Zacks Small-Cap Research

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Spotlight Innovation (STLT-OTC)

STLT: Experienced Cancer Specialist Retained To Lead Crotoxin Cancer Study

Current Recommendation	**Hold**
Prior Recommendation	N/A
Date of Last Change	08/11/2015
Current Price (01/29/16)	$0.60
Target Price	**$1.50**

OUTLOOK

Spotlight is involved in identifying, acquiring/licensing and developing early-stage life sciences-related technologies and products. They recently acquired two separate companies which brought on promising early-stage clinical development of compounds that may have applications in the treatment of cancer, kidney disease and infectious diseases. One of the main focuses is on development of certain toxins found in snake venom for therapeutic applications in cancer and chronic kidney disease (CKD). These toxins have shown promise in early stage studies as cancer-fighting and pain relieving agents. STLT expects to initiate additional clinical trials in the near-term. The other major focus is with a platform technology called Immunoplex which is being developed to improve vaccine efficacy by using more efficient targeting and delivery. Immunoplex is in preclinical development for certain infectious diseases including influenza as well as for cancers of the breast, prostate and skin (melanoma).

SUMMARY DATA

52-Week High	**$1.25**
52-Week Low	**$0.51**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**1,459**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med/Dental-Supp**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 A	0 E	0 E
2016					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.01 A	-$0.01 A	-$0.01 A	-$0.83 A	-$0.96 A
2014	-$0.01 A	-$0.13 A	-$0.07 A	-$0.07 A	-$0.28 A
2015	-$0.07 A	-$0.07 A	-$0.15 A	-$0.09 E	-$0.39 E
2016					-$0.36 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Lead Investigator Retained for Crotoxin Study, Balance Sheet Cleansing and Crotalin for Vet Market…
Recent progress includes bringing on a renowned cancer specialist to lead STLT's Crotoxin study, cleaning up the balance sheet/capital structure – perhaps in anticipation of a future raise and an announcement that the recently formed veterinary subsidiary will pursue commercialization of Crotalin as a cancer therapeutic for animals.

Highly Experienced Cancer Expert Will Lead Crotoxin Phase I Cancer Study…
Yesterday (1/28) STLT announced that they have retained Dr. David Khayat to lead their Phase I Crotoxin dose escalation study which will evaluate the compound as a cancer therapy. Dr. Khayat is a renowned cancer specialist who currently heads the Department of Medical Oncolody at Pitie-Salpetritere Hospital (Paris) – this is also where the Crotoxin study will be conducted. Khayat is also a board member of the American Society of Clinical Oncology, recognized as the world's leading cancer organization. STLT's press release also notes that he had previously been appointed by then French President Jacques Chirac to lead the formation and development of the French National Cancer Control Plan, had served as President of the French National Cancer Institute from 2004 to 2006, was the first President of the French Federation of Medical Oncologists, has received numerous awards including the National Order of Merit and the ASCO Distinguished Achievement Award, and is a co-founder of World Cancer Day.

As a reminder, the study, titled *Crotoxin in Patients with Advanced Cancer Using an Intravenous Route of Administration*, hopes to address some of the questions that came out of an earlier study (Cura et al., which we discuss in detail in our initiation report) - including whether adverse side effects could be tempered through induction of tolerance and, concurrently, whether the cancer would show effective response to higher crotoxin doses. Unlike the earlier study, Celtic's Phase I study has used intra-patient dose escalation. In addition, the previous study used intramuscular injection while this study administered crotoxin via intravenous (IV) drip which is intended to reduce toxic side effects. This study also used a maximum dose which was much higher than the previous study's MTD (0.32mg/m^2 vs. 0.21mg/m^2).

Primary objective is to "assess whether human subjects can be made tolerant to intravenously administered Crotoxin and achieve higher and more therapeutically effective dose levels without the previously reported adverse effects associated with bolus i.m. (intramuscular) administration." Secondary objective is evidence of anti-cancer response to crotoxin.

The trial was separated into two cohorts. While both cohorts, per the initial protocol, were to enroll up to 12 patients each, Part 1 enrolled 6 patients and Part 2, which is expected to commence shortly, is still expected to enroll up to 12 patients. Below is from the original trial protocol. However, Spotlight / Celtic has yet to announce the final part 2 protocol, which may be amended from the original - we expect this will be announced prior to initiation of part 2.

