Zacks Small-Cap Research

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Spring Bank Pharmaceuticals Inc. (SBPH - NASDAQ)

Hep B: Large Market and Dominant Pricing Potential; Initiating with $33.00 Target.

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 (9/2/2016)	$11.70
Valuation	**$33.00**

INITIATION

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. Currently, SBPH has sufficient capital to complete its Phase 2a trials and will need additional funding to support Phase 2b trials that we anticipate will begin in 2H:17.

At the current price, we view Spring Bank shares as undervalued, with substantial upside given the size of the Hepatitis B market. We initiate with a 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	**7.62**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**9,050**
Shares Outstanding (mil)	**7.76**
Market Capitalization ($mil)	**104.1**
Short Interest Ratio (days)	**0.8**
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 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
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 E	$0.0 E	$0.4 E
2017					$0.0 E
2018					$0.0 E

Earnings per Share

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2015	-$0.37 A	-$0.39 A	-$0.58 A	-$0.67 A	-$2.03 A
2016	-$1.11 A	-$0.62 A	-$0.58 E	-$0.58 E	-$2.89 E
2017					-$1.79 E
2018					-$1.85 E

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INITIATING COVERAGE

We are initiating coverage of Spring Bank Pharmaceuticals Inc. (NASDAQ: SBPH) with a $33.00 price target based on our estimates of a 2022 worldwide launch of Spring Bank's lead compound, 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.

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.

As of June 30 2016, Spring Bank held approximately $20 million in cash on its balance sheet and expects to burn from $3.5 to $4.5 million per quarter in clinical trial and operational costs. The company currently holds sufficient cash to complete the in-progress Phase 2a trial in chronic HBV patients and continue the preclinical development of the company's fixed-dose combinations of SB 9200/nucleoside/nucleotides (referred to as "nucs") and the STING agonist compound. Spring Bank will need to raise additional capital prior to the launch of future clinical trials in chronic HBV and the advancement of the IND-enabling efforts for the SB 9200/nucs fixed-dose combinations and the STING agonist compound.

Based on the anticipated length of the Phase 2a trial and the sequential cohort design of the study, we expect the initial topline data readout from the first treatment cohort to occur in 1H:17. The remaining escalating dose cohorts should read out as we progress through the second half of 2017 and into 1H:18. Assuming positive data from the Phase 2a study examining the monotherapy use of SB 9200 in chronic HBV at escalating doses followed by the sequential dosing of the antiviral tenofovir, the company plans to conduct a Phase 2b trial to look at the combined use of SB 9200 and tenofovir in chronic HBV patients. The company's preferred strategy is to seek a partnership with a global pharmaceutical firm to continue the development program for SB 9200, pursue global market registrations, and ultimately market SB 9200 worldwide.

Given the large potential market of 240 million chronic cases of HBV, and the lack of an oral effective approved compound that effectively addresses the immunomodulatory approach to a potential functional cure, we have a very favorable view on the shares of Spring Bank and initiate with a target price of $33.00.

INVESTMENT THESIS

Spring Bank Pharmaceuticals has developed a core technology that employs small molecule nucleic acid hybrid (SMNH) compounds that evolved from work done by one of the company's founders in antisense technology and oligonucleotide–based therapeutics. SMNH uses small segments of nucleic acids including dinucleotides that can be administered orally and permeate the cell to target proteins that are critical to certain cell functions. Currently, the technology is focused on therapeutic applications in viral diseases, cancers, and inflammatory diseases.

The company's lead product, SB 9200, is a panviral agent that has shown activity against a number of RNA viruses via its ability to modulate key proteins that are responsible for engaging immunity. The primary indication that is being pursued for SB 9200 in clinical development is the treatment of chronic Hepatitis B (CHB). The profile of SB 9200 is favorable given that many scientific, regulatory, and public health agencies have placed a high degree of importance on the development of a functional cure for CHB. The market for SB 9200 is substantially large, since the competitive environment lacks other immunomodulators in its class. The off-target effects of SB 9200 could be minimal and the compound has shown antiviral activity in the first human trial against HCV.

The Hepatitis B virus (HBV) infects the liver and, according to the World Health Organization (WHO), is one of the most prevalent chronic viral infections in humans. The WHO estimates that 240 million people are chronically infected worldwide with approximately 6% of this total in the United States and Europe. It is anticipated that approximately one to two percent of the global total chronically infected population will constitute the addressable market in the initial year of launch. Currently, there is no effective functional cure for HBV[1], and the virus can only be suppressed through a lifetime of treatment using oral antiviral HBV DNA polymerase inhibitors. The novel action of SB 9200 may provide a functional cure for the disease by upregulating the key proteins responsible for allowing the body to activate its own immune response.

A functional cure for HBV is highly desirable since it permits a finite duration of therapy and potentially prevents the progression to the long-term negative effects of untreated CHB patients including cirrhosis, liver failure and liver cancer. There is a singificant unmet medical need for a functional 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 liver cancer. Currently there are no other therapeutics in the market or in an advanced state of clinical development that can offer functional cures in CHB. If SB 9200 is found to be safe and effective as monotherapy or in combination with other compounds and approved for commercialization by global regulatory authorities, the product will be strongly positioned for favorable pricing and substantial market penetration.

SB 9200 could be devloped potentially as part of a combination therapy with antivirals and/or disease-modifying agents with differing mechanisms of action including siRNA compounds, capsid inhibitors, and compounds with other MOAs in early development . Similar to the approach used by Pharmasset [which is best known for developing sofosbuvir, Gilead's (NASDAQ: GILD) Hepatitis C treatment], Spring Bank is cultivating relationships with other entities developing therapies for HBV. The hope is that SB 9200 will function as the backbone immunomodulator in combination therapy with nucleoside/nucleotide antivirals and/or disease-modifying agents with differing MOAs. This approach will help develop significant supportive data that can be published and obtain broader recognition and support for SB 9200 as a key component of the clinical efforts to achieve a functional cure in a sizable percentage of patients with chronic HBV.

Key reasons to own SBPH shares:

- **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**
- **SB 9200 was well tolerated in a Phase 1 study in Hepatitis C patients with no dose limiting toxicities and exhibitied promising antiviral activity**
- **A proprietary technology platform that can be broadly applied in multiple therapeutic indications**

In the following sections we provide additional detail regarding the impact of HBV. We further elaborate on the etiology of the disease and review other competing and complementary therapies. The report also discusses Spring Bank's small molecule nucleic acid hybrid (SMNH) technology and SB 9200's method of action. A review of Spring Bank's other exciting pipeline constituents is provided.

Hepatitis B: A Global Disease

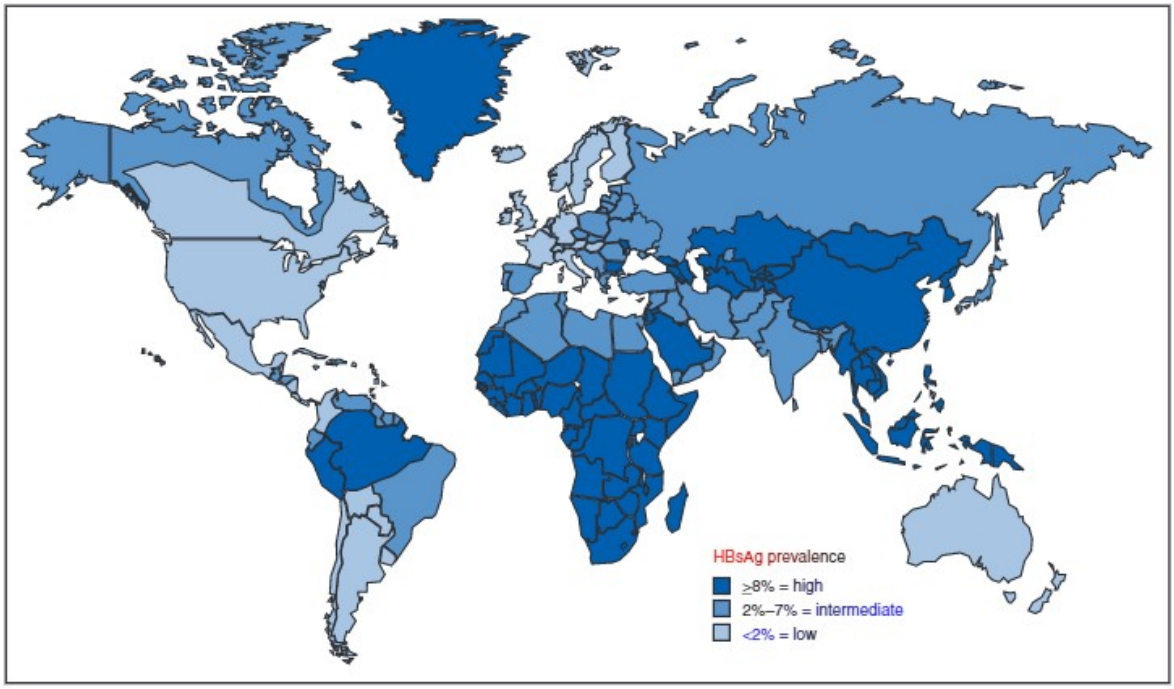
Hepatitis is a disease of the liver which manifests itself in the inflammation of the liver cells. Its name was taken from the Greek hêpar (□παρ), meaning "liver", and the -itis (-□τις), meaning "inflammation." The disease is usually transmitted from person to person through the exchange of bodily fluids, such as from sharing needles, unprotected sex or a mother giving birth to a child. As a result of long exposure to the virus and inflammation, CHB patients are at high risk of developing liver fibrosis, liver cirrhosis, and liver cancer.

[1] We note that the scientific literature indicates interferon therapy can yield a functional cure in approximately 10% of chronic HBV patients. Not only is this a very low threshold, but interferon side effects are severe and unpleasant, therefore, patient compliance is poor and physician use quite low.

Geographical Distribution of HBV

HBV is most common in Asia and Sub-Saharan Africa with prevalence rates above 8 percent. Western Europe and North America are at the other end of the spectrum with infection rates below 1 percent. HBV disproportionately affects Asians and those of Asian-descent because in many cases it has been passed from mother to child in these geographic regions with high endemicity. Risk for chronic HBV infection is significantly higher for newborns than it is for adults. Infants who acquired HBV infection from their mothers at birth, will become chronically infected as much as 90% of the time, whereas 30%–50% of children infected at age 1–5 years become chronically infected. Immunocompetent adults are generally able to clear the disease in 90 to 95% of cases.[2,3] This ability to fight the virus based on age is a key factor behind the high prevalence rate in Asia as the virus is passed from mother to child at birth. This cycle is difficult to break, and vaccine programs which have reduced disease prevalence in North America and Western Europe are less effective in Asia as the virus is passed to the child before the vaccine can provide full levels of protection.

Exhibit I – HBV Global Prevalence[4]



Viral hepatitis consists of a family of viruses which are categorized by the letters A, B, C, D and E. Hepatitis A and E are spread via fecal – oral transmission and cause acute infectious hepatitis; but are not chronic. Hepatitis C is spread via blood borne contact predominantly through intravenous drug use, blood product transfusion and non-sterilized medical transmission. Hepatitis B and D are transmitted in several ways, all of which include contact with bodily fluids of an infected person. Some of the most common include:

- Birth (spread from an infected mother to her child)
- Sex with an infected partner
- Sharing needles, syringes or other drug paraphernalia
- Sharing razors or toothbrushes
- Direct contact with blood or open sores of an infected person
- Hepatitis D can be acquired as a coinfection with HBV or as superinfection in people with HBV.

