

**BeyondSpring, Inc. (BYSI)**  
**Rating: Buy**

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**Plinabulin Validation Train Grows With New Data; KOL Gives Insight to Plinabulin Benefits**

Stock Data		12/14/2017
Price		\$29.11
Exchange		NASDAQ
Price Target		\$60.00
52-Week High		\$48.49
52-Week Low		\$16.55
Enterprise Value (M)		\$624.3
Market Cap (M)		\$665
Public Market Float (M)		5.2
Shares Outstanding (M)		22.8
3 Month Avg Volume		2,246
Short Interest (M)		0.02
Balance Sheet Metrics		
Cash (M)		\$40.7
Total Debt (M)		\$0.0
Total Cash/Share		\$1.78

General: BYSI completed its IPO on March 9, 2017.

EPS Diluted			
Full Year - Dec	2016A	2017E	2018E
1Q	(0.12)	(2.66)A	--
2Q	(0.23)	(0.60)A	--
3Q	(0.18)	(0.68)A	--
4Q	(0.16)	(0.79)	--
FY	(0.75)	(4.41)	(4.53)

Revenue (\$M)			
Full Year - Dec	2016A	2017E	2018E
1Q	0.0	0.0A	--
2Q	0.0	0.0A	--
3Q	0.0	0.0A	--
4Q	0.0	0.0	--
FY	0.0	0.0	0.0

Quarterly EPS may not add to full year due to increases in share count and rounding.



**KOL highlights Plinabulin's differentiated profile as potentially disruptive.** Yesterday, BeyondSpring held an analyst day where the company hosted Dr. Douglas Blayney, a KOL in oncology. Dr. Blayney is an oncologist, former medical director of Stanford's cancer center, and former president of the American Society of Clinical Oncology. He has served on FDA Oncologic Drugs Advisory Committees and serves as an investigator for trials of both Neulasta and Plinabulin. Further, he was a founding member of the NCCN guidelines for the treatment of neutropenia. The initial focus of the conversation was to focus on the issue of neutropenia due to chemotherapy treatment. While G-CSF therapy is effective, there are still additional hospitalization days, emergency room visits, unnecessary medical costs, and lower quality of life. Approximately 40% of women with curable breast cancer have an emergency room visit or hospitalization due to neutropenia adverse effects. Adjunct therapy to colon cancer treatment shows similar trends. According to NCCN, 20% of patients are determined as high risk for neutropenia and warrant treatment to stabilize neutrophil count. Traditionally, expensive biologic G-CSF derivatives have been used with mild success but carry the following adverse effects and concerns: bone pain from bone marrow expansion in 20% of patients, increased chance of severe infection and sepsis by 3.6%, and high patient and hospital costs. Dr. Blayney described the bone pain side effect as a big deal for women, including comments like "no more, I'm not taking this (Neulasta)".

**What Plinabulin can bring to the table.** Dr. Blayney focused on the potential differentiated profile that Plinabulin could offer, should it be successful from a regulatory standpoint. Neulasta is expensive and needs to be given 24 hours after chemotherapy. The profile that could be disruptive for Plinabulin is a new agent with the right price point and with fewer side effects (especially bone pain), which should lead to wide use in the real world. Plinabuline is also dosed on the same day as chemo (one hour post) and data to date suggest that bone pain is about five times less likely. Plinabulin, an inexpensive drug has shown good tolerability in the clinic thus far. Recall that Study 101 showed significant decreases in neutropenia ( $P < 0.0003$ ) for the Plinabulin + Docetaxel compared to Docetaxel monotherapy. Duration of severe neutropenia (DSN) was 0.065 days for combo Plinabulin + docetaxel therapy vs Docetaxel monotherapy of 1.1 DSN.

(continued on next page)



**Two new data sets for Plinabulin further validate its activity.** BeyondSpring also announced positive top-line data for prevention of chemotherapy induced neutropenia (CIN) from the Phase 2 portion of the Phase 2/3 105 study of Plinabulin in combination with docetaxel. As a reminder, the 105 study is a non-inferiority head-to-head study comparing Plinabulin to Neulasta (long lasting G-CSF) with the primary endpoint of duration of severe neutropenia in cycle 1 with a non-inferiority margin of 0.65 days. Detailed data are expected at ASCO-SITC in January 2018. Plinabulin's clinical activity was further validated by additional positive results announced yesterday from the secondary endpoint of reduction in chemotherapy induced grade 4 neutropenia on day eight of cycle one from its ongoing Phase 3 103 study of Plinabulin in combination with docetaxel for non-small cell lung cancer (NSCLC). Data from 138 patients show Plinabulin's ability to reduce docetaxel induced grade 4 neutropenia from 27.4% to 3.1% ( $p < 0.0001$ ). These data reinforce our belief that Phase 2 data presented to date on Plinabulin's ability to prevent CIN act as a window into the upcoming 105 and 106 Phase 3 studies. We further discuss the clinical programs below.

