
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 20, 2018

Spotlight Innovation Inc.

(Exact name of registrant as specified in its charter)

<u>Nevada</u> (State or other jurisdiction of Incorporation)	<u>000-52542</u> (Commission File Number)	<u>98 0518266</u> (IRS Employer Identification No.)
<u>11147 Aurora Avenue, Aurora Business Park, Building 3, Urbandale, IA</u> (Address of principal executive offices)		<u>50322</u> (Zip Code)

Registrant's telephone number, including area code: (515) 274-9087

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8 K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a 12 under the Exchange Act (17 CFR 240.14a 12)
 - Pre commencement communications pursuant to Rule 14d 2(b) under the Exchange Act (17 CFR 240.14d 2(b))
 - Pre commencement communications pursuant to Rule 13e 4(c) under the Exchange Act (17 CFR 240.13e 4(c))
-

Item 8.01 Other Events.

On June 20, 2018, Spotlight Innovation Inc. issued a Company Overview that it plans to present to potential and existing investors. A copy of this Company Overview is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. The Company Overview is also posted on Spotlight Innovation Inc.'s website at <http://ir.spotlightinnovation.com/>.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

The following document is furnished as an Exhibit pursuant to Item 8.01 hereof:

[Exhibit 99.1](#) [STLT Company Overview Summer 2018.](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SPOTLIGHT INNOVATION INC.

Dated: June 20, 2018

By: /s/ John William Pim

John William Pim
Chief Financial Officer

EXHIBIT INDEX

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Exhibit STLT Company Overview Summer 2018.
99.1



Safe Harbor Statement

Statements in this document that are not purely historical are forward looking statements. Forward looking statements herein include statements regarding Spotlight Innovation's efforts to develop and commercialize its various therapies, and to achieve its stated benchmarks. Actual outcomes and actual results could differ materially from those in such forward looking statements. Factors that could cause actual results to differ materially include risks and uncertainties, such as: the inability to finance the planned development of the therapies; the inability to hire appropriate staff to develop the therapies; unforeseen technical difficulties in developing the therapies; the inability to obtain regulatory approval for human use; competitors' therapies proving to be more effective, cheaper or otherwise more preferable; or the inability to market a product. All of which could, among other things, delay or prevent product release, as well as other factors expressed from time to time in Spotlight Innovation's periodic filings with the Securities and Exchange Commission (SEC). As a result, this presentation should be read in conjunction with Spotlight Innovation's periodic filings with the SEC. The forward-looking statements contained herein are made only as of the date hereof and Spotlight Innovation undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.



Snapshot

Spotlight Innovation Inc. acquires and develops proprietary therapies to address unmet medical needs, with an emphasis on rare, emerging and neglected diseases. The Company identifies in-licensing opportunities and manages product development through partnerships with universities, medical schools, contract research organizations (CROs), and contract manufacturing organizations (CMOs).

At the appropriate stage of research and development the Company will endeavor to pursue product commercialization opportunities including, but not limited to, out-licensing and strategic partnerships with industry leaders.

MARKET DATA as of 05/21/2018

Exchange	OTCQB
Symbol	STLT
Price	\$0.04
52 Week Range	\$0.03 - \$0.42
Market Cap	\$1.37M
Average Daily Trading Volume (30 day)	~58,000
Shares Outstanding	34.3M
Float	9.6M
Inside Ownership	61.4%



OTCQB: STLT
2

Highlights

- Multiple R&D programs targeting rare, emerging and neglected diseases
- Product development via partnerships with universities, CROs, and CMOs
- First marketed product launched in August 2017
 - Venodol: non-opioid, anti-inflammatory topical analgesic for chronic pain
- Access to industry-leading companies to generate licensing and/or partnership revenues
- Experienced management team, board of directors, and scientific advisors

Selected Companies Targeting Rare Diseases

as of 06/05/2018

COMPANY	SYMBOL	IPO	MKT CAP
Alexion Pharmaceuticals	ALXN	1996	\$26.9 B
BioMarin Pharmaceutical	BMRN	1999	\$16.2 B
Bluebird Bio	BLUE	2013	\$9.4 B
AveXis	AVXS	2016	\$8.0 B
Sarepta Therapeutics	SRPT	2008	\$6.3 B
Ultragenyx Pharmaceutical	RARE	2014	\$3.8 B
Spark Therapeutics	ONCE	2015	\$2.8 B
REGENXBIO	RGNX	2015	\$1.8 B
Voyager Therapeutics	VYGR	2015	\$724.9M


