB 9200 has a very strong argument for favorable pricing and substantial penetration if found to be safe and effective.

Key reasons to own:

- **Positive public health environment for the development CHB functional cure**
- **Potential addressable market size of near 4 million patients in developed markets alone**
- **Lack of other effective immunomodulators available in the market**
- **Promising proof of concept data in important animal models for chronic HBV**
- **Well tolerated lead compound with no dose limiting toxicities and promising antiviral activity**
- **Oral therapy superior to infusion and other methods of delivery used for addressing HBV**
- **Fixed duration of therapy**
- **A proprietary technology platform that can be broadly applied in multiple therapeutic indications**
- **Based on cost of current therapies, compound has strong pricing opportunity**

In summary, we remain optimistic regarding the promise of Spring Bank Pharmaceuticals' core technology given the data generated to date and the important disease states pursued by the company's portfolio of dinucleotides. We maintain our target price of $33.00.

PROJECTED FINANCIALS

Spring Bank Pharmaceuticals Inc. - Income Statement

Spring Bank Pharmaceuticals	2015 A	Q1 A	Q2 A	Q3 A	Q4 A	2016 A	2017 E	2018 E
Grant Revenue	**$0.9**	**$0.3**	**$0.1**	**$0.0**	**$0.0**	**$0.4**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-
SB9200	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth								
	$0	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Total Revenues	**$0.9**	**$0.3**	**$0.1**	**$0.0**	**$0.0**	**$0.4**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin								
R&D	$7.5	$5.6	$2.9	$2.7	$2.8	$14.0	$10.4	$12.0
G&A	$5.0	$1.2	$1.5	$1.5	$1.6	$5.7	$7.0	$8.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($11.6)	($6.5)	($4.3)	($4.2)	($4.4)	($19.4)	($17.4)	($20.0)
Operating Margin	-					-	-	-
Total Other Income	$0.0	$0.0	$0.0	$0.0	$2.0	$2.0	$0.0	$0.0
Pre-Tax Income	($11.6)	($6.5)	($4.3)	($4.1)	($2.4)	($17.4)	($17.4)	($20.0)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($11.6)	($6.5)	($4.3)	($4.1)	($2.4)	($17.355)	($17.4)	($20.0)
Reported EPS	**($2.03)**	**($1.11)**	**($0.62)**	**($0.53)**	**($0.13)**	**($2.39)**	**($1.72)**	**($1.72)**
YOY Growth						-	-	-
Shares Outstanding	5.7	5.9	6.9	7.8	8.5	7.3	10.1	11.6

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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