

A Breakthrough For Chronic Pelvic Pain

Endometriosis,
IC, & More

SOLá THERAPY

UroShape, LLC
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Investment Highlights



- ✓ Fills unmet need in women's health care (multi-billion-dollar pelvic pain market)
- ✓ SoLá Therapy is the only on-label treatment option for 85% of women with Chronic Pelvic Pain (CPP)
- ✓ Commercialization began Q4 2019. Over 2,000 procedures have been performed
- ✓ Real-time data collection by device (Big Data) demonstrates superiority to standard of care
- ✓ Pathway to reimbursement begun. Reimbursement anticipated 2022-2023
- ✓ Transition cash-pay business with revenues that almost doubled from first half to second half of 2020.
- ✓ Platform technology
- ✓ Strong patent portfolio

The Chronic Pelvic Pain Market

1 in 10 women suffer from chronic pelvic pain.¹

Symptoms: pelvic pain with sitting, intercourse, bowel movements, exercise, urination, bladder pain, vaginal burning, pressure, and vulvar pain

Diagnoses: Interstitial Cystitis, Endometriosis, Dyspareunia, Vaginismus, Recurrent UTIs, Pelvic Congestion, Pudendal Neuralgia, Adhesions

Regardless of diagnosis, current treatments fail >50% of the time.

85% of women with CPP suffer from painful pelvic muscle spasms.⁷⁻¹⁰

SoLá Therapy effectively reduces pelvic pain associated with painful muscle spasms.



SoLá Therapy helps >80% of treated women attain rapid relief.

10 million women in the U.S. suffer from CPP and muscle spasms.

Dismal Malady for Women SoLution

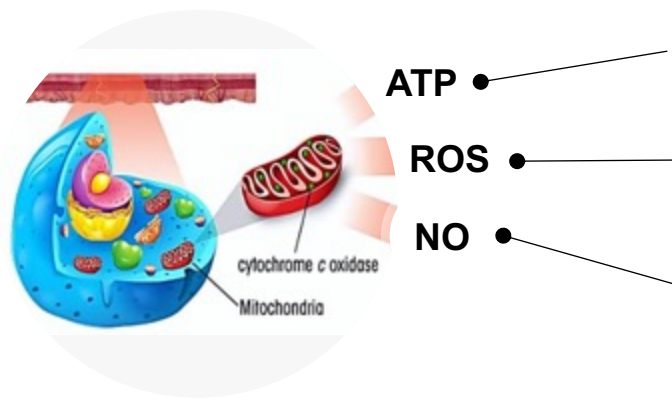
Photobiomodulation (PBM) is the Mechanism of Action (MOA)

SoLá
THERAPY

The SoLá Therapy Near IR laser imparts PBM and manual therapy through a single-use disposable wand.

- ✓ Used for more than 20 years in the treatment of muscle pain and spasms.
- ✓ Thousands of published studies validating MOA and effectiveness.
- ✓ More than one million treatments are performed each month.³³
- ✓ SoLá Therapy is the first and only method for administering PBM into the pelvis.

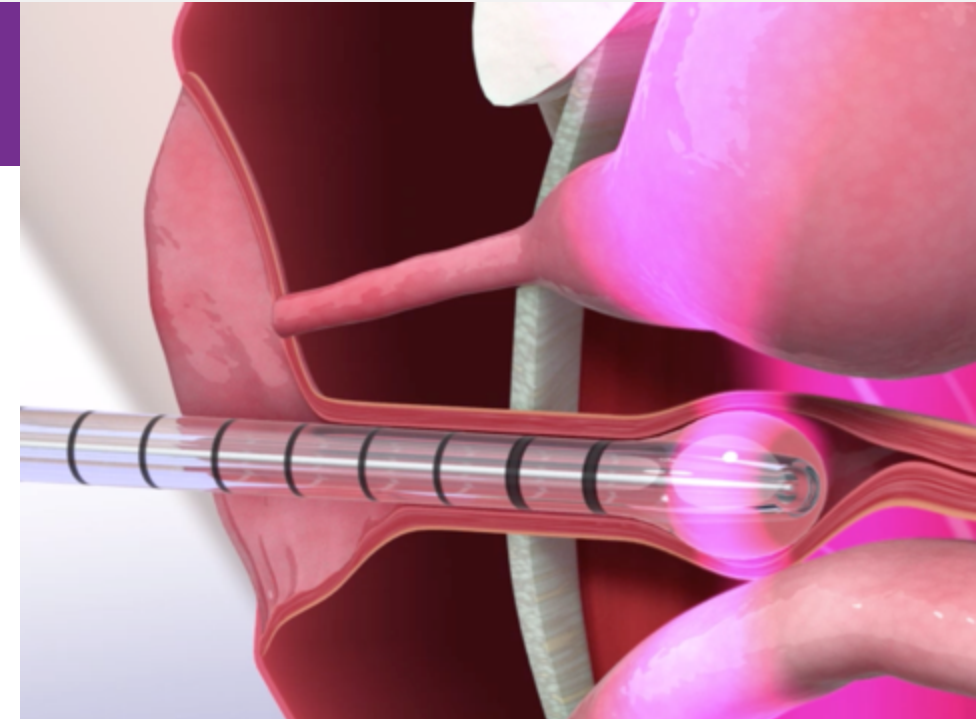
The proprietary orb of soothing near-infrared energy delivered by the SoLá Therapy Laser delivers therapeutic energy dosing to the mitochondria of the pelvic tissues.