**Upcoming 2018 milestones and catalysts**

- January 25-27: Study 105 Phase 2 top-line data to be presented at ASCO-SITC.
- 1H18: Study 106 Phase 2 first data readout of Plinabulin in combination with TAC chemotherapy for breast cancer.
- 1H18: Study 103 Phase 3 interim data in NSCLC with measurable lesion.
- 2018: Phase 2 data of Plinabulin in combination with nivolumab in the second and third line for NSCLC (Fred Hutchinson Cancer Center).
- 4Q17-2018: Phase 1/2 data of Plinabulin in combination with nivolumab in the second and third line for NSCLC (UCSD).
- 1H18: Initiation of study of Plinabulin in combination with  $\alpha$ PD-1 and  $\alpha$ CTLA-4 for small cell lung cancer.
- 1H18: Initiation of study of Plinabulin in combination with chemotherapy for KRAS mutant positive pancreatic cancer.

**Valuation and risks to price target achievement.** We maintain our Buy rating with a \$60 price target. Following the upcoming Phase 2 portion efficacy data later this year, we look to reassess our overall valuation and thesis on Plinabulin. Our valuation is based on our clinical net present value (NPV) model, which is currently driven by the company's lead asset, Plinabulin. This model allows us to flex multiple assumptions affecting a drug's potential commercial profile. Factors which could impede reaching our price target include failed or inconclusive clinical trials or inability of the company to secure adequate funding to progress its drugs through the development pathway.

**Clinical design of three major clinical trials with Plinabulin.**

**Study 105.** A Phase 2/3 non-inferiority study of Plinabulin for prevention of docetaxel chemotherapy induced neutropenia is ongoing. The Phase 2 portion consists of four arms which are as follows: 1) Neulasta 0.6 mg; 2) Plinabulin 5 mg/m<sup>2</sup>; 3) Plinabulin 10 mg/m<sup>2</sup>; and 4) Plinabulin 20 mg/m<sup>2</sup>. Each arm of the study enrolled 10 NSCLC patients who received docetaxel. The Phase 2 portion has met its primary objective of duration of severe neutropenia in cycle one with a non-inferiority margin of 0.65 days. Detailed data are expected at ASCO-SITC in January 2018.

The non-inferiority Phase 3 portion of the study is expected to consist of two arms: 1) Neulasta 0.6 mg; and 2) Plinabulin at the recommended Phase 3 dose determined in Phase 2 portion of this study. Each arm of the study is expected to enroll 77 patients with NSCLC, breast cancer, or prostate cancer. An interim analysis is expected after data for 50 patients in each arm has been obtained. The primary objective is duration of severe neutropenia. Secondary objectives include:

- Incidence of grade 4 neutropenia.
- Incidence of febrile neutropenia.
- Health related quality-of-life questionnaire evaluated with EORTC QLQ-C30.
- Neutrophil nadir.
- Incidence of docetaxel treatment modification.
- Bone pain.
- Incidence of hospitalization due to febrile neutropenia.
- Incidence of documented infections.

**Study 106.** A Phase 2/3 superiority study of Plinabulin for the prevention of TAC (taxotere, Adriamycin, and cyclophosphamide) induced neutropenia is ongoing and is geared to show superiority to Neulasta. The Phase 2 portion of the study has three arms which are as follows: 1) Neulasta 0.6 mg; 2) Plinabulin 10 mg/m<sup>2</sup>; and 3) Plinabulin 20 mg/m<sup>2</sup>. Each arm of the study is expected to enroll 20 breast cancer patients receiving TAC chemotherapy. The Phase 2 is currently enrolling patients.

