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Spring Bank Pharmaceuticals, Inc. (SBPH/NASDAQ/\$10.70/Buy)

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ACHIEVE First Cohort SB 9200 Dosing Complete

Spring Bank Pharmaceuticals announced first quarter results April 28th and provided a company update that included the news that the last patient receiving SB 9200 dosing in the **ACHIEVE** trial's first cohort occurred during the week of April 24th. The first cohort will wind-down when this patient completes the follow-on 12-week **Viread**® monotherapy dosing period. With the achievement of this key clinical milestone, Spring Bank remains on track to report topline results from this first cohort during the current quarter 2017 as well as position for the initiation of the second dose cohort (50mg dose) as soon as practical, assuming an anticipated go-ahead from the independent Data and Safety Monitoring Board (DSMB). Financial results for the quarter were largely in line with expectation with the benefit of well-managed costs offset by a change in fair value of warrant liabilities.

Status of SB9200 ACHIEVE Trial

This past week's milestone of the 20th and last Cohort 1 patient completing the SB 9200 monotherapy dosing portion of the trial is an important milestone achievement. With this first cohort moving into its final phase, and upon a favorable Data and Safety Monitoring Board (DSMB) review expected later in this month, progress in the **ACHIEVE** trial should pick up. After a bit of a slow start last year, centers in Asia are now "backlogging" potential patients that should make enrollment in Cohort 2 go considerably faster than Cohort 1. Further, the Company has already "teed-up" additional sites in Taiwan to add to patient enrollment flow.

To refresh, the Cohort 2 protocol will be the same as Cohort 1, except that the 12-week SB 9200 once daily oral dose will be double of Cohort 1, or 50mg. The SB 9200 monotherapy treatment period will also be followed by an additional 12 weeks with 300mg (SOC) of Gilead's **Viread**®, as a sequential monotherapy. In addition to assessing the

Current Price \$10.70

(SPRINGBANK LISTED ON NASDAQ MAY 2016)

FY Ended Dec 31 unless otherwise specified

| Estimates (MM's)* | FY2015A | FY2016E | FY2017E |
|--|-------------------|-------------------|-------------------|
| YR Revenues | \$0.94 A | \$0.35 A | \$0.00 E |
| 1Q | \$0.00 | \$0.28 A | E |
| 2Q | \$0.00 | \$0.07 A | E |
| 3Q | \$0.00 | \$0.00 A | E |
| 4Q | \$0.00 | \$0.00 A | E |
| 2018 Preliminary Revenue Estimate | | | \$0.0 E |
| YR EPS(loss) | (\$2.03) A | (\$2.39) A | (\$2.52) E |
| 1Q | | (\$1.11) A | NA |
| 2Q | | (\$0.62) A | NA |
| 3Q | | (\$0.53) A | NA |
| 4Q | | (\$0.28) A | NA |
| P/E (x) | NA | NA | NA |
| 2018 Preliminary EPS (loss) | | | (\$3.27) |
| REV/Share | NA | NA | NA |
| EV/EBITDA (x) | | | |
| Stock Data | | | |
| 52-Week Range | | | \$6.31-\$13.25 |
| Shares Outstanding (mil.) | | | 9.42 |
| Market Capitalization | | | \$89.45 MM |
| Enterprise Value | | | \$61.9 MM |
| Current Ratio (3/17) | | | 7.30X |
| Book Value/Share (3/17) | | | \$1.81 |
| Price/Book | | | 5.26X X |
| Average Trading Volume (3-Month) | | | 19,300 |
| Insider Ownership | | | 46.1% |
| Institutional Ownership | | | 11.0% |
| Short interest (Million shares) | | | 0.04 |
| Dividend / Yield | | | \$0.00/0.0% |

*Some numbers may not add due to rounding



primary trial endpoints of safety and antiviral effect at 12 weeks, patients are being tested for serum HBV DNA, HBsAg (surface antigen) and HBeAg (envelope antigen) at baseline for changes at 6, 12, 14, 16 and 24 weeks.

