Zacks Small-Cap Research

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Spotlight Innovation (STLT-OTC)

STLT: Reallocation of Resources to Higher Potential Targets Including Zika and SMA

Average EV and development phase rating of our 13 comparable companies is $34.2 million and 3.0, respectively. Which equates to $11.4 million (= $34.2M / 3.0) of EV for each development stage. As STLT is in the preclinical to phase I stage, we assign an EV of approximately $23 million (= 2 x $11.4M), which equates to a market value of approximately $21 million or ~ $1.50/share.

Current Price (10/26/16)	$0.92
Valuation	**$1.50**

OUTLOOK

Spotlight has recently revamped their development focus, bringing on two new programs (Zika and Spinal Muscular Atrophy) which could prove to hold relatively greater near-term potential and complement their ongoing research in venom-based compounds to fight cancer and pain.

As part of the consolidation of resources around these programs, Spotlight shed ownership of Memcine Pharmaceuticals, which was in preclinical development of an immune vaccine technology called Immunoplex. Spotlight similarly mothballed operations of CDT Veterinary, which among other activities, was looking at the potential to develop snake venom-based therapies related to cancer and kidney disease. These moves have helped to free up resources which can now be allocated towards other programs.

SUMMARY DATA

52-Week High	**$1.22**
52-Week Low	**$0.34**
One-Year Return (%)	**11.25**
Beta	**-1.47**
Average Daily Volume (sh)	**21,584**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$17**
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 Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 E	0 E	0 E
2017					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
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	-$0.28 A	-$0.58 A
2016	-$0.10 A	-$0.07 A	-$0.08 E	-$0.07 E	-$0.24 E
2017					-$0.30 E

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

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WHAT'S NEW…

Refocused Strategy: *STLT sheds Memcine. New Zika and SMA programs will complement cancer candidates…*

Spotlight has recently revamped their development focus, bringing on two new programs which could prove to hold relatively greater near-term potential and complement their ongoing research in venom-based compounds to fight cancer and pain. As part of the consolidation of resources around these programs, Spotlight shed ownership of Memcine Pharmaceuticals, which was in preclinical development of an immune vaccine technology called Immunoplex. Spotlight similarly mothballed operations of CDT Veterinary, which among other activities, was looking at the potential to develop snake venom-based therapies related to cancer and kidney disease. These moves have helped to free up resources which can now be allocated towards other programs.

- **Spinal Muscular Atrophy (SMA) program:** Spotlight's newest development program, announced just last week, targets Spinal Muscular Atrophy (SMA), a rare, highly debilitating and often fatal neuromuscular condition. SMA is a genetic disease, characterized by the loss of nerve cells in the spinal column and progressive muscle weakness and atrophy.

  Etiology of SMA is a defect in chromosome 5 in the SMN1 gene, which encodes SMN, or 'survival of motor neuron', protein. The mutation(s) in SMN1 means that most of the SMN proteins are not correctly coded. The SMN2 gene which is unaffected by Spinal Muscular Atrophy, also has a role in encoding SMA, although typically codes only relatively small amounts – around 10% - 20% of SMN. As the SMN protein is essential for sustenance of motor neurons, compromised existence (i.e 80% - 90% loss) of the protein leads to loss of voluntary muscle function. Weakness in respiratory muscles, particularly in those afflicted early in life, is also not uncommon and can be life-threatening.

  SMA, which is believed to affect 1 in every 6k to 10k people in the U.S., is an inherited condition. Onset of the disease can vary from as early as birth (i.e. type 1) to adulthood (i.e. type 4). As the condition is progressive, the earlier the onset, the more debilitating the symptoms and the higher likelihood of related death. Newborns afflicted with the condition typically have a very poor prognosis – oftentimes estimated to live two years or less.

  While SMA is largely unfamiliar to the general public, the disease gained national attention earlier this year when a 14 year-old girl afflicted with the condition announced that she would host a dance to celebrate her life. The girl, Jerika Bowlen, was wheelchair bound and only able to move her hands and parts of her face. Due to the extreme pain caused by the disease, she decided that after the dance she would voluntarily remove herself from the ventilator that was sustaining her life. She died in September.