The superiority Phase 3 portion of the study is expected to consist of two arms: 1) Neulasta 0.6 mg; and 2) Plinabulin at the recommended Phase 3 dose determined in Phase 2 of this study. Each arm of the study is expected to enroll 60 patients. The primary objective of the head-to-head study is duration of grade 4 neutropenia. Secondary outcomes include:

- Bone pain.
- Incidence of grade 4 neutropenia.
- Incidence of febrile neutropenia.
- Incidence of hospitalization due to febrile neutropenia.
- Duration of hospitalizations due to febrile neutropenia.
- Frequency of antibiotic use.

**Study 103.** A Phase 3 study of Plinabulin in combination with docetaxel compared to docetaxel alone for advanced NSCLC with at least one measurable lung lesion is ongoing. The study expects to enroll 550 patients. The treatment regimen is on a 21 day cycle and on day one patients are to be dosed with 75 mg/m<sup>2</sup> of docetaxel. Patients on the Plinabulin arm are expected to receive Plinabulin on days one and eight of the 21 day cycle. Patients who failed checkpoint inhibitor therapy (αPD-1 or αPD-L1) are to be stratified. Patients with mutant EGFR driven NSCLC are excluded from the study. The statistical analysis

plan includes KRAS mutant subgroup, PD-L1 expression subgroup, tumor size subgroup, and patients with prior treatment with  $\alpha$ PD-1 or  $\alpha$ PD-L1 therapies.

Primary objective is overall survival. Secondary objectives include:

- Progression free survival.
- Response rate.
- Duration of response.
- Incidence and severity of treatment emergent adverse events.
- Incidence of serious adverse events.
- Incidence of discontinuation of study treatment due to safety reasons.

### NDA package for neutropenia

BeyondSpring expects to file an NDA for Plinabulin in the neutropenia setting in China and the U.S. In October new regulatory rules in China were announced that may accelerate Plinabulin approval. The CPC Central Committee and State Council of China announced new regulatory framework in order to reform the management of clinical trials. The guidelines aim to accelerate approval of new therapies for unmet medical needs. We believe such changes favor BYSI and the development of Plinabulin and it gives us confidence that the company may meet an accelerated projected timeline for NDA filing to the CFDA in 2018 (instead of originally projected 2019) while expected filing in the U.S. remains for 2019. In addition, the Plinabulin program is courting the interest of major pharmaceutical companies, which are in advanced stages of discussions for potential partnering. The figure below shows what BeyondSpring expects to submit as part of the NDA filing package to each of the regulators.

### Packages That are to be Submitted for NDA Filings

#### CHINA (Conditional NDA Filing 2018)

##### Clinical Efficacy Trend

- 105 study: Phase 2 and Phase 3 (~80 patients in each Plinabulin & Neulasta study groups)
- 106 study: Phase 2 (20 patients in each study group)
- Safety Database requirement (300 cancer patients – with data from 101, 103, 105, and 106 study)

#### USA (NDA Filing 2019)

##### Full Package

- 105 study: Phase 2 and Phase 3 (around 100 patients in each Plinabulin & Neulasta study groups)
- 106 study: Phase 2 and Phase 3 (100 patients in same study group)
- Safety Database (~550 cancer patients)

Source: Company presentation, December 2017.

**BeyondSpring is preparing for triple combinations.** BeyondSpring detailed studies in NSCLC with Plinabulin + PD1-inhibitor + CTLA4-inhibitor to demonstrate overall survival and decreased immune related adverse effects. Triple combination therapy is expected to reveal a similar result plus the added benefit of decreased neutropenia. The immune related adverse events in combination PD1/CTLA4-I occur in 60% of patients, leading to discontinuation. Steroid use has shown to resolve symptoms. Plinabulin exhibits steroid properties ( $P < 0.03$ ), thereby curtailing the side effects that limit the use of validated combination therapies. Additionally, Plinabulin has anti-cancer properties by producing neo-antigens from T cell stimulation.