- cohort 1: receive crotoxin doses of 0.04mg/m^2 to 0.32mg/m^2 via two hours of I.V. drip for five consecutive days followed by two off. Doses be escalated to a maximum of 8 levels over the course of 40 treatment days (five days per dose level). MTD defined as the dose level where no toxicity is observed for three consecutive patients or not more than one DLT is observed for six patients.
- cohort 2: receive the same dose levels as cohort 1 but dose escalation will be more rapid. The eight doses will be escalated over 27 days (instead of 40). This, however, may be amended - see below.

Part 1 of the study was completed but Part 2 was subsequently suspended for reasons, per the notation on clinicaltrials.gov, related to "funding issues." However, per the company's August 24th press release, data from Part 1 of the study is now being aggregated and prepared for analysis. Results had recently been expected potentially as soon as sometime in November 2015, however that timeline was obviously not met. We view the hiring of Dr. Khayat as a positive sign that preparations are moving forward to restarting the study. In 2015 the company engaged ImmunoClin, Inc., a contract research organization, to manage it.

Protocol of the study is still not clear, however. Per Spotlight's July 21, 2015 press release announcing consummation of a Clinical Study Management Agreement with Immunoclin to manage the second part of the study, protocol of the second part may be amended from the original – so we still expect to hear more details about this. The press release did provide some detail on the second part, however, including; expected enrollment of 12 patients at 3 sites in France, treatment duration is expected to be 37 days with 30-day follow-up and total duration of the study expected to be ~18 months.

Balance Sheet Cleaning…
Perhaps in preparation to raise additional funds to help finance upcoming clinical trials, STLT did some balance sheet cleaning. This included swapping outstanding convertible notes, terminating other convertible notes and terminating several potentially toxic unit subscription and other outstanding securities agreements. While the impetus for doing so was not disclosed in the January 7, 2016 8-k, these types of cleansings are often a precursor to a capital raise. We view this as a positive development as STLT would use the funds to advance its clinical programs and for general operating purposes.

CDT Veterinary Therapeutics to Pursue Crotalin Development…
In November 2015 STLT formed CDT Veterinary Therapeutics Inc, a subsidiary which will focus on the development of animal therapeutics using product candidates in Celtic Biotech's pipeline. An impetus for branching out into veterinary medicine is the (generally) shorter and less stringent regulatory pathway associated with animal therapeutics.

In early December the company announced that CDT will pursue development and commercialization of Crotalin, venom from a tropical rattlesnake, as a cancer therapeutic for the veterinary market. While STLT did not offer specifics in terms of which cancers they may pursue with Crotalin, an earlier investor presentation indicated their Crotalin program may include canine tumors as well as potentially colon cancer, pancreatic cancer and brain cancer. We think the animal cancer programs could be relatively fast-moving and expect to hear more about progress on this front over the near term.

FINANCIAL MODEL

Spotlight Innovation, Inc.

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-
COGS	$0.0	$0.00	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin	-	-	-	-	-	-	-
SG&A	$1,486.6	$649.5	$733.6	$1,799.5	$908.0	$4,090.6	$4,414.0
% SG&A	-	-	-	-	-	-	-
R&D	$0.0	$0.0	$3.7	$254.8	$148.0	$406.5	$447.0
% R&D	*#DIV/0!*	-	-	-	-	-	-
Operating Income	($1,486.6)	($649.5)	($737.2)	($2,054.3)	($1,056.0)	($4,497.1)	($4,861.0)
Operating Margin	-	-	-	-	-	-	-
Total Other Income (Expense)	($2,138.6)	($311.8)	($265.8)	($150.7)	($244.0)	($972.8)	($2,128.0)
Pre-Tax Income	($3,625.3)	($961.3)	($1,003.0)	($2,205.0)	($1,300.0)	($5,469.8)	($6,989.0)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred dividends	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income to non-contrl interest	-$1.8	$0.2	-$1.3	-$21.1	$0.0	-$22.2	$0.0
Net Income	($3,623.5)	($961.6)	($1,001.8)	($2,183.8)	($1,300.0)	($5,447.7)	($6,989.0)
YOY Growth	*-46.8%*	*751.8%*	*-12.7%*	*184.9%*	*-18.5%*	*50.3%*	*28.3%*
Net Margin	-	-	-	-	-	-	-
EPS	($0.28)	($0.07)	($0.07)	($0.15)	($0.09)	($0.39)	($0.31)
YOY Growth	*-71.0%*					*40.0%*	*-21.7%*
Diluted Shares O/S	13,007	13,413	13,742	14,277	14,455	13,972	22,900