As the 25mg Cohort 1 dose is very low, investors should keep in mind that this is a dose escalation trial with an efficacy signal more appropriately expected in higher dose cohorts. However, if Spring Bank sees a sufficiently strong efficacy signal in the 50mg or 100mg cohorts (evidence of a possible trend towards viral load log reductions trending towards “functional cure” benchmarks), the Company has the option of closing the dose escalation phase of the trial and moving directly into the Phase IIb study. At this juncture, the target threshold for an efficacy signal is at least a ½ log reduction in HBsAg, which is an accepted predictor of the probability of treatment reaching “functional cure” status. Management intends to release top-line results as each SB 9200 treatment phase and after each **Viread** follow-on treatment cohort is completed. Based upon the timing of the completion of Cohort 1, management is now guiding investor expectation for results for all patients on SB 9200 monotherapy to be available in the second half of 2018 (assuming continued favorable DSMB review). This guidance has slipped slightly from prior guidance of late 1H 2018.

Update on SB11285

As noted in prior comments, Spring Bank’s second SMNH candidate, SB11285, is progressing through the pre-clinical phase of development. Continuing the Company’s strategy to roll-out increasing amounts of data surrounding SB11285 after its “debut” last fall with the release of preliminary *in vitro* data, Spring Bank presented two additional posters in March of this year at the prestigious Keystone Symposia Conference-C7. These posters provided further mechanism of action and therapeutic effect data of SB 11285 from *in vitro* model and newly released *in vivo* cancer models. The posters provided further evidence that SB 11285 is a potent immune-modulator, capable of inducing various interferon species and a number of other cytokines that lead to apoptosis, across a number of tumor-derived cell lines. In the 4T1 breast cancer syngeneic mouse model, SB 11285 showed anti-tumor activity when administered by intraperitoneal route. In the A20 lymphoma model, SB 11285 showed significant tumor growth inhibitory, or TGI, activity and tumor growth delay, or TGD, when used as a monotherapy and administered intratumorally. In the same A20 lymphoma model, when SB 11285 was used in combination with cyclophosphamide (**Cytoxan®**), additive TGI and TGD effects were also seen.

Current Product Pipeline

| Product Candidate | Indication/ Therapeutic Area | Stage of Development | Anticipated Milestones |
|-------------------|---|----------------------|--|
| SB 9200 | Chronic HBV | Phase 2 | Top-line data on first monotherapy dosing cohort of Phase 2a clinical trial expected Q2 2017 |
| | HBV/fixed dose combinations | Research | Establish preclinical proof-of-principle |
| | HBV/ collaborations for combination therapy | Research | Establish preclinical proof-of-principle |
| SB 11285 | Immuno-oncology | Research | Advance to IND submission in mid-2018 |
| SB 11177/11179 | PDE4 inhibitors | Research | Establish preclinical proof-of-principle |

Source: Spring Bank Pharmaceuticals 10Q

Financial Results

Spring Bank reported no revenue in Q1 2017 as the prior year’s grant award has now been fully deployed. Management held operating expenses to levels slightly below our expectation, but on a net loss basis, the non-

cash charge for the change in fair value of derivative liabilities offset the benefit of the control in operating expense. Research and development expenses were reported at \$2.5 million for the three months ended March 31, 2017, compared to \$5.6 million for the three months ended March 31, 2016. The decrease of \$3.1 million was comprised of a reduction of approximately \$2.7 million in non-cash charges related to the amended and restated license agreement with BioHE, decreased spending for pre-clinical studies and clinical trial related activities for SB 9200. General and administrative expenses were \$2.0 million for the three months ended March 31, 2017, compared to \$1.2 million for the three months ended March 31, 2016. The \$0.8 million year-over-year increase was largely due to public company related expense, a higher non-R&D headcount and the change in non-cash charges. Spring Bank finished the quarter with cash, cash equivalents and marketable securities of \$21.1 million compared to a cash and equivalents balance of \$25.5 million on December 31, 2016. The net loss reported for the March quarter was \$6.5 million or \$0.69 per share compared to \$6.5 million or \$1.11 per share in the March 2016 quarter. Management is maintaining its guidance that the Company has sufficient cash to fund its operations into the Q3 2018.