Symptoms of acute HBV include loss of appetite, nausea, vomiting, body aches, mild fever, and dark urine, and progression to jaundice.

[2] McMahon BJ, Alward WL, Hall DB, Heyward WL, Bender TR, Francis DP, et al. Acute hepatitis B virus infection: relation of age to the clinical expression of disease and subsequent development of the carrier state. J Infect Dis. 1985;151(4):599-603.
[3] Lok AS, McMahon BJ. Chronic hepatitis B. Hepatology 2007;45(2):507-39.
[4] Centers for Disease Control, Atlanta, Georgia.

Diagnosis

HBV is simply diagnosed using serological tests that are standardized and well validated. Patients with chronic HBV have elevated levels of HBsAg[5] and can be HBeAg[6] positive or negative. HBV DNA and ALT levels can vary. Current treatment guidelines recommend treating patients with HBV DNA > 2,000 IU/ml and elevated ALT for HBeAg negative and > 20,000 IU/ml for HBeAg positive patients.

Current Therapies to Address HBV

Currently, there is no approved cure for Hepatitis B and overall treatment has focused on viral suppression with nucleosides/nucleotides. Functional cure is considered to be HBsAg loss and eventual HBsAb[7] development with associated loss of viral replication resulting in undetectable HBV DNA. To achieve functional cure of HBV, treatment needs to:

- Prevent viral replication
- Clear virally infected cells which can only occur through restoration of innate and humoral immune response

The medicines below, in the case of the nucleosides/nucleotides suppress HBV replication, while the interferons function as an anti-viral agent acting through host immune responses. Below are the seven therapies that have been approved in the United States.

Exhibit II – FDA Approved Antiviral Therapies for HBV

Nucleosides/Nucleotides	Trade Name	Marketed By	Year
Tenofovir	VIREAD	Gilead Sciences	2008
Telbivudine	TYZEKA	Idenix & Novartis	2006
Entecavir	BARACLUDE	Bristol-Myers Squibb	2005
Adefovir Dipivoxil	HEPSERA	Gilead Sciences	2002
Lamivudine	EPIVIR-HBV	GlaxoSmithKline	1998
Interferons			
Peginterferon alfa-2a	PEGASYS	Roche Laboratories	2005
Interferon alfa-sb, recombinant	INTRON A	Schering Corporation	1992

The standard care for CHB include pegylated interferon-a, which is administered by injection and is a slow-release form of interferon. Interferon has some advantages compared to the nucleoside analogs in that there is minimal risk of drug resistance, there is a finite course of treatment and a greater likelihood of HBsAg clearance. Studies have shown that alpha interferon is successful in clearing the disease after 12 to 24 months of therapy in approximately 10% of cases. However, side effects are severe and include fatigue, flu-like symptoms, itching, mouth sores, decreased appetite, anxiety, depression and mood swings. As a result of the poor tolerability, many patients do not complete their course of therapy and fail to gain the benefit from it. A positive attribute of interferon therapy is that after 12 weeks, if diagnostic testing shows a > 0.5 log reduction in the level of HBsAg, there is a 50% chance that the patient will lose HBsAg and clear HBV after a full 12 or 24 month course of therapy. If, on the other hand, the patient does not show a 0.5 log reduction in HBsAg then almost 100% will fail to achieve functional cure and treatment is usually stopped for futility.

The other category of drug are the nucleoside/nucleotide analogs (the "nucs"), which include the commonly used tenofovir[8] [Gilead's (NASDAQ: GILD) Viread®[9]] and entecavir[10] [Bristol-Myers' (NYSE: BMY) Baraclude®, now off

[5] HBsAg is the surface antigen of the hepatitis B virus (HBV). It indicates current hepatitis B infection.
[6] HBeAg is a hepatitis B viral protein. It is an indicator of active viral replication; this means the person infected with Hepatitis B can likely transmit the virus on to another person (i.e. the person is infectious).
[7] HBsAb is the abbreviation for antibody to the hepatitis B surface antigen.
[8] Tenofovir disoproxyl is an antiretroviral medication used to prevent and treat HIV/AIDS and to treat chronic hepatitis B. Tenofovir is a defective adenosine nucleotide that selectively inhibits the action of reverse transcriptase, while only weakly interfering with mammalian DNA polymerases α, β, and mitochondrial DNA polymerase γ. Tenofovir prevents the formation of the 5′ to 3′ phosphodiester linkage essential for DNA chain elongation. A phosphodiester bond cannot be formed because the tenofovir molecule lacks an —OH group on the 3′ carbon of its deoxyribose sugar. Once incorporated into a growing DNA strand, tenofovir causes premature termination of DNA synthesis. The drug is classified as a nucleotide analogue polymerase inhibitor (NtRTI). Polymerase is a crucial viral enzyme that allows viruses to replicate including human immunodeficiency virus (HIV) and in hepatitis B virus infections.

patent] but still under exclusivity until 2017. This class of drugs functions as polymerase inhibitors and prevents the hepatitis B virus from replicating. The "nucs" achieve seroconversion in one to two percent of patients after 5 to 10 years of therapy, while the rest who tolerate it well remain on the therapy for the rest of their lives. Side effects are less severe than those of interferon therapy, and are tolerable. With a substantially higher percentage of patient adherence with the "nucs," these have become the medicine of choice for chronic HBV patients.

A vaccine for HBV is available and has been used to inoculate children in the United States since the 1980s and a government program made it part of the childhood vaccination schedule in 1991.[11] There are vaccine programs worldwide that over the long run will reduce the incidence of HBV. However, one of the most important routes of transmission in the high-incidence Asian, Pacific Islander and Eastern European populations is a vertical transmission of the disease. In these populations, HBV is transmitted is from mother to child, usually perinatally.

Background on Small Molecule Nucleic Acid Hybrid (SMNH) Platform

Nucleic acids are large polymers comprised of purine and pyrimidine nucleotides. SMNH compounds are smaller segments of nucleic acids and are prepared by use of combinatory chemistry. Typically, the SMNH technology is employed to create nucleic acid segments of up to 6 nucleotides long with substantial chemical modifications to provide druggable characteristics. In the case of dinucleotide compounds, two modified nucleotides are linked together. Spring Bank has discovered that the SMNH compounds bind to specific proteins that are part of the signaling pathway of cells. Modulating these interactions through agonism and antagonism supports broad therapeutic potential and provides an opportunity to target proteins and influence their complex biological functions in cells. The SMHN compounds are used to regulate the interaction between proteins and nucleotides or nucleic acids. SMNH-derived compounds are similar to the body's own nucleotides and nucleic acids, allowing for more direct and selective action as compared to other small molecule approaches. Spring Bank has used structure-based drug design, combinational chemistry, structural biology and phenotypic screening approaches to develop compounds with attractive and desirable attributes. Successful compounds are able to bind to protein targets with high selectivity. The dinucleotides such as SB 9200 are designed to bind to specific regions in proteins associated with intracellular immunity and activate immunity for antiviral defense.

Additionally, SMNH compounds are designed to act directly on signaling protein receptors to either upregulate or downregulate their activity. This has led to the pursuit of several targeted pathways including cancer and inflammation. This is achieved by using different chemical modifications in SMNH compounds.

The SMNH technology was developed out of Dr. Radhakrishnan "Kris" Iyer's work with antisense and RNA interference technologies. While these programs initially exhibited tremendous promise, two issues limited their effectiveness. First, the backbone (phosphodiester bond) of the oligonucleotides was prone to breaking down in the blood and stomach due to enzyme action and the acidic environment. Furthermore, the molecules were too large to effectively pass through the pores in the intestine and the cellular lipid bilayer to eventually reach the intended targets. Although the stabilization of oligonucleotides with a phosphorothioate backbone[12] was achieved, significant side-effects resulted because of non-specific binding of the oligonucleotides to a variety of protein targets. As a result, Dr. Iyer hypothesized that small segments of nucleic acids with a modified backbone could be designed to target proteins involved in disease processes with high specificity and selectivity. Furthermore, being small molecules, these chemically modified SMNH compounds can be designed to be orally bioavailable and withstand the acidic environment of the stomach and penetrate the intestinal layer[13] to reach the target area.

The initial form of tenofovir used in studies had limited potential for widespread use because it was not absorbed when administered orally. A medicinal chemistry team at Gilead developed a modified version of tenofovir called tenofovir disoproxil. This version of tenofovir is often referred to simply as "tenofovir". In this version of the drug, the two negative charges of the tenofovir phosphonic acid group are masked, thus enhancing oral absorption.

[9] Viread will come off patent in late 2017. Currently Gilead's follow-up drug to Viread, tenofovir alafenamide fumarate (TAF), which was approved in November 2015 is expected to be available in the coming months and may also be used in SBPH Phase 2 trials.

[10] Entecavir is an oral antiviral drug used in the treatment of hepatitis B virus (HBV) infection approved by the FDA in 2005. Entecavir is a HBV polymerase inhibitor. It prevents the hepatitis B virus from multiplying and reduces the amount of virus in the body. The medicine belongs to a class of drug called carbocyclic nucleosides that inhibit reverse transcription, DNA replication and transcription in the viral replication process.

[11] The two single-antigen hepatitis B vaccines are Engerix-B and Recombivax HB.

[12] Phosphorothioate bonds substitute a sulfur atom for a non-bridging oxygen in the phosphate backbone of an oligonucleotide. This modification renders the internucleotide linkage resistant to nuclease degradation.

[13] We note that the average molecular weight of oligonucleotides is around 7,000 daltons, whereas the weight of dinucleotides is closer to 700 daltons.