  While Spotlight has publicly revealed only limited information about their SMA-related development program, they have noted that they obtained an exclusive, worldwide license from Indiana University Research and Technology Corp to commercialize "an orally-available small molecule that may have therapeutic potential for treating Spinal Muscular Atrophy". The company furthers notes that preclinical testing of STL-182, which was supported by grants from the National Institute of Health (NIH), was done via a collaboration between Elliot Androphy of Indiana University School of Medicine and Kevin Hodgetts, director of the Laboratory for Drug Discovery in Neurodegeneration at Brigham and Women's Hospital. Spotlight has indicated that STL-182 may be focused towards increasing levels of SMN which are encoded my SMN2 in individuals afflicted with SMA. We expect to hear more about the development program and related updates in the near future.

  If eventually approved to enter clinical studies, STL-182 could possibly follow an orphan designated regulatory pathway. The FDA considers diseases that affect less than 200k people (~1 in 1,500) as candidates for orphan designation – which affords several benefits including seven-year marketing exclusivity from the date of FDA approval (or until patent expiration, whichever is longer), tax credits equal to 50% of related development costs (with a 15-year carry-forward provision), grant funding, waiver of PDUFA (Prescription Drug User Fee Act) application fees, FDA fast-track approval and research design support.

  While there are no currently approved therapies available to treat SMA, several companies have candidates in clinical studies. And Biogen/Ionis Pharmaceuticals has submitted an NDA to FDA for Nusinersen, their antisense oligonucleotide compound, seeking approval for the treatment of SMA. The companies filed for approval in September 2016 after stopping their phase III study in type 1 SMA patients due to positive efficacy. And while STLT's candidate, assuming eventual regulatory approval, might not launch until many years after competing therapies, benefits such as an already established market as well as reimbursement could act as significant catalysts to uptake.

- **Zika***: Spotlight Teams With Researchers Credited With Breakthrough Zika Drug Findings***…**

Researchers from Florida State University, Johns Hopkins University and the National Institutes of Health, interested in shortening time-to-market of a potential Zika therapy, looked at 6,000 drug compounds which had either already been approved by FDA or were in clinical trials and may have efficacy against the virus.

Led by a team including Dr.Hengli Tang, Professor of Biological Science at Florida State University, Guo-Li Ming of Johns Hopkins and Hongjun Song of the NIH, the scientists found two classes of drugs - one that hinders replication of the virus and another that prevents it from killing brain cells – has having promise in treating Zika.

They further identified that Nicolsamide, an already available drug used to fight tapeworm (and which has also shown promise against MRSA), as a potentially effective in suppressing Zika replication - it has also shown to be safe for pregnant women, an important attribute given Zika's association with severe birth defects. Another compound, emricasan, which is being evaluated by Conatus Pharmaceuticals (CNAT) for the treatment of liver disease, was found to prevent Zika from killing brain cells.

The findings were published August 29th in the journal Nature Medicine. The researchers hope that by concentrating on already commercialized drugs and compounds in late stage development that their work will result in a Zika therapy that can rapidly come to market and help to head off the escalating spread of the virus. They expect to soon begin animal testing of these drugs.

And Spotlight is involved with helping to fund the related research into development of drugs to fight Zika through a Sponsored Research Agreement (SRA) with Florida State University Research Foundation (FSURF) which commenced September 1st. Dr. Tang will lead the program. The SRA spans two years and relates to the discovery, synthetic modification, and preclinical validation of drug like compounds intended to treat patients with Zika virus infection. Per terms of the agreement, Spotlight will make payments to FSURF of $147k on September 1, 2016 and March 1, 2017.

- **Caretta Therapeutics**: Another recent product development related announcement came earlier this month when STLT revealed that they established Caretta Therapeutics which will be involved the development of products derived from snake venom for analgesic relief of moderate to severe chronic pain. Caretta entered into a licensing agreement with Dr. Paul Reid, a member of STLT's Scientific Advisory Board and President of STLT's subsidiary, Celtic Biotech. Spotlight's October 6 press release notes that Caretta intends to begin manufacturing its first products by late 2016 and to begin commercial distribution of OTC formulations in 2017.