Therapeutic Focus



Drug Development Process



Diverse Development Pipeline

PRODUCT	INDICATION	DESCRIPTION	STATUS	
Venodol[®]	Chronic Pain	Over-the-counter (OTC) analgesic with cobra venom as active ingredient	Marketed	
Crotoxin	Solid Tumors	Intravenous therapy with rattlesnake venom-based drug	Phase I	
Small Molecules	Zika Virus (ZIKV) Infection	Repurposed drugs	Preclinical	
STL-182	Spinal Muscular Atrophy (SMA)	Novel, orally-available small molecule	Preclinical	

Chronic Pain

Market for OTC Chronic Pain Treatments

- Chronic pain diminishes quality-of-life for approx. 25 million Americans
- OTC analgesic pain reliever sales in 2016: \$5B
- Since 1999:
 - the amount of prescription opioids sold in the U.S. nearly quadrupled
 - deaths from prescription opioids have quadrupled since 1999



Sources: <https://www.cdc.gov/drugoverdose/epidemic>, *Global Analgesics Trends Report 2017*, and IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the US 2015*

Chronic Pain: Venodol® Roll-on

Homeopathic Topical Analgesic

- Non-opioid, non-addictive, over-the-counter (no prescription needed)
 - Active ingredient: cobra venom
- Master Broker Agreement signed with premier distributor targeting supermarket, drug store, mass merchandise and warehouse chains
- Launched August 2017
 - First format – Roll-on
 - Multiple formats will be introduced
 - Available at walmart.com, amazon.com and venodol.com



Chronic Pain: Venodol Go-to-Market Strategy

- Develop distribution into supermarket, drug store, mass merchandise and warehouse chains through Master Broker Agreement in place with premier global distribution brokerage firm
- Multi-channel Marketing
 - Social Media: multi-platform campaigns targeting chronic pain sufferers
 - Advertising: online display, retargeting, social media, print
 - Video: in-aisle infomercial, YouTube channel, broadcast
 - In-store Promotion: product education, etc.
 - Spokespeople: athletes and medical professionals
- Introduce multiple formats and strengths in coming months



Selected Products Derived From Toxins

DRUGS	COMPANY	MOA	SOURCE	ANNUAL SALES
Captopril	Bristol-Myers Squibb	ACE inhibitor	Pit viper venom	N/A
Integrilin	Merck	Antiplatelet drug	Rattlesnake venom	\$200M (2015) ¹
Botox	Allergan	Antispastic drug	<i>C. botulinum</i> toxin	\$1.98B (2016) ²
Exenatide	AstraZeneca	Incretin mimetic	Gila monster venom	\$832M (2016) ³
Prialt	Jazz Pharmaceuticals	Analgesic	Cone snail toxin	\$29M (2016) ⁴



1 <https://www.comerofberkshireandfairfax.ca/fairfax/mvz/mvz-koas/mpn-to-medicals/>

2 <https://www.pmswire.com/news-releases/allergan-reports-strong-2016-finish-with-7-percent-increase-in-gmp-net-revenues-to-35-billion-in-fourth-quarter-2016-306433996.html>

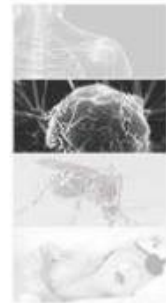
3 <https://www.pharmacompass.com/sales-force/exenatide>

4 <https://www.enr.com/news/us/money/companies/jazz-pharmaceuticals-plc-jazz-q4-2016-results-earnings-call-transcript/4-24-16-2746>

Solid Tumors

Unmet Need for Cancer Treatments

- Globally, cancer is the second leading cause of death (nearly 1 in 6 deaths)
- In the U.S., approximately 1.7 million new cancer cases are expected to be diagnosed in 2018
- More than 15 million Americans with a history of cancer were alive on January 1, 2016