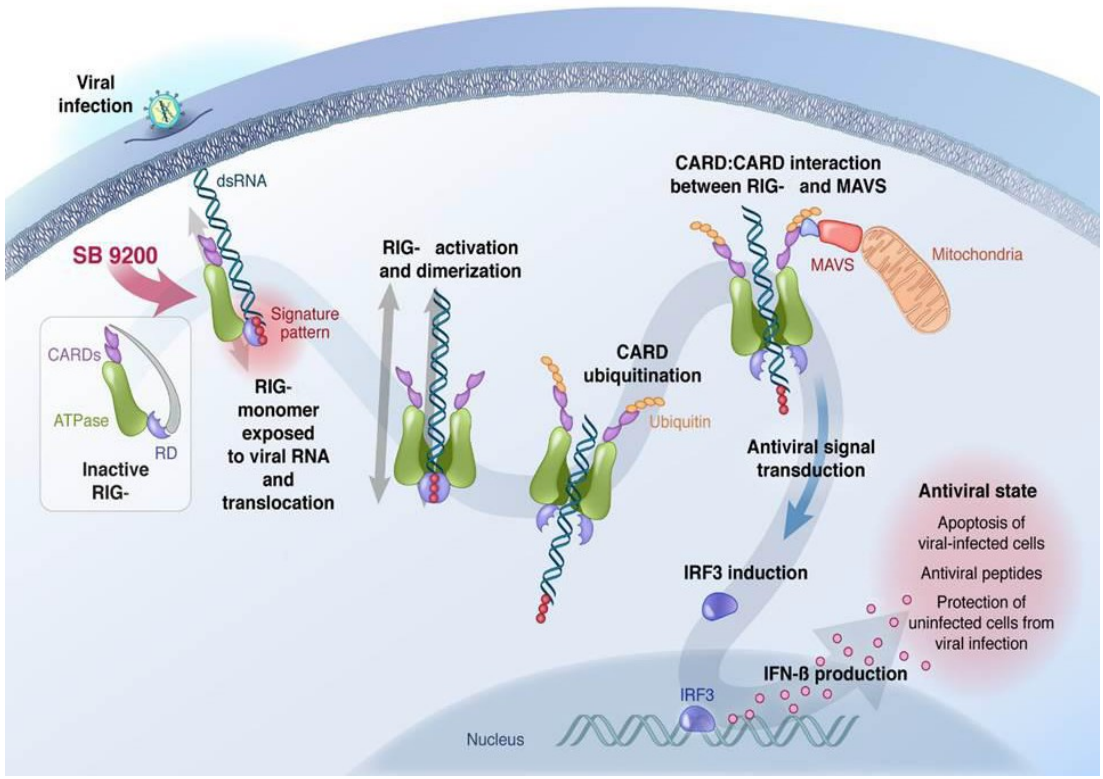
The SMNH compounds can be designed as agonists or antagonists of aberrant protein, and alternatively upregulate or downregulate its function to achieve a desired therapeutic effect.

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[14] 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. The following excerpt from Spring Bank Pharmaceuticals' materials describes the mechanism of action via RIG-I.

> RIG-I is a protein that has three regions: (1) a caspase-activation and recruitment, or CARDs, region, which is implicated in interferon signaling, (2) the adenosine triphosphatase, or ATPase, region that is important for producing energy and (3) a regulatory domain, or RD, region that is important in recognizing characteristic fingerprints of viral double stranded RNA, or dsRNA. Upon exposure to viral double stranded RNA by the regulatory domain region of RIG-I, the ATPase region of RIG-I produces energy allowing the protein to move to and translocate on the dsRNA to confirm the presence of viral RNA, resulting in the full activation of RIG-I. Following activation, RIG-I combines with another molecule of RIG-I resulting in a dimerized RIG-I protein complex. Activation also exposes the CARDs region of RIG-I, leading to its ubiquitination, a process that involves the attachment of ubiquitin, a protein involved in signaling, to the CARDs region of both RIG-I molecules. The activated RIG-I complex then migrates to the mitochondria, where it interacts with the CARDs region of the mitochondrial antiviral signaling, or MAVS, protein. The interaction between the RIG-I complex and the MAVS protein causes the activation of interferon regulatory factor 3, or IRF3, which results in the induction and translocation of IRF3 into the nucleus where it leads to the expression of genes encoding proteins, including interferon-ß, or IFN-ß. The production of interferon causes cells to enter into an antiviral state, leading to apoptosis, or cell death, of virally infected cells, production of antiviral peptides and protection of uninfected cells.

Exhibit III – SB 9200 Method of Action via RIG-I

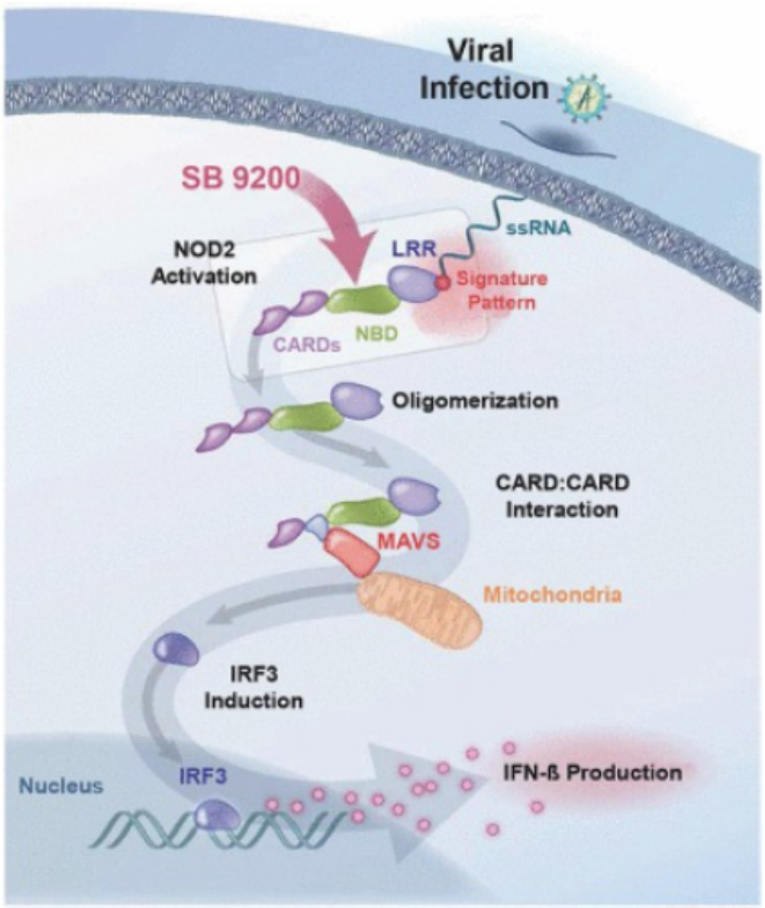


[14] A prodrug is a precursor drug that undergoes chemical conversion and is metabolized into an active pharmacological agent.

As described by Spring Bank, SB 9200 also upregulates the NOD2 protein through the following process:

> NOD2's three regions: (1) a CARDs region, (2) a nucleotide-binding oligomerization domain, or NBD, region and (3) a leucine-rich repeat, or LRR, region that detects characteristic fingerprints of viral single-stranded RNA, or ssRNA are activated upon its exposure to viral RNA. This trigger leads to changes in its structure and fosters self-association, or oligomerization, of NOD2 leading to activation of its CARDs region. Similar to RIG-I, activated NOD2 migrates to the mitochondria where it interacts with the CARDs region of the MAVS protein. The interaction between NOD2 and MAVS causes the activation of IRF3, resulting in the induction and translocation of the activated IRF3 into the nucleus where it leads to the expression of genes encoding proteins, including IFN-ß, that are implicated in the response to viral infection. Viral RNA encodes proteins that can disrupt these and other processes to block interferon synthesis and signaling. In the presence of viral RNA, SB 9200 binds to, activates and increases the sensitivity of RIG-I and NOD2 to viral infection to cause the induction of intracellular interferon signaling pathways for antiviral defense.

Exhibit IV – SB 9200 Method of Action via NOD2

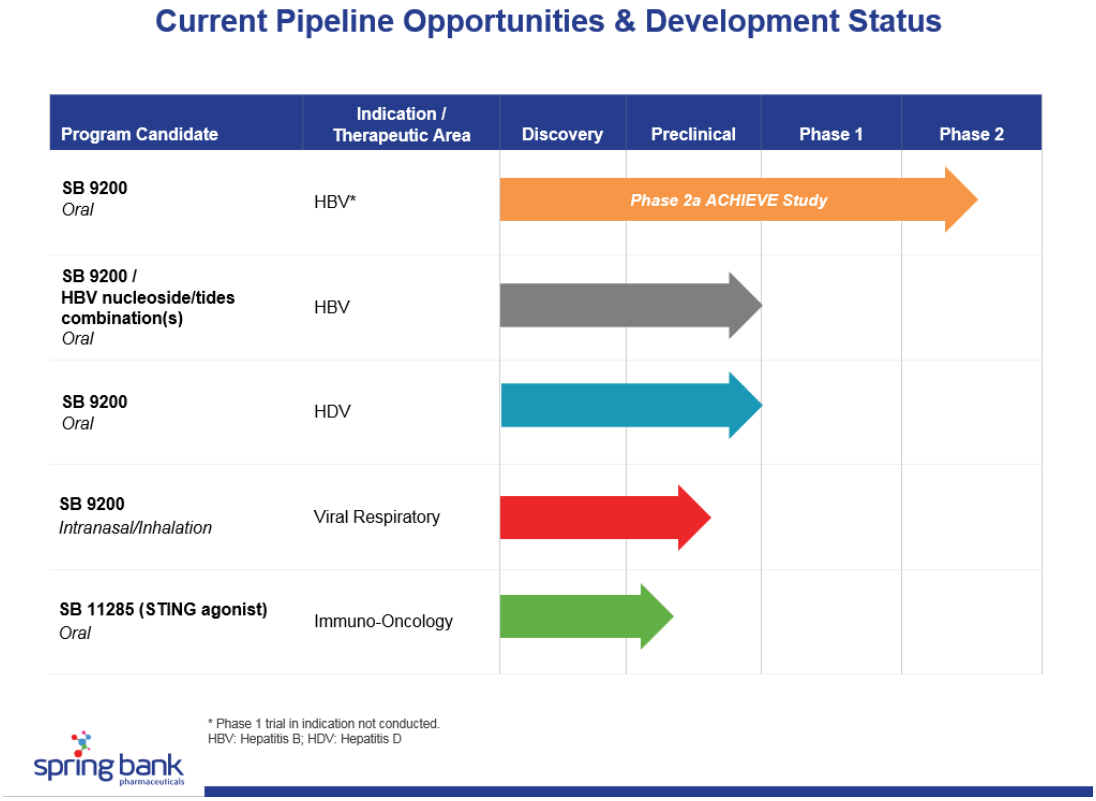


RIG-I and NOD2

Retinoic acid inducible gene 1 (RIG-I) and nucleotide-binding oligomerization domain-containing protein 2 (NOD2) receptors play an important role in the body's immune defense system. These proteins are inactive in uninfected cells, but are activated in the presence of a virus. When RIG-I and NOD2 are activated they signal the production of interferon, which in turn triggers the production of proteins that block viral replication. In cases of chronic HBV, the virus has the ability to block the protective effects of antiviral signaling proteins such as RIG-I and NOD2. HBV and other viruses[15] can block interferon synthesis and signaling, inhibit the function of interferon-induced antiviral proteins and produce interferon receptor decoy molecules to prevent induction of interferon signaling. Blocking the two receptors is a universal approach used by viruses to replicate which enables them to rapidly multiply in cells.

[15] Some of the other viruses that also downregulate the RIG-I and NOD2 signaling pathway include para-influenza, respiratory syncytial virus (RSV), noroviruses, rhinoviruses and hepatitis C.