  While STLT has yet to provide background on Caretta's development program or the related compounds, we note that Crotoxin cytotoxic phospholipase isolated from the venom of Crotalus durissus terrificus (South American rattlesnake), has shown efficacy in the reduction of both pain and tumor mass in clinical trials with cancer patients. Also, in early 2015 STLT had announced that Celtic launched EPISORB, a topical gel expected to be sold to compounding pharmacies for use as a transdermal drug delivery agent with analgesic and scar reduction creams. The company has not talked about EPISORB recently and while we have no particular insight, it is possible the Caretta product may also have some relation to EPISORB and/or its active ingredients which (per a PR in 2015) "makes use of the attributes of cardiotoxin as a cell penetrating peptide." As a reminder, EPISORB had already been registered with FDA and listed in the Pharmacy Benefit Managers database which is used by third party payors for reimbursement purposes. We have yet to model any revenue related to Caretta but will update our model if appropriate when additional information becomes available.

- **Cancer:** Meanwhile, STLT continues with its venom-based cancer programs. This includes a study, titled *Crotoxin in Patients with Advanced Cancer Using an Intravenous Route of Administration*, which 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/m2 vs. 0.21mg/m2).

  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 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/m2 to 0.32mg/m2 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." We expect to hear updates on this study in the future. As a reminder, in 2015 the company engaged ImmunoClin, Inc., a contract research organization, to manage it.

Additional progress: Spotlight made progress away from R&D as well. This includes successfully renegotiating the terms of its debt financing and further beefing up the Scientific Advisory Board. The debt renegotiating provides additional liquidity-related breathing room. Relative to the Scientific Advisory Board, STLT recently announced that Professor Hengli Tang (Zika development), Professor Elliott Androphy (SMA program) and Kevin Hodgetts SMA program) were added.

Earlier events this year include Dr. Laff joining the company in July and progress with establishment of a drug production facility

Dr. Laff, who joined Spotlight in July, is responsible for STLT's R&D strategy, evaluation of new potential acquisitions and will assist with clinical management. He brings ~20 years of experience in drug development, biotechnology, drug research and healthcare-related investment. His industry work has largely focused on oncology and immunotherapy - Spotlight's therapeutic focus area – and has involved advising large pharma including Pfizer (PFE), Bristol-Myers Squibb (BMY), Sanofi (SNY) and Boehringer Ingelheim. Dr' Laff's full bio (from STLT's July 14th press release is below).

Dr. Laff is a life sciences industry veteran with nearly 20 years of experience in healthcare venture capital, public equity investment, biotechnology, drug development, market research, and medical communications. Specializing in oncology and immunology, he has advised leading pharmaceutical companies including Pfizer, Bristol-Myers Squibb, Sanofi and Boehringer Ingelheim.

After earning a B.S. in Biology and a Ph.D. in Molecular Cell Biology from Yale University, Dr. Laff was a postdoctoral research fellow at Harvard Medical School. While at Yale he received the Sterling Prize Fellowship and the Dwight Hall Humanitarian Service Award.

Drug Production and Drug Development Facility…
In June STLT announced that it was in the process of finalizing an agreement with Maitland Labs, of Orlando, FL, to establish cGMP drug production and product development facilities at Maitland's sterile fill production plant. STLT noted that they expected construction would be completed and the facility operational by September. Spotlight will use the facility to support production requirements of its preclinical and (expected future) clinical trials of its immunotherapy candidates.

VALUATION

Given the pre-revenue stage of Spotlight, typical valuation methodologies such as P/E, P/EG, P/S and others which require financial metrics as components are unsuitable. As such, we believe the most appropriate valuation methodology is to compare STLT to other pre- (and very early) revenue stage companies focused on cancer therapeutics (we may include other disease areas in the future such as pain and orphan indications, depending on STLT's development progress). Our list below does not include any that are involved with venom-based cancer therapeutics as there are none that we were able to find which are publicly traded and solely or almost entirely focused on that area. We note that most venom-based research is housed at academic institutions, private companies or very large, multi-disciplinary publicly traded companies - none of which are appropriate comps for STLT.

So we think our comparable cohort is a fair representation of mostly pure-play oncology-related therapy companies at various stages of development. We use a comparable enterprise value (EV) by ranking the development phase of each of the companies' main product candidates. Lowest ranking (1) is associated with preclinical stage while highest ranking (4) is associated with phase 3 clinical testing stage. See our "Key" for specifics of each rating's association to their respective development phase.