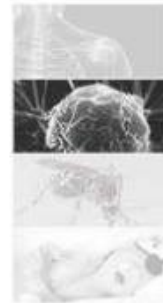


Sources: WHO and American Cancer Society

Solid Tumors: Crotoxin

Dose escalation safety study in patients with metastatic solid tumors: *Crotoxin in Patients with Advanced Cancer using an Intravenous Route of Administration*

- Phase I Cohort 1 and Cohort 2 completed
 - Results reported at the American Association for Cancer Research (AACR) Annual Meeting, April 16, 2018
 - Evaluation of antitumor response under Phase I Cohort 2 showed that two of the six subjects had stable disease on Day 36
- Phase I Cohort 3, incorporating faster and higher dosing regimes than Cohort 2, has been approved by the French National Agency for Medicines and Health Products Safety (ANSM)



ZIKV Infection

Unmet Need for ZIKV Treatments

- No FDA approved therapies exist
- ZIKV can be passed from a pregnant woman to her fetus, which can cause neurological birth defects (including microcephaly), and may cause rare but serious complications in healthy adults



Image Credit: Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities

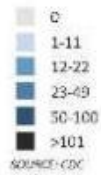


ZIKV Infection in the United States

Cumulative Zika Virus Disease Case Counts, Jan. 2015 – Sept. 2017

- 5,400+ symptomatic disease cases in U.S. States
- 37,000+ symptomatic disease cases in U.S. Territories

Laboratory-confirmed Symptomatic ZIKV Cases Reported in 2017



(provisional data
as of Feb. 2018)



ZIKV Infection: Small Molecules

- Multiple candidate drugs in preclinical studies at Florida State University (FSU)
 - Company-sponsored research directed by Prof. Hengli Tang aimed at developing safe and effective drugs to treat patients infected with ZIKV

Professor Hengli Tang, Dept. of Biological Science, FSU



Photo: Courtesy Florida State University

- In March 2016, Prof. Tang co-authored a study published in the journal *Cell Stem Cell* that demonstrated for the first time the ability of ZIKV to target human embryonic cortical neural progenitor cells
- In August 2016, Prof. Tang co-authored a paper published in *Nature Medicine* that reported two classes of compounds: one that protects ZIKV-infected neural cells from programmed death, and another that directly inhibits ZIKV replication



SMA

Overview

- Autosomal recessive motor neuron disease carried by 1 in 40, to 1 in 50 adults
- Leading genetic cause of death in infants and toddlers
- 1 in 6,000, to 1 in 10,000 newborns are affected
- 60% of patients progressively lose muscle control and die by age two
- Multiple treatment strategies, including combination therapies, are feasible



SMA: STL-182 and additional compounds

March 2018

- Newly Issued U.S. Patent Covers Spotlight Innovation's Spinal Muscular Atrophy Drug Candidates

August 2017

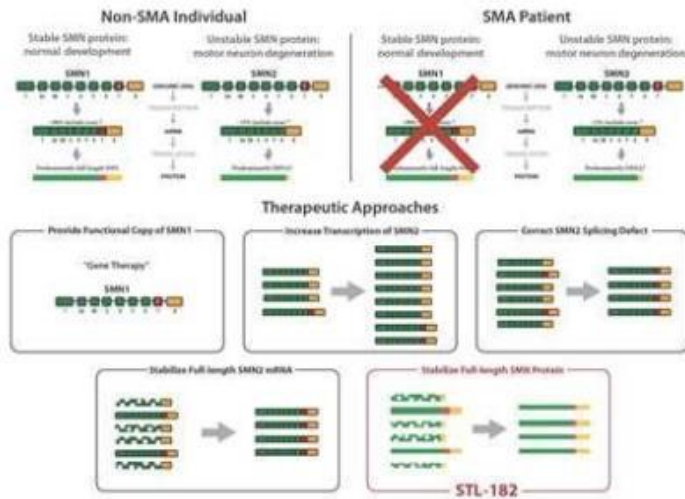
- Sponsored Research Agreement with Indiana University to support research directed by Elliot Androphy, M.D.

June 2017

- Sponsored Research Agreement with Brigham and Women's Hospital to support research directed by Kevin Hodgetts, Ph.D.