Exhibit V – Summary of Spring Bank Pharmaceutical Pipeline[16]



Pre-clinical Animal Model Trials (Completed)

The woodchuck is a widely accepted and suitable model for studying hepatitis B given the animal model's proclivity to develop severe hepatitis and hepatocellular carcinoma after being infected with woodchuck hepatitis virus (WHV). The hepatitis morphology in the woodchuck is very similar to that of HBV in humans with respect to genome structure, replication, epidemiology, the course of infection and in the development of the illness. The woodchucks are bred in the lab to produce pups which are then infected with WHV to produce carriers that are useful in epidemiological and molecular virological studies. Woodchucks also evidence a similar pattern of toxicity and hepatic injury as do humans when dosed with fluorinated pyrimidines, making them an effective model for testing HBV therapies.[17]

Spring Bank conducted a monotherapy woodchuck study in conjunction with the National Institutes of Health (NIH) where two groups of five chronic WHV woodchucks were administered SB 9200 once daily at 15mg/kg or 30 mg/kg for 12 weeks, with follow-up evaluations for eight weeks post-dosing. Blood and liver chemistry were monitored during the study to evaluate the severity of the disease. The study observed the following:

- Dose-dependent decline in serum WHV DNA in each of the woodchucks up to a maximum of 2.5 log10 in the 15 mg/kg dose group and 4.2 log10 in the 30 mg/kg dose group at the end of 12 weeks of dosing;
- Dose-dependent decline in woodchuck hepatitis surface antigen, or WHsAg, in each of the woodchucks up to a maximum of 0.9 log10 in the 15 mg/kg dose group and 2.2 log10 in the 30 mg/kg dose group and at the end of 12 weeks of dosing;
- Decline in hepatic levels of virus-associated replication intermediates, or RI DNA, covalently closed circular DNA, or cccDNA, which is the major reservoir for chronic viral replication, and WHV RNA;
- Induction of interferons, interferon stimulated genes and other cytokines associated with activation of RIG-I and NOD2;
- Induction of gene expression of RIG-I and NOD2 during and after treatment;
- Reduction in inflammation of the liver and slower progression of liver disease; and
- SB 9200 was well tolerated.

[16] Source: http://springbankpharm.com/technology-2/product-pipeline-2/
[17] The woodchuck model of hepatitis B virus infection. Tennant BC, Gerin JL.

Below, we provide the data over the twelve week course of the therapy related to the viral load (WHV DNA) and the woodchuck hepatitis surface antigen (WHsAg). The two cohorts were administered 15 mg/kg of SB 9200 and 30 mg/kg of SB 9200. The data show that there was a positive relationship between dose and reduction in both viral load and surface antigen for the two cohorts. Graphics were sourced from Spring Bank's January 2016 S-1.