Average EV and development phase rating of the 12 comparable companies is $31 million and 2.5, respectively. Which equates to $12.4 million (= $31M / 2.5) of EV for each development stage. As STLT is in the preclinical to phase I stage, we assign an EV of approximately $25 million (= 2 x $12.4M), which equates to a market value of approximately $22 million or ~ $1.50/share.

The shares are very thinly traded and have recently priced at between $0.51 and $1.20. Float is listed at approximately 56% of o/s shares. Our calculated fair value implies some upside in the most recent quoted price although the extremely low volume creates inherent risk of mispricing and potential difficulty in exiting an investment.

Company	Tkr	EV (M)	Dvlpmt Phase	Dvlpmt Ph Rating
OXIS International Inc	OXIS	$14	Phase 1	2
Cellectar Biosciences Inc	CLRB	$3	Phase 1/2	2.5
OncoVista Innovative Therapies	OVIT	$2	Phase 1/2	2.5
Del Mar Pharmaceuticals Inc	DMPI	$59	Phase 2	3
TapImmune Inc	TPIV	$42	Phase 2	3
Kyto BioPharma	KBPH	$10	Preclinical	1
Bio-Path Holdings Inc	BPTH	$99	Phase 2	3
Arno Therapeutics	ARNI	$16	Phase 1	2
ArQule	ARQL	$57	Phase 1/2	2.5
OncoSec Medical Inc	ONCS	$5	Phase 2	3
CASI Pharmaceuticals Inc	CASI	$51	Ph 1 thru 3	3
DanDrit Biotech	DDRT	$17	Phase 2	3
Average		**$31.25**		**2.54**

KEY:		
Development Phase	equates to	**Development Rating**
Preclinical		1
Phase 1		2
Phase 1/2		2.5
Phase 2		3
Phase 3		4

FINANCIAL MODEL

Spotlight Innovation, Inc.

	2014 A	Q1 A	Q2 A	Q3 A	Q4 A	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$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	$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	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$1,486.6	$649.5	$733.6	$1,799.5	$1,449.9	$4,632.5	$1,082.2	$1,238.1	$1,144.2	$1,255.2	$4,719.7	$6,160.0
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$0.0	$0.0	$3.7	$254.8	$16.4	$274.9	$0.0	$16.0	$64.0	$87.0	$167.0	$870.0
%R&D	*#DIV/0!*	-	-	-	-	-	-	-	-	-	-	-
Operating Income	($1,486.6)	($649.5)	($737.2)	($2,054.3)	($1,466.3)	($4,907.4)	($1,082.2)	($1,254.1)	($1,208.2)	($1,342.2)	($4,886.7)	($7,030.0)
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-
Total Other Income (Expense)	($2,138.6)	($311.8)	($265.8)	($150.7)	($2,451.0)	($3,179.8)	($382.5)	$111.9	($313.0)	($171.0)	($754.6)	($687.0)
Pre-Tax Income	($3,625.3)	($961.3)	($1,003.0)	($2,205.0)	($3,917.3)	($8,087.2)	($1,464.6)	($1,142.3)	($1,521.2)	($1,513.2)	($5,641.3)	($7,717.0)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$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%*	*0.0%*	*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	$0.0
Income to non-contrl interest	($1.8)	$0.2	($1.3)	($21.1)	($23.3)	($45.5)	($21.4)	($7.4)	($22.8)	($22.7)	($74.3)	($115.8)
Net Income	($3,623.5)	($961.6)	($1,001.8)	($2,183.8)	($3,894.0)	($8,041.7)	($1,443.3)	($1,134.9)	($1,498.4)	($1,490.5)	($5,567.1)	($7,601.2)
YOY Growth	*-46.8%*	*751.8%*	*-12.7%*	*184.9%*	*144.0%*	*121.9%*	*50.1%*	*13.3%*	*-31.4%*	*-61.7%*	*-30.8%*	*36.5%*
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-
EPS	($0.28)	($0.07)	($0.07)	($0.15)	($0.28)	($0.58)	($0.10)	($0.07)	($0.08)	($0.07)	($0.24)	($0.30)
YOY Growth	*-71.0%*					*108.4%*	-	-	-	-	*-58.1%*	-
Diluted Shares O/S	13,007	13,413	13,742	14,277	13,973	13,851	14,696	15,412	18,220	20,610	22,900	25,140

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