STL-182, an Orally-available Small Molecule that Stabilizes SMN Protein



SMA: Competitive Landscape

SPONSOR(S)	DRUG	ROA	MOA	STATUS
Biogen/Ionis	SPINRAZA	Intrathecal	SMN2 splicing modifier	Marketed
Roche/PTC	RG-7916	Oral	SMN2 splicing modifier	Phase 2
Astellas/Cytokinetics	CK-107	Oral	Skeletal muscle troponin activator	Phase 2
Novartis	LMI-070	Oral	SMN2 splicing modifier	Phase 1/2
AveXis	AVXS-101	Intravenous	Gene therapy	Phase 1/2
Spotlight Innovation	STL-182	Oral	SMN protein stabilizer	Preclinical



SMA: Benefits Of Recent Advances In Therapy

FDA approval and commercial launch of SPINRAZA™ should:

- Validate commercial viability of SMA
- Increase public awareness of SMA
- Establish protocols for insurance coverage
- Justify routine newborn genetic screening
 - Identification of subjects for future clinical trial recruitment
 - Identification of patients for early therapeutic intervention
- Clarify regulatory pathway for approval of additional products



Key Milestones Over Next 12 Months

- Venodol Roll-on into mass merchandise retailers
- Additional product formats for Venodol brand
- Begin Phase 1 Cohort 3 of Crotoxin solid tumor study
- Continue pre-clinical testing of ZIKV drug candidates
- Continue pre-clinical testing of STL-182 and related SMA drug candidates

Corporate Leadership



John M. Krohn
*Chief Executive Officer,
President and Chief
Operating Officer*

- 20+ years as financial services executive and entrepreneur
- 10+ years public accounting and CFO experience



**John William
"Bill" Pim, CPA**
Chief Financial Officer

- 30+ years financial and business development experience
- Auditing, financial reporting, SEC compliance, risk management and M&A activity
- Senior level financial positions with numerous companies



Scientific Leadership



Chitra Edwin, Ph.D. RAC
SVP Regulatory / Compliance

- 20+ years in regulatory affairs and compliance
- 7 years Harvard Medical School as research fellow and instructor
- Regulatory approvals in infectious disease, oncology and cardiology
- Ph.D. in Microbiology and Immunology, U. of Minnesota



Geoffrey Laff, Ph.D.
SVP Business Development

- 20+ years in venture capital, competitive intelligence, market research, and business development
- Ph.D. in Molecular Cell Biology, Yale University
- Postdoctoral research scientist, Harvard Medical School



Paul Reid, Ph.D.
President
Celtic Biotech Iowa, Inc.

- 20+ years in clinical study of neuroactive components from rattlesnake and cobra venoms
- Ph.D. in Neurobiochemistry, Imperial College, England

Scientific Advisory Board

Elliot Androphy, M.D.

Indiana University

- Chair of the Department of Dermatology, Indiana University
- Postdoctoral fellowship in virology at the Laboratory of Cellular Oncology of the National Cancer Institute/ National Institutes of Health

Kevin Hodgetts, Ph.D.

Brigham and Women's Hospital

- Head of Medicinal Chemistry and Director of the Laboratory for Drug Discovery in Neurodegeneration *Harvard Medical School*
- Assistant Professor of Neurology

Hengli Tang, Ph.D.

Florida State University

- Faculty Member at Florida State University's Department of Biological Science

Board of Directors

John M. Krohn

Chairman of the Board

Craig A. Lang | *Director*

- President of The Prairie Strategy Group and of Windward Iowa
- Past Chairman of FBL Financial and Pres. of the Iowa Farm Bureau Federation

Sanjeev Agarwal, Ph.D. | *Director*

- President of Technochem International, Inc.
- Ph.D. in Business from Ohio State U.

Ralph Arthur | *Director*

- 40+ years experience in logistics and transportation

June Beetler, D.O. | *Director*

- Board Certified in Pediatrics
- Expertise spans general pediatrics, integrative medicine and holistic care

Key Takeaways

- Multiple R&D programs targeting rare, emerging and neglected diseases
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- Experienced management team, board of directors, and scientific advisors

Contact

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