Exhibit VI – Viral Load Using SB 9200 at 15 mg/kg

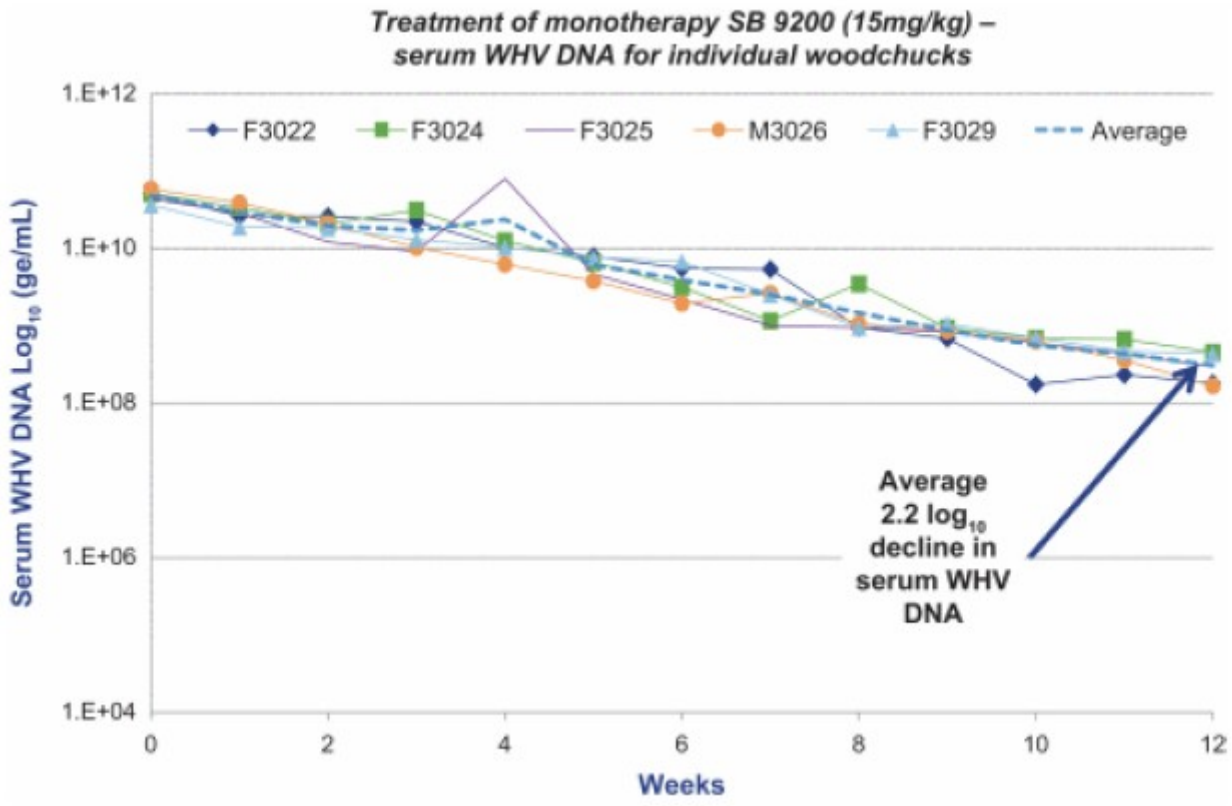


Exhibit VII – Surface Antigen Using SB 9200 at 15 mg/kg

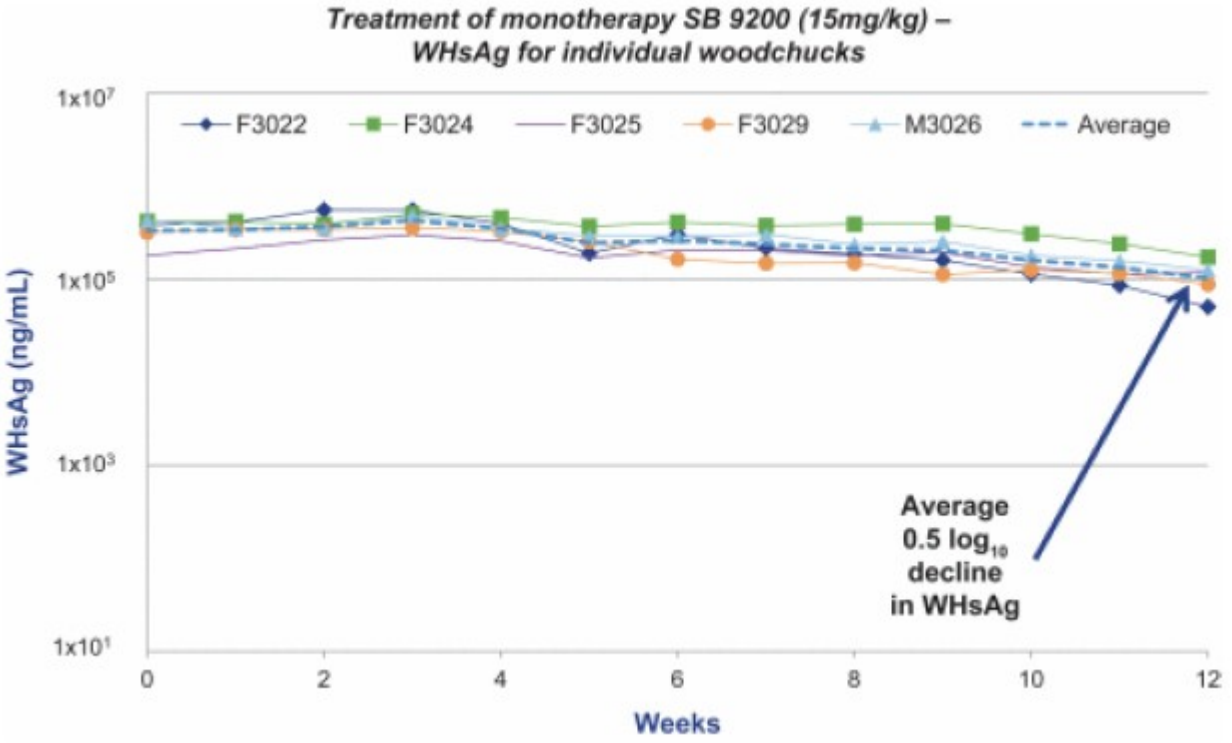


Exhibit VIII – Viral Load Using SB 9200 at 30 mg/kg

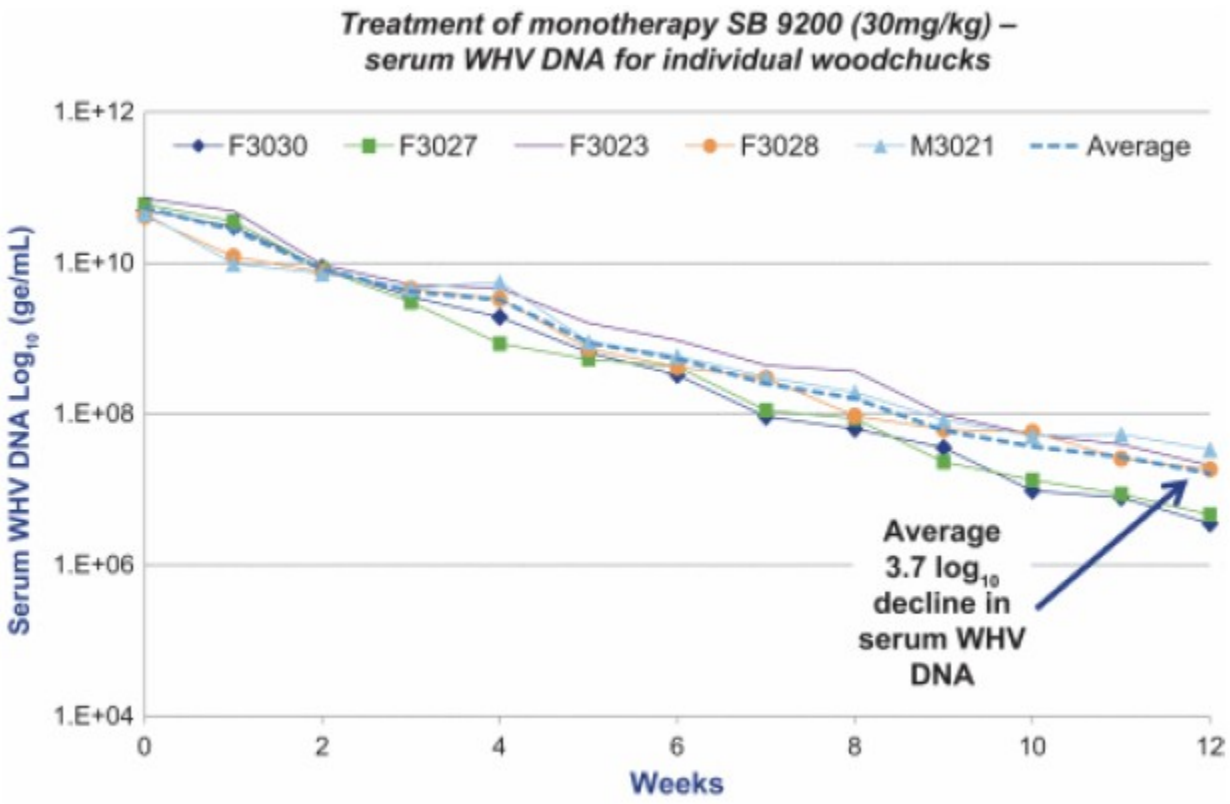
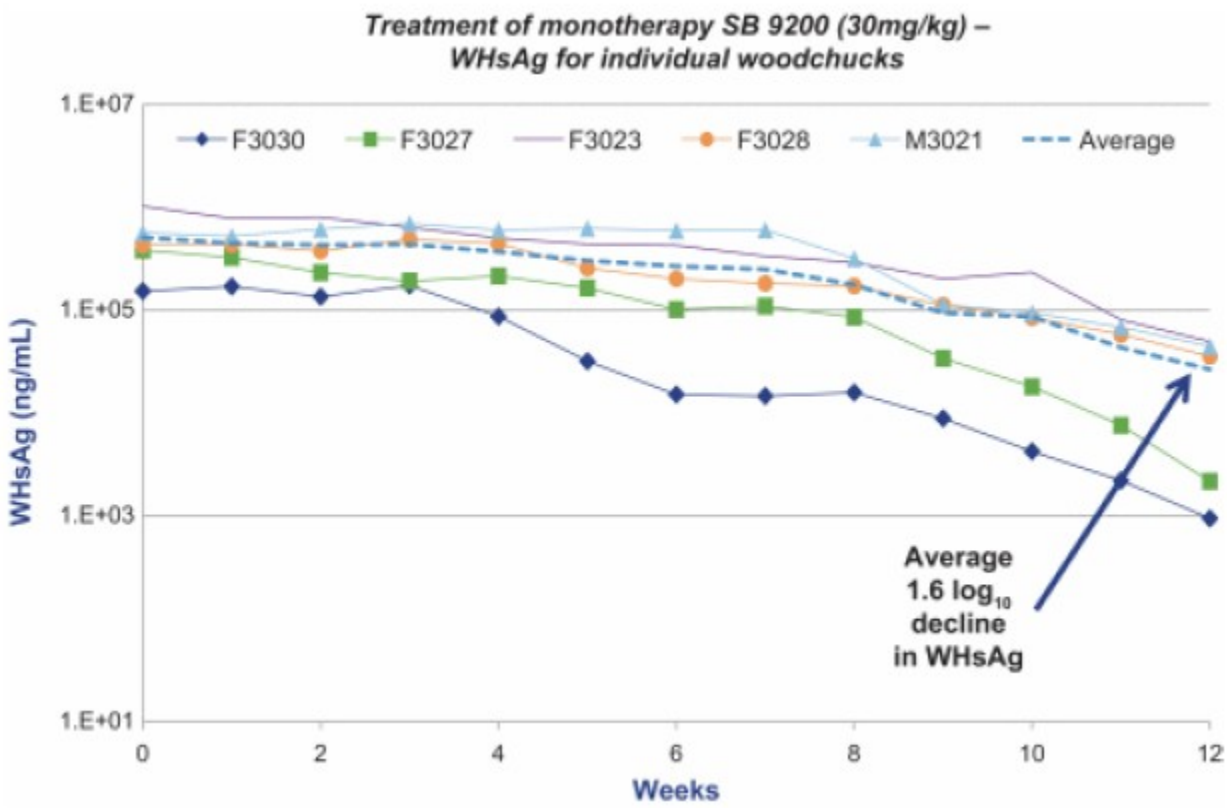


Exhibit IX – Surface Antigen Using SB 9200 at 30 mg/kg

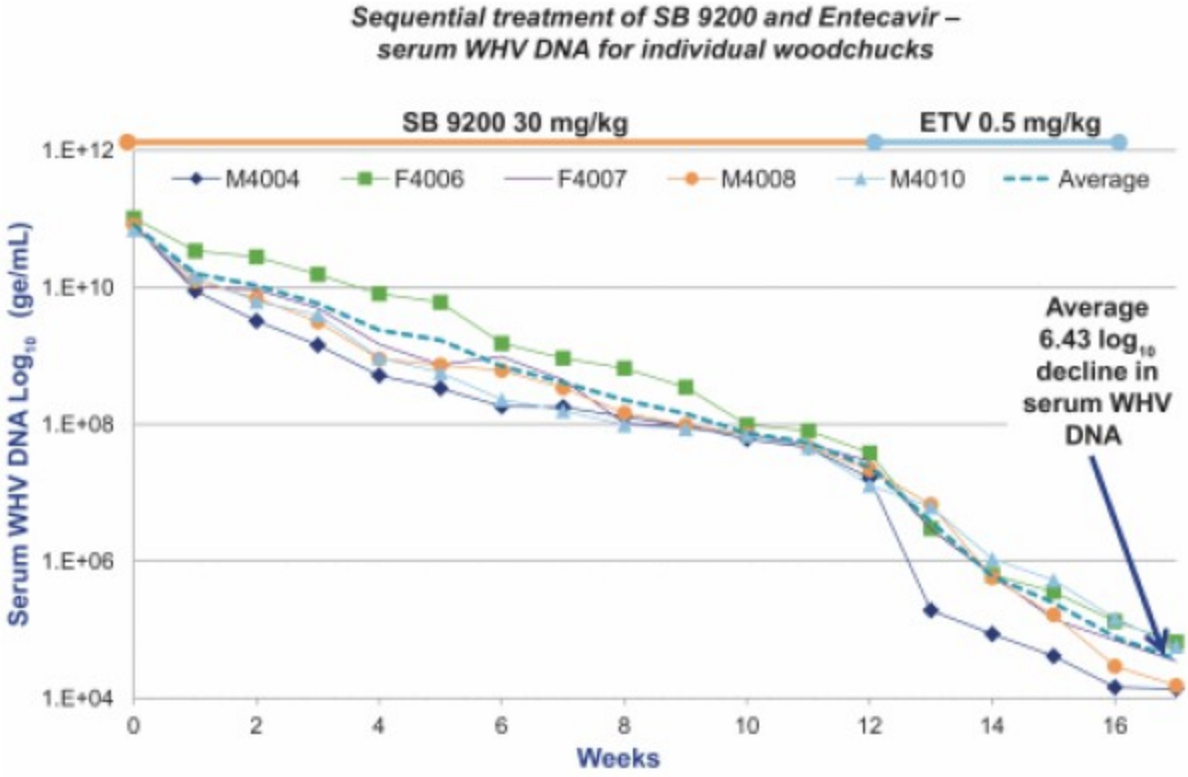


Following the 12 weeks of treatment with SB 9200, WHV viral load increased, but a delay in the onset of the increase was noted in the woodchucks in the 30 mg/kg dose group. SB 9200 administration at both dose levels was well tolerated with complete blood count, hematology and serum biochemistry parameters all appearing normal through the treatment period.

The woodchuck model enabled Spring Bank to verify the method of action for SB 9200. The first factor was that interferon was being upregulated and the second was to measure a decline in the viral replication intermediates (cccDNA reservoir and HBV RNA). The woodchuck trial was very promising as all 20 animals showed a response (as indicated in the exhibits above). In a previous woodchchuck study conducted by Roche, the NIH and Georgetown Univeristy School of Medicine,[18] interferon was administered to woodchucks and the study observed that over 40% were full responders to the therapy, and just under 30% were either partial responders or non-responders. Compared to this interferon study, SB 9200 results are extremely promising.

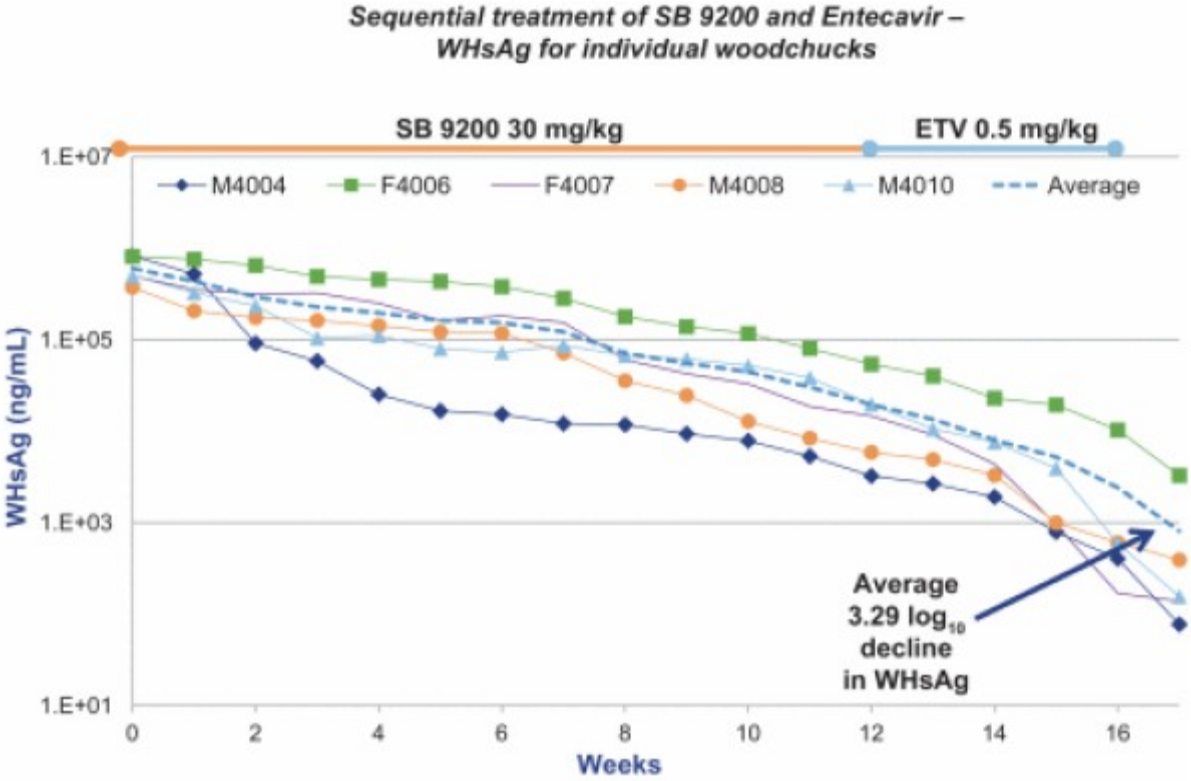
A sequential dosing woodchuck study was also performed, where SB 9200 was administered for 12 weeks followed by four weeks of entecavir. Five woodchucks with WHV were dosed 30 mg/kg of SB 9200 and then 0.5 mg/kg of entecavir which resulted in substantial declines in both viral load and surface antigen. The viral load (WHV DNA) declined by 6.43 log10 and surface antigen fell 3.29 log10 compared to pretreatment levels. There were also significant reductions of hepatic viral DNA, viral RNA and cccDNA. The following two exhibits illustrate the overall delcine in the two markers.