Consolidated Statement of Operations and Loss

| Income Statement [Abstract] | 3 Months Ended | |
|---|----------------|---------------|
| | Mar. 31, 2017 | Mar. 31, 2016 |
| Grant revenue | | \$ 280 |
| Operating expenses: | | |
| Research and development | \$ 2,527 | 5,589 |
| General and administrative | 1,987 | 1,226 |
| Total operating expenses | 4,514 | 6,815 |
| Loss from operations | (4,514) | (6,535) |
| Other income (expense): | | |
| Interest income | 41 | 17 |
| Change in fair value of warrant liabilities | (2,027) | |
| Net loss | (6,500) | (6,518) |
| Unrealized loss (gain) on marketable securities | 3 | (1) |
| Comprehensive loss | \$ (6,497) | \$ (6,519) |
| Net loss per common share – basic and diluted | \$ (0.69) | \$ (1.11) |
| Weighted-average number of shares outstanding – basic and diluted | 9,416,259 | 5,877,135 |

Source: SBPH 10Q

In light of the results reported for the first quarter, we are not making any modifications to our model at this time.

| | 2014 | 2015 | USD\$ in Thousands (except for shares outstanding) | | | | 2017E | 2018E | |
|---|----------------|-----------------|--|-------------------|-------------------|-------------------|-----------------|-----------------|-----------------|
| | | | Year End 12/2016 | | | | | | |
| | | | Q1 2016A | Q2 2016A | Q3 2016A | Q4 2016A | | | |
| Revenue | | | | | | | | | |
| Product Sales | | | | | | | | | |
| Contract Revenue/Milestone Payments | | | | | | \$0 | \$100 | \$500 | |
| Grant revenue | \$738 | \$946 | \$ 280 | \$ 72 | \$0 | \$0 | \$352 | | |
| Total Revenue | \$738 | \$946 | \$ 280 | \$ 72 | \$0 | \$0 | \$352 | \$100 | \$500 |
| Operating expenses: | | | | | | | | | |
| Research and development | 6,132 | 7,539 | 5,589 | 2,935 | 2,723 | 2,770 | 14,017 | 18,082 | 24,049 |
| General and administrative | 2,412 | 5,003 | 1,226 | 1,458 | 1,452 | 1,603 | 5,739 | 6,542 | 7,458 |
| Total operating expenses | 8,544 | 12,542 | 6,815 | 4,393 | 4,175 | 4,373 | 19,756 | 24,624 | 31,507 |
| Loss from operations | (\$7,806) | (11,596) | (6,535) | (4,321) | (4,175) | (4,373) | (19,404) | (24,524) | (31,007) |
| Other income (expense) | | | | | | | | | |
| Interest income (expense) | (1,906) | 32 | 17 | 21 | 27 | 31 | 96 | 35 | 15 |
| Change in fair value of warrant liabilities | | | | | | | 1,942 | 1,942 | |
| Pre-tax income (loss) | (9,712) | (11,564) | (6,518) | (4,300) | (4,148) | (2,400) | (17,366) | (24,489) | (30,992) |
| Income tax expense (income) | | | | | | | | | |
| Net loss | (9,712) | (11,564) | (6,518) | (4,300) | (4,148) | (2,400) | (17,366) | (24,489) | (30,992) |
| Unrealized gain (loss) on marketable securities | | | (1) | 4 | (3) | (7) | 11 | | |
| Comprehensive loss | | | \$ (6,519) | \$ (4,296) | \$ (4,151) | \$ (2,407) | (17,355) | (24,489) | (30,992) |
| Net loss per common share - basic and diluted | (0.78) | (2.03) | \$ (1.11) | \$ (0.62) | \$ (0.53) | \$ (0.28) | (2.39) | (2.52) | (3.27) |
| Weighted-average number of shares outstanding - basic and diluted | 3,118,344 | 5,932,799 | 5,877,135 | 6,923,941 | 7,759,630 | 8,447,367 | 7,256,671 | 9,723,684 | 9,478,664 |

