Light-Assisted Medical Needle Guidance
PLATFORM TECHNOLOGY
$1.5M Raise

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The Technology:

Light-assisted needle guidance systems
• The device operates based on the changes in reflected light from different tissue types encountered at the tip of the needle. Provides real-time visual assistance

Multiple high-value commercial uses
• Epidural needle guidance, Orthopedic pedicle screw placement and joint access, Urology catheter introduction, Vascular access, Cardiac catheter introduction, Ophthalmic treatments, Veterinary use

Epidural needle guidance - First product
• Assist physicians with needle placement during epidural procedures for childbirth, spine/back pain therapies, and surgical procedures such as knee and hip replacements
Epidural procedures are done by hand—touch and feel. Known as “Loss of Resistance” (LOR)

- When the needle penetrates the ligament and enters the epidural space there is a loss of resistance (LOR)
- Performed by hand (LOR) for almost 100 years
- About 50 – 100 training procedures (patients) for new clinicians to be certified
- Higher complication rates for new clinicians
- Most people know someone who has had complications from an epidural
BRIGHTPOINT™ NEEDLE GUIDANCE

• A pair of sterile, disposable fiber optics inserted into needle
• Fiber optics connected to electronic controller
• Controller sends pulsed light down one fiber optic
• Receiving fiber returns reflected light from tissue at tip of the needle to be interpreted by controller
• The color of the tissue and relative reflectance is displayed on the controller screen.
• Allows the clinician to “see” the color of the tissue at the tip of the needle and track training procedures in real time
• Distinct change from white of the ligament to dark or black upon entering epidural space
Epidural Product: BrightPoint™

- 12 million epidurals performed in the US each year and 30 million worldwide
- Go-to-market strategy targeting 1200 teaching hospitals in US (~20% of the ~5,500 hospitals)
- International sales begin in year two.
- Sales forecasts listed below are for BrightPoint™ only. (Additional platform product sales not included).

**Market Sales Estimates:**

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Market Share</td>
<td>1.5%</td>
<td>5.0%</td>
<td>10.0%</td>
<td>20.0%</td>
<td>30.0%</td>
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<tr>
<td>Controller Revenue</td>
<td>$491K</td>
<td>$1.49M</td>
<td>$2.84M</td>
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<tr>
<td>Disposable Revenue</td>
<td>$1.73M</td>
<td>$6.64M</td>
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<td>Total Revenue</td>
<td>$2.22M</td>
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<td>$34.69M</td>
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<td>EBITDA</td>
<td>-$1.34M</td>
<td>$772K</td>
<td>$3.76M</td>
<td>$10.06M</td>
<td>$17.16M</td>
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</table>
Frank Lyman, President & CEO

Frank is a medical device professional who has over 25 years’ experience with both large companies and start-up ventures.
- He has taken over 50 medical devices through the FDA 510(k) process.
- Frank has raised over $15M in investments for multiple companies from private investors and large corporate partners.
- Frank started Source Tech Medical a manufacturer of radioactive seed implants to treat prostate cancer and sold the company to Bard Medical (in 5yrs) for $39M providing investors a multiple ROI.

Frank earned his bachelor degree in microbiology from Michigan State University and his MBA from the Kellogg Graduate School of Management at Northwestern University.

Don Verlee Chief Scientific Officer

Don is an Inventor, and Biochemical engineer with 26 years in research & development with Abbott Laboratories. Don is an expert in multiple medical device engineering disciplines.
- At Abbott Laboratories, Don developed products for both the Diagnostics Division, and Hospital Products (Hospira).
- Don has over 30+ patents, many of them covering products that are currently on the market, including FactPlus™ lateral flow immunoassay pregnancy tests, Aluer® Vial needleless access drug vials, and XIENCE® the world's leading drug-eluting stent (DES). Don has been a senior executive for two different medical device start-up companies before joining Lumoptik.

Don earned his Bachelor of Science degree in Biochemical Engineering from the University of Michigan and his MBA from Lake Forest Graduate School of Management.
What physicians want:
• Product must use same needles & accessories
• Product must not interfere with the current LOR method
• Should be cost effective – reduces capital cost and reimbursement issues

• Must be easy to use:
  — Stay focused on the needle in the patient’s back
  — Not open to operating complex equipment
• Should reduce the time required to train new people
  — Typically takes 50-100 training procedures (patients) to be trained
• Should reduce complications/risk (wet taps, etc.)
Sterile, single-use disposable component
- Contains optical fibers that fit in a standard Tuohy epidural needle
- Sends and receives light through a needle
  - Works with LOR method - it actually requires LOR with saline
  - Uses existing needles and accessories (Drs. can use their current procedure)
- Communicates with reusable Controller through fiber optic connection

Reusable Controller composed of screen, electronic hardware and operating software - similar in size to a large smartphone
- Displays graphic and color information of tissue at tip of the needle
  - All visual, no sounds to concern the patient
- 2 year warranty - thousands of procedures
Reduces training time for new clinicians