Exhibit X – Decline in Viral Load (SB 9200 & Entecavir)



[18] Identification Of An Intrahepatic Transcriptional Signature Associated With Antiviral Response To Treatment With Interferon In The Woodchuck. Chin, Daniel, et al.

Exhibit XI - Decline in Surface Antigen (SB 9200 & Entecavir)



The data above show a remarkable synergistic response from the combination therapy.

Phase 1 Trial (Completed)

Phase 1 trials are employed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of a novel formulation in humans. The scientific literature and Spring Bank's own research have shown that the target proteins that SB 9200 binds to, RIG-I and NOD2, are not activated in the cell in the absense of a virus, therefore, the usual healthy subject was not appropriate for a complete assessment of safety and tolerability. Given this constraint, Spring Bank sought treatment naïve, hepatitis C (HCV)-infected adults to conduct the trial.

The trial, A Multiple Ascending Dose Phase I Study of SB 9200 in Treatment Naïve Adults With Chronic Hepatitis C Infection, was a two-stage, multi-center study conducted in Australia and New Zealand in genotype 1 and genotype 3 treatment-naïve HCV-infected adults. Part A of the trial was an open-label, single ascending dose study in eight treatment-naïve, HCV-infected adults in fasted and fed states. In Part A, each subject in a particular dose group received a single oral dose of 100 mg, 200 mg, 400 mg or 800 mg of SB 9200, with subjects in each subsequent dose group receiving a pre-determined higher dosage than subjects in the preceding dose group. Part B of the trial was a randomized, placebo-controlled, multiple ascending dose study in 30 treatment-naïve adults infected with HCV. In Part B, subjects were randomized on a 6:2 basis to SB 9200 or placebo. Each subject in the SB 9200 arms received an oral dose of 200 mg, 400 mg or 900 mg of SB 9200 once daily for seven days, with subjects in each subsequent dose group receiving a higher dosage than subjects in the preceding dose group.

In the trial, SB 9200 was well tolerated in all dose groups, and there were no dose limiting toxicities or systemic interferon-like side effects such as flu-like symptoms or fever. Adverse events were mostly mild in severity. The one serious adverse event that was observed post-treatment in one subject, acute gallstone cholecystitis, was classified by the study investigator as unrelated to SB 9200. There was no relationship between incidences, severity or relationship of adverse events and the dose of SB 9200 received.

In addition to safety, the researchers assessed antiviral activity in both stages of the Phase 1 clinical trial. An antiviral response was seen at the 200mg, 400mg and 900 mg dose levels in both the single and multiple dose cohorts. Specifically, in the multiple ascending dose study, the peak individual serum HCV DNA drop improved from 1.5 log10 in the 200 mg dose cohort to 1.9 log10 in the 400 mg dose cohort. Increasing the dose to 900 mg did

not increase the peak individual serum HCV DNA declines observed in patients in the 900 mg dose cohort. A 1.0 log10 reduction indicates a 90% reduction in virus concentration in the treated patient from baseline.

A statistically significant relationship between maximum or peak serum concentration, or Cmax, of SB 9200 and maximum suppression of HCV RNA on Day 7 was observed (p=0.015) after exclusion of two subjects in the multiple dose study with extreme Cmax values for SB 9200 in a retrospective analysis of the data.. The company also assessed biomarker data to further support SB 9200's mechanism of action. This included measuring gene expression of ISG-15 and OAS-1, two genes typically associated with the induction of the interferon signaling pathway. The results demonstrated an increase in gene expression of ISG-15 and OAS-1 following administration of SB 9200.

The Phase 1 clinical trial demonstrated proof of principle of the mechanism of action of SB 9200 as a host antiviral immunomodulator. No interferon-like side effects were observed and SB 9200 was shown to be generally well-tolerated with no drug-related serious adverse events (SAEs) reported up to doses of 900 mg. The pharmaco-kinetic and safety data and the antiviral immunomodulatory activity observed in the Phase 1 clinical trial of SB 9200, and the preclinical and toxicology studies of SB 9200 that have been conducted, were sufficient to encourage the company to move SB 9200 forward into a Phase 2a clinical trial in chronic HBV patients.

Although SB 9200 demonstrated an antiviral effect in the Phase 1 trial in treatment naïve HCV patients, Spring Bank does not intend to pursue an HCV development program for SB 9200 given the impressive effectiveness of the therapies currently available for the treatment of HCV as well as the potential opportunity for SB 9200 in chronic HBV.

Phase 2a Trial (In Progress)

The Phase 2a trial is a proof of principle, dose finding study called "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. 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 potentially ascertain more 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 to hear top-line data from the first cohort in the first half of 2017. Studies are currently taking place in Canada, and investigative sites in the countries of Hong Kong, Taiwan and Korea should come on-line over the next several months. 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.

Results from this Phase 2a trial in CHB patients will be the near-term driver for the stock. We assume that 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.

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[19] 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.

Phase 3 Trials

Spring Bank's preferred goal for the development of SB 9200 is to engage a biopharmaceutical partner to assist in the future clinical development to take the drug through Phase 3 trials, global regulatory approval and ultimately, commercialization. The company is focused on research and development and will leverage the infrastructure of a larger global entity to efficiently and effectively conduct remaining trials, shepherd the product through the labyrinth of regulatory approval requirements and eventually commercialize the drug.

We anticipate that targeted results for the Phase 3 trial will be HBV cure as defined by loss of HBsAg.

The duration of the trial is uncertain, but we estimate a 48 week course of treatment. The ultimate length will depend on phase 2 results and we believe it will be a combination study including both SB 9200 and an antiviral. We forecast total trial length, including the time needed to enroll new patients and conduct the necessary analysis of the combination therapy to be approximately two years. Following the completion of data collection, we anticipate it will take several months to compile and analyze data, followed by a filing of an NDA with the FDA and a concurrent filing of a marketing authorization application (MAA) in the EU. Sample size is estimated to be from 1,400 to 1,500 patients divided into e antigen positive and e antigen negative groups.

We anticipate the normal regulatory review period in the United States and the EU for SB 9200 followed by approval in 2022.

STING Agonist Program

One of the more exciting investigational targets in cancer therapy is the stimulator of interferon genes (STING) pathway. This pathway is considered important in initiating an immune response to certain cancerous cells. STING is a downstream protein that is activated by binding to its ligand called cyclic dinucleotide (cyclic cGAMP). Cyclic dinucleotides are generated by an enzyme called cyclic GMP-AMP Synthase (cGAS) which is activated by binding to viral or celluar DNA in the cytoplasm of cells. The cGAMP binds to STING causing the induction of IRF3 protein which then induces the production of interferon and NF-κB . Activation of STING also results in the production of cytokines and chemokines which, along with interferon, enables the cells to launch a potent innate and adaptive immune response to kill cancer cells.

Cancerous tumors can produce immuno-inhibitory molecules that can prevent dendritic cells from initiating an immune response. By doing this they are able to downregulate STING and avoid the action of the immune system.

Spring Bank has developed a novel SMNH compound that specifically binds to STING which results in a very potent release of intracellular (or endogenous) interferon. The company's analysis shows that their nucleotide compound

[19] The study may use tenofovir alafenamide fumarate (TAF) instead of the closely related tenofovir disoproxil (Viread) used in the prior studies. TAF was recently approved and has greater antiviral activity, and better distribution at much smaller doses and therefore lower incidence of side effects.

is substantially more effective in generating interferon and NF-κB than than the natural ligand (cGAMP) leading to anti-tumor activity via the apoptosis of cancer cells.

Some of the cancers that could be pursued with a future STING agonist development program include melanoma, hepatocellular carcinoma, lymphoma and thyroid cancer. These are effective targets because of the presence of inactive STING in the cancerous cells. Early preclinical experiments suggest that SMNH lead compounds are highly active in cell cultures and activates the STING pathway.

Spring Bank is pursuing a development effort for the lead STING agonist compound with an objective to potentially demonstrate preclinical proof of principle in 2017 and conduct the necessary IND enabling activities. If the pre-clinical and nonclinical programs are successful, the company will prepare to advance the lead STING agonist compound into human trials afterwards, assuming sufficient funding is available to do so.

A precedent for the potential interest in compounds that activate the STING pathway was disclosed in March 2015. Aduro BioTech Inc. (NASDAQ: ADRO) announced a collaboration with Novartis (NYSE: NVS) for the development of Aduro's STING program. Novartis made an upfront payment of $200 million, with additional milestones of $500 million and an equity investment. We believe the publicly-announced economics of this collaboration between Novartis and Aduro Biotech is indicative of the potential future interest in Spring Bank's STING agonist program if future development efforts yield compelling data.

SB 9200 Use in Combination Therapy

As we mentioned above, 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. 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. Currently, the company is pursuing discussions with other companies about these opportunities.

Orphan Disease Program

While hepatitis B affects hundreds of millions of people worldwide, another form of the disease, called hepatitis D, impacts far fewer individuals, but is more deadly. Hepatitis D (HDV) only occurs among people who are infected with the HBV because HDV is an incomplete virus that requires the presence of HBV to replicate. According to the WHO, approximately 15 million persons have HBV and HDV, indicating approximately 6% of the HBV population has the delta version. This suggests that based on the estimates of approximately 1.5 million chronic HBV individuals in the United States, some 100,000 of this group may also suffer from HDV as well. This falls below the 200,000 person threshold in the United States required to qualify for orphan status. Literature on HDV suggests that activating RIG-I and NOD2 may be effective in the treatment of HDV, and the orphan pathway may allow for Spring Bank to market the drug earlier than they would for the HBV indication.

Other Indications

Based on a unique mechanism of action, SB 9200 has the potential to be a pan-viral agent and possibly demonstrate a benefit in the treatment of other diseases caused by RNA viruses such as HIV latency, certain upper and lower respiratory tract viral diseases such respiratory syncytial virus (RSV) and colds caused buy the rhinovirus, and the hepatitis delta (HDV) virus. Spring Bank has conducted preclinical experiments of SB 9200 in an RSV mouse model and may pursue further studies based on availability of future funding.

According to the CDC, RSV hospitalizes 177 thousand persons in the United States each year and causes death to approximatley 14 thousand. There are no FDA approved therapies to cure RSV, however, there are anti-virals and antibody injections that can be given. In preclinical studies SB 9200 was shown to demonstarte an antiviral effect and a reduction in lung inflammation in a mouse model for RSV.

HIV latency occurs when the virus is in a patient's body, but they do not experience any symptoms. While current suppression therapies prevent the virus from replicating, the virus remains dormant inside the host T-cells. Spring Bank's compound potentially has the ability to kill the virus. The process would first allow the virus it to replicate by

halting the anti-viral medication, allowing the virus to stimulate the production of RIG-I and NOD2. Then, in turn, SB 9200 would be administered, upregulating the RIG-I and NOD2 proteins, thus stimulating the innate immune response and clearing the virus.

Given SB 9200's ability to jump-start the immune system, the compoud could potentially provide a novel treatment for many diseases caused by an RNA virus. Currently, SBPH is focusing on its HBV program and will need further funding to pursue additional indications.