Source: SEC filings, DJ estimates

Upcoming Milestones

1. Q2 2017: 1st cohort DSMB review
2. Q2 2017: Top line results from 1st cohort (25mg) SB9200 monotherapy dosing
2. Q3 2017: Top line results from 1st Phase IIa ACHIEVE trial cohort (25mg)
3. Q3 2017: Initiation of 2nd (50mg) ACHIEVE cohort enrollment
4. 2H 2017: Presentation of SB11285 pre-clinical in vivo model data
5. Late 2017: Top line results from 50mg ACHIEVE trial cohort

Changing Competitive Landscape

Since our initial report on SBPH, the competitive landscape among our “innovators” group has changed significantly now that Arrowhead Pharmaceutical’s Phase II RNAi program has been abandoned due to safety issues. In addition to direct competitors in HBV such as Arbutus Biosciences and Assembly Biosciences whose primary focus is on HBV, other companies with broader platforms including Transgene SA, Alnylam Pharmaceuticals, Arcturus Therapeutics, Janssen et al, Roche, Ionis Pharmaceuticals and Inovio are all advancing in Phase I or Phase Ib/IIa clinical trials with oligonucleotide, capsid inhibitor or immune-directed therapies. In fact, there appears to be about a dozen capsid inhibitor candidates under development and a further half dozen or more oligonucleotide-based therapeutics in the clinic aside from Arrowhead. No less than some 16 clinical trials (clinicaltrials.gov and HEP-B org) are now at or nearing a similar stage as is Spring Bank’s ACHIEVE trial.

Comment

While under normal circumstances, a therapeutic indication that becomes quickly crowded clinically can be a significant challenge for smaller companies. But in this case, we are encouraged that almost all of this effort is directed towards HBV DNA/RNA or transcription processes. Further, in recent quarterly update calls from both Arbutus and Assembly Biosciences, a common theme is emerging. Combination therapies were required to cure Hepatitis C and to improve the long-term outcomes in HIV. HBV is going to be no different. Combination therapies will be required to reach a HBV cure, and it is becoming increasingly clear that currently-approved single agents, by themselves, will not be able to achieve the HBV “cure” benchmarks being discussed in industry working groups and FDA-related panel meetings.

Discussion is now moving towards an evolving therapeutic target that not only seeks to drive down and maintain low levels of HBV DNA, but also will likely require benchmarks concerning levels of HBV “s” (surface) antigen. HBV’s antigen has a more direct involvement with impairing the body’s immune system. Companies, like Arbutus who is a collaborator of Spring Bank, are already laying out clinical strategies that envision triple combination therapies, where one element is an immunomodulator or immunostimulator. Spring Bank’s SB 9200, with its inherent immuno-modulation mechanism of action, sits in a perfect position to fit into any of these multi-combination strategies. Regardless of that opportunity, the fact that SB 9200 by itself acts with a dual action against HBV that includes interaction within the interferon pathway, makes it a unique asset.

We are maintaining our BUY rating on Spring Bank shares. SG

Companies Mentioned in this report:

Gilead Sciences Inc. -- NASDAQ/GILD/\$67.65/Not rated
 Arbutus Biopharma Corporation -- NASDAQ/ABUS/\$3.33/Not rated
 Arrowhead Pharmaceuticals, Inc. -- NASDAQ/ARWR/\$1.74/Not rated
 Transgene SA -- Paris/TRNG.PA/€3.34/Not rated
 Alnylam Pharmaceuticals -- NASDAQ/ALNY/\$54.55/Not rated
 Ionis Pharmaceuticals, Inc. -- NASDAQ/IONS/\$47.35/ Not rated
 Inovio Pharmaceuticals Inc. -- INO/NASDAQ/\$6.46/Not rated
 Roche Holdings– Zurich/ROG.VX/SF 268.90/Not rated



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