• Useful to reduce epidural complications from training new practitioners
  — At $18 per procedure compare this to reducing the number of “practice” procedures (patients) from the current 50 – 100
  — Training requires 2 physicians, BrightPoint™ will reduce that cost considerably

Reduce risk/cost to hospitals & physicians

• At $15 per Lumoptik disposable plus $900 for controller
  — The average cost (per practitioner) is $4,350/yr
• The cost of a single prevented wet-tap hospital stay is approximately $32,000 or higher. (two-day hospital stay for a wet tap spinal migraine)
• The cost of a single lawsuit can be even greater.
There are no other light-based needle guidance products

**Rivanna Accuro**
- Handheld ultrasound needle guidance system
  - Does not provide real time guidance
  - Much higher cost ($14,500 vs $900 for BrightPoint™)
- Start-up company with recent FDA clearance

**Compuflo Epidural by Milestone Scientific**
- Pressure sensor
- Replaces LOR; therefore physician adoption has been slow
- Much Higher Cost ($25,000.00 vs $900 for BrightPoint™)
- On the market since mid 2017 - low physician adoption and sales
BRIGHTPOINT™ Revenue Model

Razor - Razor Blade Commercial Design

- $900 for electronic controller
  - Feasible to have multiple units in a medical practice
- $18 for disposable per procedure
  - ~60% gross margin
  - Disposable drives profitability
- Patent and trademark protected
  US Patent filed October 2018 (#Ref: 06089.002US1)
  Trademark Application filed in April 2019 (# 88348345)
• FDA Pre-submission completed December 2018
• FDA face-to-face meeting held in mid-February
  • FDA agrees our device is not high risk and can move forward with the DeNovo 510(k) process
  • Verbal understanding reached with FDA that our device has benefit as a training tool for new anesthesiologists as a pathway to market clearance.
• FDA Conference call May 14, 2019 states the proposed clinical plan “reasonable”
  • FDA human trial ~60 days at University Hospital, Cleveland OH
  • Not a significant risk device; no IDE required; only IRB/ *not restricted to training
Use of Funds. Path to FDA Marketing Clearance

Current round of funding ($1.5M) sufficient to reach FDA 510(k) filing
- Estimate is February/March 2019 to file 510(k)
- FDA review time of about 5 - 7 months
- Live animal trials completed
- Human trial begins January 2019 (~2 months)
- **Commercial product launch estimate 3rd quarter 2020**

Next Funding ~$4.5M (late 2019)
- Expected to be sufficient to reach cash flow positive revenue.
- Establish physical location & company infrastructure
- Hire staff—operations & sales
- Inventory scale-up

~$1.5M (of the $4M) to build infrastructure
~$3M (of the $4M) to fund operations.
Forecast cash flow positive in 2nd year of sales
## Forward valuation at the end of sales Years 3 and 5

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<tr>
<th>Year 5</th>
<th>Revenue</th>
<th>$54,241,950</th>
<th>EBITDA</th>
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<td>Ave Valuation</td>
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<table>
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<tr>
<th>Year 3</th>
<th>Revenue</th>
<th>$17,281,950</th>
<th>EBITDA</th>
<th>$3,760,196</th>
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<tr>
<td>Revenue Multiple</td>
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$1.5 MILLION INTERIM ROUND

• Convertible Note
• Pre-money valuation of $6.7 million (22% of the company)
• 8% interest rate
• Warrants equal to 40% of the amount invested at a pre-money valuation of $13.4 Million. The warrants have a four-year expiration.
• Management forecasts this round will be sufficient to take us through the FDA submission process

$4.5 Million Institutional round early 2020

• Valuation cap over $10 million is forecasted
• After clinical trial and FDA submission
• Forecasted to propel the company through commercial launch and cash-flow positive revenue
Potential Strategic Acquirers - Distribution Partners

- Becton Dickinson (BD)
  - Acquired Bard Medical
- Medline
- Halyard Health
- B Braun
- Smith Medical
- Integra Life Sciences
Visual guidance for placing Pedicle Screws during spinal surgery

- Over 1.5M procedures annually in US market
- Disposable + incursion tool + electronic controller
- Already conducted Proof-of-Concept live animal study (pig) with an orthopedic surgeon

Suprapubic catheter introduction

Insertion of a urinary catheter through the body wall to reach the bladder (Instead of through the urethra) for chronically catheterized patients

- Urology procedure that is currently performed blindly, using touch and feel
- Problems with catheter placement
- Popular urology procedure for chronically catheterized patients
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• Low investment valuation—estimated exit over $100M
• Large world-wide market
• Addresses a long-standing problem
• Works with LOR standard of care
• No current competitors
• Easy to use
• Low cost
• Developed according to anesthesiologist input
• Experienced management “We have done this before”
• Already conducted Proof-of-Concept test for next platform product