Chemistry, Manufacturing and Control (CMC)

Spring Bank is working with multiple partners to manufacture the active pharmaceutical ingredient (API) in SB 9200. Currently the product is manufactured in Cincinnatti, Ohio by global contract manufacturer Avecia,[20] but eventually Spring Bank will transition to another manufacturer as Avecia will eventually exit the small molecule business. The company is currently evaluting scale-up with other providers and plans to transition to a company either in South Korea or the United States to manufacture commercial batches of the product. The current supply chain has Avecia deliver the API to Patheon (NYSE: PTHN), a contract manufacturer that also makes tenofovir. Patheon encapsulates the product, operates the stability program and performs the analytical testing. Preparing the CMC supply chain is an important precursor to finding a partner as it will validate the process.

Intellectual Property

Spring Bank currently has over 20 patents around the globe and several applications that are currently in process for its lead product candidates. The patent that covers the composition of matter for SB 9200 is in place in the United States and Europe will expire in December 2026. There is a second composition of matter patent in the United States for SB 9200 that will expire in June 2030. Other patents protecting SB 9200 include:

- Compositions of matter for SMNH compounds
- Processes for synthesizing and manufacturing SMNH compounds
- Methods of using SMNH compounds to treat or prevent disorders such as microbial infections, including dosage forms and formulations
- Methods relating to course of treatment
- Methods of assembling libraries of SMNH compounds

The company also maintains patents that cover the active ingredient and composition of matter for SB 9200 in several Asian countries that expire in 2022 and 2026 respectively. Additionally, there are current applications for additional patents that, if approved, will expire in 2031. Certain patent extensions are available in the US, Europe and Asian countries that provide for up to a five year extension of patent protection to a maximum of 14 or 15 years (in the US and EU respectively) following regulatory agency approval. There are additionally pediatric indication extensions that add six months to the duration of the protection period. Our analysis assumes that there will be ten years of patent protection and exclusivity following approval and that generic competition will begin in 2032.

License Agreement with BioHEP Technologies Ltd.

BioHEP Technologies is a private bio-pharmaceutical company based in Vancouver, British Columbia, Canada focused on therapies to address hepatitis and possibly other medical conditions with viral activity. Spring Bank has an exclusive, global license from BioHep to develop SB 9200 and all analogs for all viral diseases. In January 2016, Spring Bank amended its license agreement with BioHEP.to broaden the development opportunities for SB 9200 and the related analogs.

In return for the rights to the compounds, Spring Bank issued stock and warrants to BioHep and will make milestone payments for each developed licensed product. Additionally, BioHEP will receive tiered royalties in the low to mid-single digits on net product sales.

Financial Position

As of June 30, 2016 Spring Bank Pharmaceuticals held approximately $20 million in cash and cash equivalents on its balance sheet. We believe this is sufficient to fund the entirety of the Phase 2a trial, which will take place over the next year. For the first six months ended June 30, 2016, Spring Bank consumed approximately $9.0 million in

[20] Avecia is a subsidiary of Nitto Denko Corporation and expects to exit the manufacture of small molecules. Spring Bank or its successor will find an alternate manufacturer for the product by the time commercialization is reached.

cash from operations and capital expenditures. The company holds no debt on its balance sheet. We anticipate a capital raise in the first half of 2017 in order to fund continued development of SB 9200 and potentially other projects.

Management has made clear that current cash levels are only sufficient to support the conclusion of the Phase 2a program. We anticipate that the company will have to raise an additional $20 million or more to fund the Phase 2b trial for SB 9200 and to support other pipeline programs. The actual amount of capital raised will be dependent on market conditions and estimated dilution at the time of issuance.

RISKS

All investments contain an element of risk which reflects the uncertainty of the business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are betting on a new technology that has not yet even been fully defined have a much higher level of perceived risk.

The biotechnology space includes companies at both ends of the spectrum, from mega-cap pharmaceutical powerhouses that have multiple products currently generating revenues, to small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products yet.

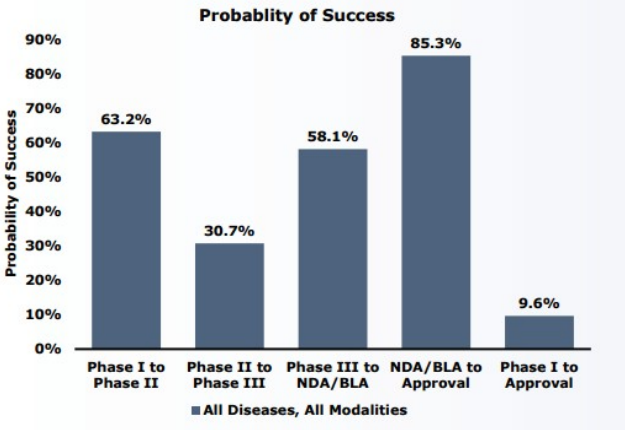
For smaller early-stage companies, investing in drug development is an extended process. The timeframe for conducting pre-clinical research to eventually marketing a drug can take from 12 to 15 years or even longer given market conditions. And with, on average, only one in one thousand compounds eventually making it to the market, the risks are substantial.

Even if a company has a strong, experienced team that is developing a therapy with a high likelihood of success and a large addressable market, securing funding may pose a substantial risk. Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to access; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain the company and it is not readily available, it may be forced to suspend operations, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route for progressing or force a company to accept onerous terms.

FDA or other governmental regulatory approvals are a material uncertainty to which all drugs must submit before they are legally marketed. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Isolating companies that have a long history of research success in drug development, with opinion leaders and experts in the field are key elements that can help mitigate this risk. Companies that have had previous success with the FDA or other regulatory agencies also are more attractive than those who may be new to the process. Some accelerated pathways to approval have been put forth such as the Orphan Drug Act, however, changes in sentiment or perceived safety for pharmaceuticals drugs could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place.

Currently, Spring Bank is taking its lead compound through Phase 2 trials. Historically, Phase 2 trials have the lowest success rates of any of the trial segments as we illustrate in the exhibit below. On average, approximately 30% of Phase 2 compounds move on to Phase 3 trials.

Exhibit XII – Success of Phase Trials and Regulatory Approval[21]



In recent years, contract research organizations (CROs) have taken on a larger role in the development of drug candidates as the complexity and cost of trials has increased. Finding appropriate populations to participate in clinical trials has become increasingly difficult due to the shift to personalized medicine and orphan indications that address a small population. This shift has increased the dependence on these specialized CROs for project management and clinical monitoring services which add additional risks and dependence on third parties. Spring Bank is working with the largest of the public CROs, Quintiles (NYSE: Q) which is a relatively low risk provider given their experience, market size and history.

In addition to CROs, Spring Bank relies of third party manufacturers for sourcing API and encapsulating the product. Risks of poor manufacturing processes, quality control issues and product delays may postpone ultimate production of the drug. Additionally, the company intends to work with a partner to conduct Phase 3 trials, take the product thorough the regulatory process and ultimately market it worldwide. The partner may lack the desire or skill to successfully take the product thorough the regulatory process and the partner may have other competing products under its control that receive greater company resources.

Drug price inflation has gained increased attention over the last several years and has contributed materially to the increase in health care costs over the last decades. As new therapies have been approved, drug prices have set new records and increased at a substantial rate. For example, in 1996, new cancer drugs cost roughly $54,000 for each additional year of life they provided. However, by 2013, this amount increased to over $200,000. The inflation rate for established drugs has also been very high. In a Forbes article, Novartis' leukemia drug Gleevec was highlighted. This drug cost $24,000 in 2001 when it was first approved; and 14 years later, in 2015, had risen to a cost of $90,000. This represents a 10% compound annual growth rate over that period. Other price moves such as the 5,000% price hike for Turing Pharmaceutical's Daraprim and Valent Pharmaceuticals 500% and 200% price increase for Isuprel and Nitropress last year combined with similar moves by other companies may create a situation where further increases are unsustainable. We also cite the broad response to Mylan's (NASDAQ: MYL) EpiPen price increases which have pressured the company to offer lower priced alternatives.

We highlight three risks that come from these pricing increases. First, health care may become unaffordable for a broad segment of the population, reducing the market size to a level below what we could otherwise reasonably forecast. Second, sharp price increases will attract the attention of elected officials and regulators who may create legislation and implement regulations that limit drug profitability. Third, the government may impose additional non-price related regulation and disclosure that can increase costs for the industry. We note that Spring Bank will not have control over the pricing decision if they pass the program on to the partner; however, a substantial portion of their revenues will likely be a fixed percentage of ultimate revenues collected for the drug.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these eventualities and our target price reflects an assumption of these risks faced by all biotechnology companies.

[21] Clinical Development Success Rates 2006-2015. David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

COMPARABLES

There are several other participants in the HBV and closely related spaces, the most important of which we include below, ranked by market capitalization.

Exhibit XIII – Spring Bank Pharmaceuticals' Peers[22]

Ticker	Price	Market Cap ($USD)	Company Name	Therapeutic Areas
GSK	$44.26	$109 B	GlaxoSmithKline	HBV Polymerase Inhibitor
GILD	$76.89	$99.54 B	Gilead Sciences, Inc.	Hepatitis/TLR7 Selective Immunomodulator
BMY	$56.35	$92.5 B	Bristol-Myers Squibb Co	HBV Reverse Transcriptase Inhibitor
ALNY	$69.17	$5.9 B	Alnylam Pharmaceuticals, Inc	HBV RNAi
1177	$5.14 HKD	$4.9 B	Sino Biopharmaceutical Limited	Hepatitis
ADRO	$14.49	$965 mm	Aduro BioTech Inc.	STING
ARWR	$7.15	$448 mm	Arrowhead Pharmaceuticals Inc	HBV RNAi
ABUS	$3.76	$203 mm	Arbutus Biopharma Corp	HBV RNAi
ASMB	$6.13	$106 mm	Assembly Biosciences Inc	HBV core protein allosteric modifiers

GlaxoSmithKline (NYSE – GSK) manufactures ENGERIX-B, which is a vaccine for HBV.

Gilead (NASDAQ – GILD) is the most dominant player in the hepatitis market, with medicines that treat HIV, chronic hepatitis C, chronic hepatitis B. Gilead has also provided Spring Bank guidance in terms of trial design and has also donated tenofovir to support the Spring Bank's clinical work. The company is developing a TLR7 selective immunomodulator for HBV. The drug was effective in animal models, but Phase 1 trials in humans did not show a meaningful impact on viral load or surface antigen.

Bristol-Myers Squibb Co. (NYSE: BMY) manufactures entecavir (Baraclude), a treatment for HBV. The drug is a reverse transcriptase inhibitor belonging to a class of carbocyclic nucleosides that inhibits reverse transcription, DNA replication and transcription in the viral replication process. Entecavir may show promise as part of a combination therapy with immunomodulators such as SB 9200.

Alnylam Pharmaceuticals (NASDAQ: ALNY) is developing therapies using small interfering RNAs (siRNAs) to address HBV and HDV. siRNAs work by reducing the virus' ability to suppress the immune system.

Sino Biopharmaceuticals (HKG: 1177) provides treatments for hepatitis and is working with Johnson & Johnson (NYSE: JNJ) on a HBV drug. The stock is China focused and trades on the Hong Kong exchange.