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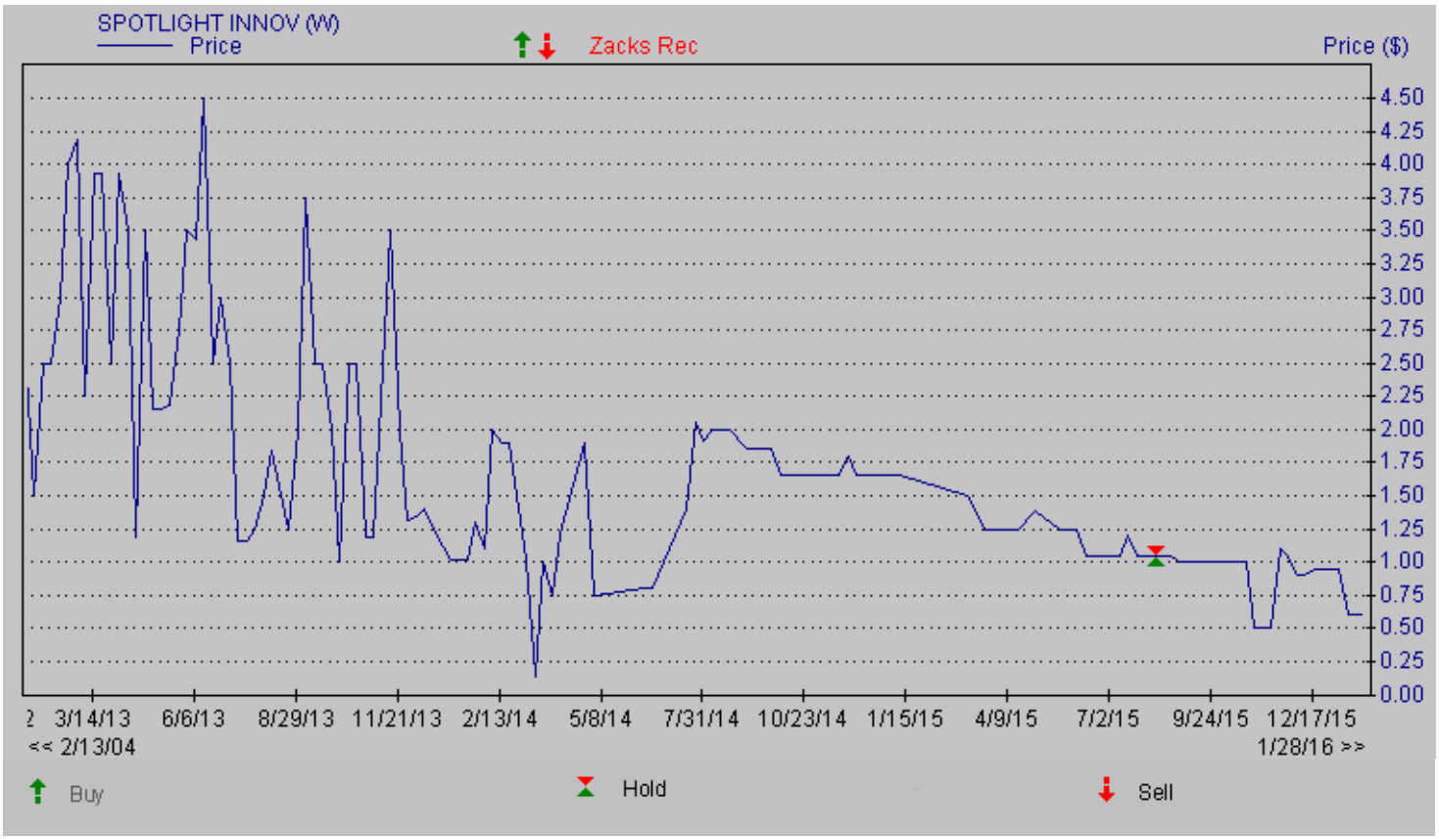

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