(\$ in millions except per share data)

<b>Profit &amp; Loss</b>	<b>2014A</b>	<b>2015A</b>	<b>2016A</b>	<b>2017E</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>
Licensing and R&D revenue	0.0	0.0	0.0	0.0	0.0	15.0	45.0	20.0	15.0	15.0
Grant revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Product and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	96.7	358.2	751.0	1,092.8
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Revenues</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>15.0</b>	<b>141.7</b>	<b>378.2</b>	<b>766.0</b>	<b>1,107.8</b>
CoGS	0.0	0.0	0.0	0.0	0.0	0.0	11.6	43.0	90.1	131.1
<b>Gross Profit</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>15.0</b>	<b>130.1</b>	<b>335.2</b>	<b>675.9</b>	<b>976.6</b>
<i>Gross margin</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>100%</i>	<i>92%</i>	<i>89%</i>	<i>88%</i>	<i>88%</i>
G&A	0.2	1.2	1.9	10.5	11.7	15.4	27.0	33.7	47.9	69.5
R&D	1.9	6.3	10.4	89.9	102.4	140.3	189.5	269.0	417.0	675.6
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.0
<b>EBIT</b>	<b>(2.1)</b>	<b>(7.5)</b>	<b>(12.4)</b>	<b>(100.4)</b>	<b>(114.1)</b>	<b>(140.8)</b>	<b>(86.4)</b>	<b>32.5</b>	<b>209.9</b>	<b>229.6</b>
<i>EBIT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>9%</i>	<i>27%</i>	<i>21%</i>
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Amortisation Intangibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.0
<b>EBITDA</b>	<b>(2.1)</b>	<b>(7.5)</b>	<b>(12.4)</b>	<b>(100.4)</b>	<b>(114.1)</b>	<b>(140.8)</b>	<b>(86.4)</b>	<b>32.5</b>	<b>210.9</b>	<b>231.6</b>
<i>EBITDA margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>9%</i>	<i>28%</i>	<i>21%</i>
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	(0.1)	0.0	0.4	6.0	0.8	0.5	0.1	0.1	0.5	0.9
Interest expense	0.8	0.5	0.0	0.0	0.0	0.0	0.0	0.0	1.5	5.1
<b>EBT</b>	<b>(3.0)</b>	<b>(8.0)</b>	<b>(12.0)</b>	<b>(94.4)</b>	<b>(113.3)</b>	<b>(140.3)</b>	<b>(86.3)</b>	<b>32.6</b>	<b>208.9</b>	<b>225.4</b>
<i>EBT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>9%</i>	<i>27%</i>	<i>20%</i>
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	(32.8)	12.4	79.4	85.7
<b>Net Income</b>	<b>(3.0)</b>	<b>(8.0)</b>	<b>(12.0)</b>	<b>(94.4)</b>	<b>(113.3)</b>	<b>(140.3)</b>	<b>(86.3)</b>	<b>32.6</b>	<b>208.9</b>	<b>225.4</b>
Participation of preferred stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.0
<b>Source: SEC filings.</b>	<b>(3.0)</b>	<b>(8.0)</b>	<b>(12.0)</b>	<b>(94.4)</b>	<b>(113.3)</b>	<b>(140.3)</b>	<b>(53.5)</b>	<b>20.2</b>	<b>130.5</b>	<b>141.8</b>
<i>net margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>5%</i>	<i>17%</i>	<i>13%</i>
	13.9	15.2	16.1	21.4	25.0	28.0	31.0	33.2	36.0	37.0
<b>EPS - basic</b>	<b>(0.22)</b>	<b>(0.53)</b>	<b>(0.75)</b>	<b>(4.41)</b>	<b>(4.53)</b>	<b>(5.01)</b>	<b>(1.73)</b>	<b>0.61</b>	<b>3.63</b>	<b>3.83</b>
<b>EPS - diluted</b>	<b>(0.22)</b>	<b>(0.53)</b>	<b>(0.75)</b>	<b>(4.41)</b>	<b>(4.53)</b>	<b>(5.33)</b>	<b>(1.73)</b>	<b>0.61</b>	<b>3.63</b>	<b>3.83</b>

Source: SEC filings and H.C. Wainwright estimates

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(\$ in millions except per share data)