Aduro Biotech Inc. (NASDAQ: ADRO) is developing STING activator candidates as immunomodulators for addressing cancer. The company signed a material deal with Novartis for development of the STING program.

Arrowhead Pharmaceuticals (NASDAQ: ARWR) has two drugs in the pipeline for HBV in Phase 1 and Phase 2 trials. Arrowhead uses RiboNucleic Acid interference (RNAi) therapeutics in its HBV compounds.

Arbutus Biopharma Corp (NASDAQ: ABUS) is currently developing RNAi interference, Cyclophilin Inhibitors and Capsid Assembly Inhibitors, which can potentially be combined with existing nucleoside or nucleotide analogs, as well as immune stimulation therapies, to impact HBV viral load.

Assembly Biosciences Inc. (NASDAQ: ASMB) technology employs core protein allosteric modifiers to prevent development of new cccDNA, inhibit HBV proteins and eliminate (or silence) existing cccDNA. Phase 1 trials anticipated to begin in 2H:16.

Spring Bank may work with one or more of these peers in the HBV space in development of a combination therapy. Working with partners provides several benefits in that it provides data and research for the scientific and regulatory community in trials conducted by other sponsors and opens up additional possibilities for combination therapy and creates the opportunity for cash infusion for the use of its product in trials.

[22] Price and market capitalization data is as of September 2, 2016

MANAGEMENT PROFILES

Martin Driscoll – President, Chief Executive Officer and Chairman

Martin Driscoll has been Spring Bank's President, Chief Executive Officer and Director since August 2015 and in September 2015, Mr. Driscoll was appointed Chairman of the Board of Directors. From October 2010 until July 2015, he served as CEO of Asmacure Ltée, a venture-backed clinical-stage biopharmaceutical company, which was acquired by a privately held Canadian life sciences company in July 2015. Prior to Asmacure, from March 2008 until July 2010, Mr. Driscoll was the Chief Executive Officer and a director of Javelin Pharmaceuticals, Inc., a publicly traded developer of acute care pain products that was acquired in July 2010 by Hospira, Inc. Prior to that, he served in various senior management roles at Schering-Plough Corporation, ViroPharma, Inc. and Reliant Pharmaceuticals, Inc. In 2007, Mr. Driscoll co-founded Pear Tree Pharmaceuticals, Inc., a privately held developer of women's healthcare products. He serves on the board of directors of MetaStat, Inc., a publicly traded company, and Asmacure Inc., a privately held company, and previously served on the board of directors of two publicly traded companies: Javelin Pharmaceuticals, Inc. and Genta, Inc., and two privately held companies: Asmacure Ltée and Pear Tree Pharmaceuticals, Inc. Mr. Driscoll holds a B.Sc. in communications from the University of Texas at Austin.

R. P. "Kris" Iyer, PhD – Chief Scientific Officer

R. P. "Kris" Iyer, PhD is one of Spring Bank's founders and has been the company's Chief Scientific Officer and a member of the board of directors since the company's inception in 2002. Dr. Iyer was co-founder and VP of Discovery at Origenix Technologies, Inc., a clinical-stage biotech company, from 1998 to 2002. From 1993 to 1998, Dr. Iyer was a Senior Scientist and Associate Director of the Discovery Group at Hybridon, Inc. (now known as Idera Pharmaceuticals, Inc.). Previously, Dr. Iyer was a Professor of Medicinal Chemistry at the University of Bombay, a Visiting Scientist at the University of Texas, M. D. Anderson Cancer Center and a Visiting Scientist at the Center for Biologics Evaluation and Research at FDA/NIH. Dr. Iyer received his BS, with honors, in chemistry and physics, his BS degrees in the Technology of Pharmaceuticals and Fine Chemicals and his MS in Medicinal and Pharmaceutical Chemistry from the University of Bombay. He received a PhD degree in Pharmaceutical Sciences from the University of the Pacific in Stockton, California and carried out postdoctoral work at the Oak Ridge National Laboratory and at Johns Hopkins University.

Nezam H. Afdhal, MD – Chief Medical Officer

Nezam H. Afdhal, MD has been Spring Bank's Chief Medical Officer since November 2015 and served as a consultant to the company from early 2011 to November 2015. Dr. Afdhal has served as a Senior Physician in Hepatology at the Beth Israel Deaconess Medical Center since January 2015 and served as Chief of Hepatology from January 2000 to December 2014. Dr. Afdhal has also served as a Professor of Medicine at Harvard Medical School since 2000. Dr. Afdhal serves on the scientific advisory board of multiple pharmaceutical companies, including Gilead Sciences, Inc., GlaxoSmithKline Plc, Bristol Myers Squibb Company and Novartis Pharmaceuticals. Dr. Afdhal received his MB BCh degree in 1981 from the Royal College of Surgeons in Ireland and did fellowship training at University College in Dublin and at Boston University School of Medicine.

Jonathan Freve, CPA – Chief Financial Officer, Treasurer and Secretary

Jonathan Freve, CPA, has been the company's Chief Financial Officer, Treasurer and Secretary since January 2015. From March 2014 to November 2014, he served as the Senior Director of Finance of Santaris Pharma A/S, which was acquired by F. Hoffmann-LaRoche Ltd., a biotechnology company. Prior to Santaris, Mr. Freve was the Controller of Brookfield Renewable Energy Partners, L.P., a company that owns, operates and develops renewable power generation facilities, from April 2011 to March 2014. Mr. Freve served as Corporate Controller of Virtusa Corporation, an information technology consulting company, from October 2007 to April 2011. Mr. Freve began his career at the FASB and PricewaterhouseCoopers, where he worked in the audit and transaction services practices. Mr. Freve is a certified public accountant in the Commonwealth of Massachusetts and holds a BBA in accounting from the University of Massachusetts Amherst.

Financial Results

Spring Bank reported second quarter results on August 1st, 2016. The company announced that it had begun dosing the first patients in the Phase 2a ACHIEVE trial during the quarter and also presented its preclinical data at two major conferences in the United States and Spain.

Financial results for the second quarter 2016 were a loss of ($4.3) million or ($0.62) per share, compared to a loss of ($2.3) million and ($0.39) per share in the same period in 2015. Research and development expenses grew to $2.9 million in 2Q:16 from $1.5 million in 1Q:16 due to the launch of the Phase 2a trial and the addition of personnel. General and administrative expenses were also higher on a year over year basis rising to $1.5 million from $1.1 million in the same quarter in the prior year. Factors responsible for the G&A increase include additional public company costs and higher employee costs partially offset by the elimination of certain consulting activities shifted in-house.

Revenues were $72 thousand for the April to June period, falling from $331 thousand in the same period in 2016. These revenues represent NIH funding to support the company's research and development activities, including the preclinical animal studies.

Cash as of June 30, 2016 was $19.6 million, an increase from year-end 2015 cash levels of $12.9 million. The rise in cash levels originated from the issuance of stock on May 11, 2016 and the net receipt of $10.2 million from the public transaction. Spring Bank carries no debt on its balance sheet but does have long-term lease liabilities of $0.9 million that extend until 2021.

VALUATION AND RECOMMENDATION

We are initiating coverage of Spring Bank Pharmaceuticals Inc. (NASDAQ: SBPH) with a price target of $33.00. Spring Bank's lead clinical stage candidate, SB 9200, is a dinucleotide small molecule immunomodulator that is able to upregulate immune-stimulating proteins to clear RNA viruses. Based on our review, there are approximately 240 million individuals globally with chronic HBV, with the majority located in Asia. Based on CDC data, we conservatively see 1.5 million of these individuals in the United States and about 13 million in the greater European Union. Our estimates assume that about 30% of chronic sufferers will be diagnosed with chronic HBV. Penetration will begin in the high single digits when the anticipated approval date occurs in 2022 and will grow steadily to two thirds of the addressable market by 2032 in developed markets. We anticipate a lower level of individuals will seek treatment in developing economies in the mid to high single digits as a percentage of diagnosed chronic sufferers.

We take a conservative view on pricing and review related therapies to provide boundaries for our estimates. If SB 9200 is similarly effective as HCV drugs Solvadi and Harvoni, then the actual price may exceed our numbers. According to the National Kidney Foundation, who research organ transplant costs, a liver transplant averages $314,500 in the United States.[23] Citing analysis in a study performed by the Henry Ford Hospital, the economic cost of advanced liver disease when there is compensated cirrhosis or end stage liver disease is $450 per month and $3,511 per month more than for patients without cirrhosis.[24] Over a 20 year period, on an undiscounted basis, this represents an additional cost of $108,000 and $843,000 for compensated cirrhosis and end stage liver disease.

Interferon treatment with peginterferon alfa-2a runs approximately $40,000 for an 11 month course of treatment; however, the most common therapy is the use of nucleoside/nucleotide antivirals. With a monthly cost of near $1,200[25] for tenofovir and a lifelong commitment to taking the drug, lifetime costs (20 years, undiscounted) would be $288,000 for the therapy. Entecavir runs at about half of this amount and similar to tenofovir must be taken perpetually. Solvaldi and Harvoni therapies have a defined duration, similar to what we expect for SB 9200. These drug regimens run $85,000 to $95,000 for a course of treatment in the United States.

Based on this review and with a dose of conservatism, our model forecasts a $40,000 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 also included in the gross margin.

Spring Bank is seeking 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 $3.5 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.

[23] https://www.kidney.org/atoz/content/livertx
[24] http://www.henryford.com/body.cfm?id=46335&action=detail&ref=1465
[25] https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/459/cost-considerations-and-antiretroviral-therapy

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 based on the cumulative probability found by in the Biomedtracker analysis.[26]

We anticipate that Spring Bank will raise a total of $25 million through share offerings in the first half of next year. Our model forecasts the sale of 2.5 million shares at $11 apiece with proceeds after fees and commissions of $25 million.

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

[26] Clinical Development Success Rates 2006-2015. David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

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 for the rest of their lives. 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.

Due to the lack of strong immunomodulating competitors, SB 9200 will likely have dominant pricing power. Competing therapies run from approximately $40,000 for interferon to hundreds of thousands of dollars over the lifetime of a patient for antivirals, providing substantial support for our pricing forecasts.

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 currently 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**
- **SB 9200 was well tolerated in a Phase 1 study in Hepatitis C patients 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 are very 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 initiate SBPH with a target price of $33.00.

PROJECTED FINANCIALS

Spring Bank Pharmaceuticals Inc. - Income Statement

Spring Bank Pharmaceuticals	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	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	$2.9	$2.8	$14.2	$10.4	$12.0
G&A	$5.0	$1.2	$1.5	$1.6	$1.7	$6.0	$6.9	$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)	($4.5)	($4.5)	($19.9)	($17.3)	($20.0)
Operating Margin	-					-	-	-
Total Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($11.6)	($6.5)	($4.3)	($4.5)	($4.5)	($19.8)	($17.3)	($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)	($4.5)	($4.5)	($19.8)	($17.3)	($20.0)
Reported EPS	**($2.03)**	**($1.11)**	**($0.62)**	**($0.58)**	**($0.58)**	**($2.89)**	**($1.79)**	**($1.85)**
YOY Growth						-	-	-
Shares Outstanding	5.7	5.9	6.9	7.8	7.8	7.1	9.7	10.8

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

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