<b>Quarterly P&amp;L</b>														
	Q1'16A	Q2'16A	H1'16A	Q3'16A	9M'16A	Q4'16E	FY'16E	Q1'17A	Q2'17A	H1'17A	Q3'17A	9M'17A	Q4'17E	FY'17E
Licensing and R&D revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Grant revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Product and Royalties	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Other revenues	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
<b>Revenues</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
<b>Gross Profit</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>
<i>Gross margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>0%</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>0%</i>
G&A	0.43	0.50	0.93	0.54	1.47	0.46	1.9	1.04	2.80	3.84	3.33	7.18	3.35	10.5
R&D	1.49	3.19	4.67	2.74	7.41	3.02	10.4	46.75	12.19	58.93	15.29	74.22	15.64	89.9
Other op ex	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
<b>EBITDA</b>	<b>(1.9)</b>	<b>(3.7)</b>	<b>(5.6)</b>	<b>(3.3)</b>	<b>(8.9)</b>	<b>(3.5)</b>	<b>(12.4)</b>	<b>(47.8)</b>	<b>(15.0)</b>	<b>(62.8)</b>	<b>(18.6)</b>	<b>(81.4)</b>	<b>(19.0)</b>	<b>(100.4)</b>
<i>EBITDA margin</i>							<i>nm</i>							<i>nm</i>
Non operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	0.07	0.15	0.22	0.20	0.41	(0.06)	0.4	0.40	1.69	2.08	3.09	5.17	0.81	6.0
Interest expense	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
<b>EBT</b>	<b>(1.8)</b>	<b>(3.5)</b>	<b>(5.4)</b>	<b>(3.1)</b>	<b>(8.5)</b>	<b>(3.5)</b>	<b>(12.0)</b>	<b>(47.4)</b>	<b>(13.3)</b>	<b>(60.7)</b>	<b>(15.5)</b>	<b>(76.2)</b>	<b>(18.2)</b>	<b>(94.4)</b>
<i>EBT margin</i>							<i>nm</i>							<i>nm</i>
Provision for taxes	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Participation of preferred stock														
<b>Net Income to common</b>	<b>(1.8)</b>	<b>(3.5)</b>	<b>(5.4)</b>	<b>(3.1)</b>	<b>(8.5)</b>	<b>(3.5)</b>	<b>(12.0)</b>	<b>(47.4)</b>	<b>(13.3)</b>	<b>(60.7)</b>	<b>(15.5)</b>	<b>(76.2)</b>	<b>(18.2)</b>	<b>(94.4)</b>
<i>net margin</i>							<i>nm</i>							<i>nm</i>
Source: SEC filings.														
NoSH	15.8	15.8	15.75	16.88	16.13	21.80	16.09	17.8	22.0	19.92	22.84	20.89	22.88	21.40
<b>EPS - basic</b>	<b>(0.12)</b>	<b>(0.23)</b>	<b>(0.34)</b>	<b>(0.18)</b>	<b>(0.53)</b>	<b>(0.16)</b>	<b>(0.75)</b>	<b>(2.66)</b>	<b>(0.60)</b>	<b>(3.05)</b>	<b>(0.68)</b>	<b>(3.65)</b>	<b>(0.79)</b>	<b>(4.41)</b>

Source: SEC filings and H.C. Wainwright estimates

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BYSI IPO was on March 9, 2017

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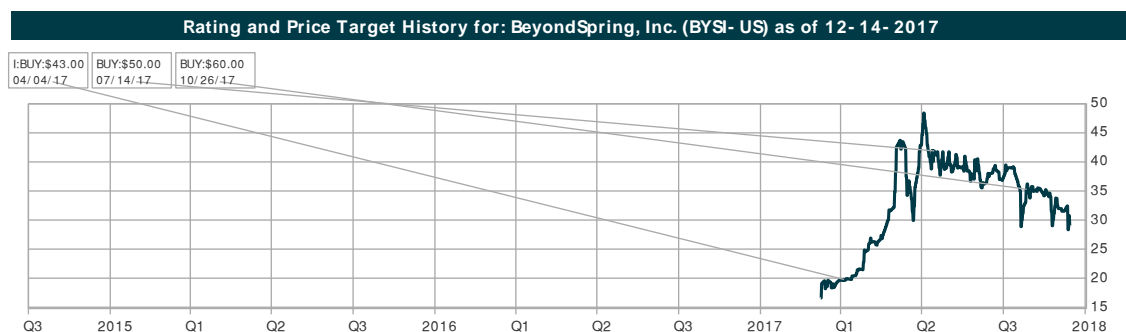
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## RETURN ASSESSMENT

**Market Outperform (Buy):** The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

**Market Perform (Neutral):** The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

**Market Underperform (Sell):** The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.



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**Distribution of Ratings Table as of December 14, 2017**

Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
Buy	236	91.47%	88	37.29%
Neutral	10	3.88%	0	0.00%
Sell	0	0.00%	0	0.00%
Under Review	12	4.65%	1	8.33%
<b>Total</b>	<b>258</b>	<b>100%</b>	<b>89</b>	<b>34.50%</b>

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