An increase in ATP, the main energy source for the majority of cellular functions, increases the cell's ability to fight infection, and it accelerates the healing process

The modulation of ROS activates transcription factors, positively impacting cellular repair and healing

The release of nitric oxide (NO), a potent vasodilator, increases circulation, decreases inflammation, and enhances the transport of oxygen and immune cells throughout the tissue



▶ Play: How it works animation

3

Treatments

3

Minutes

3

Weeks

The SoLá Therapy Laser Collects Real World Data

Every Patient & Every Treatment

SoLá
THERAPY



The SoLá Laser Touch Screen collects data on every treatment to every patient and transmits a HIPAA-compliant coded data set to our server

- Real-time review of progress with patient
- Secondary analysis provides real world evidence on a provider, regional, and national level

More than 2,000
procedures
performed

>80% of women improved
>80% still improved at 6 months
50% reduced to minimal or no pain

SoLá Therapy adopted an evidence generation program that combines clinical trials with real world data collection. This provides evidence that applies beyond the ideal conditions found in clinical trials.

More Than Pelvic Pain

SoLá patients continue to describe improvement in multiple symptoms.

These symptoms represent over one billion dollars in annually recurring revenue opportunity from ancillary markets.



Overactive
Bladder (OAB)



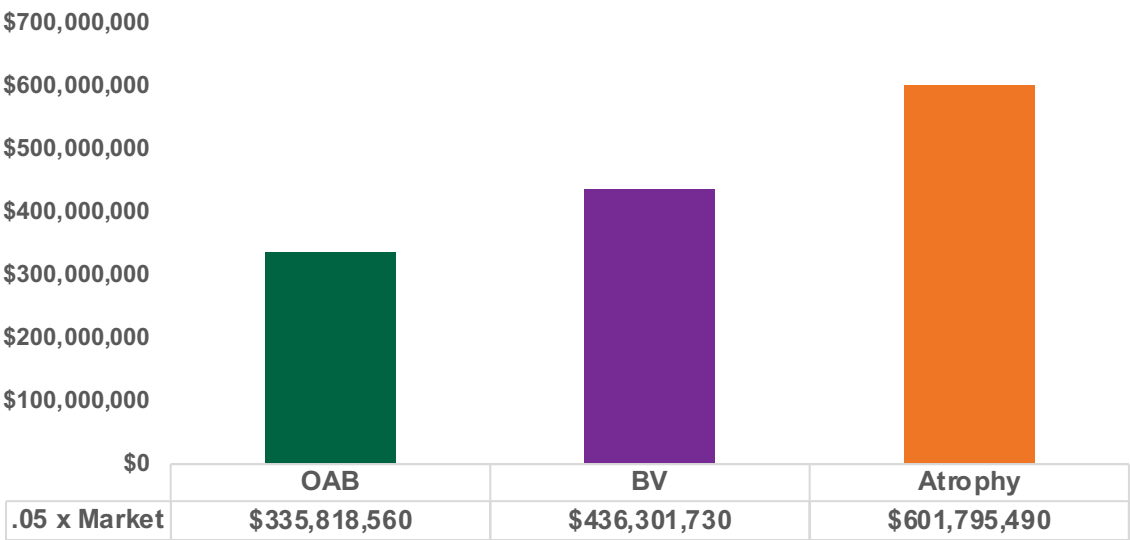
Bacterial
Vaginosis (BV)



Vaginal
Atrophy
(Atrophy)

The proprietary SoLá Therapy user interface is ideal for capturing this data.

Potential Annual Rev at 0.5% of Market



The SoLá Therapy Laser Is Marketed On-label*



The SoLá Therapy Product Code is ILY: The LTS-1500 (SoLá Laser) device emits energy in the near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a **temporary relief of minor muscle** and joint **pain and stiffness**, minor arthritis pain, or **muscle spasms**; the **temporary increase in local blood circulation**; and the **temporary relaxation of muscle**.

Food and Drug Administration [Docket No. FDA-2017-N-1129]
Medical Devices; Exemptions From Premarket Notification: Class II Devices

In 2017 The Food and Drug Administration (FDA or Agency) announced a list of class II devices that the Agency had determined no longer required premarket notification to provide reasonable assurance of safety and effectiveness.” The ILY category of devices became exempt from the premarket notification process.

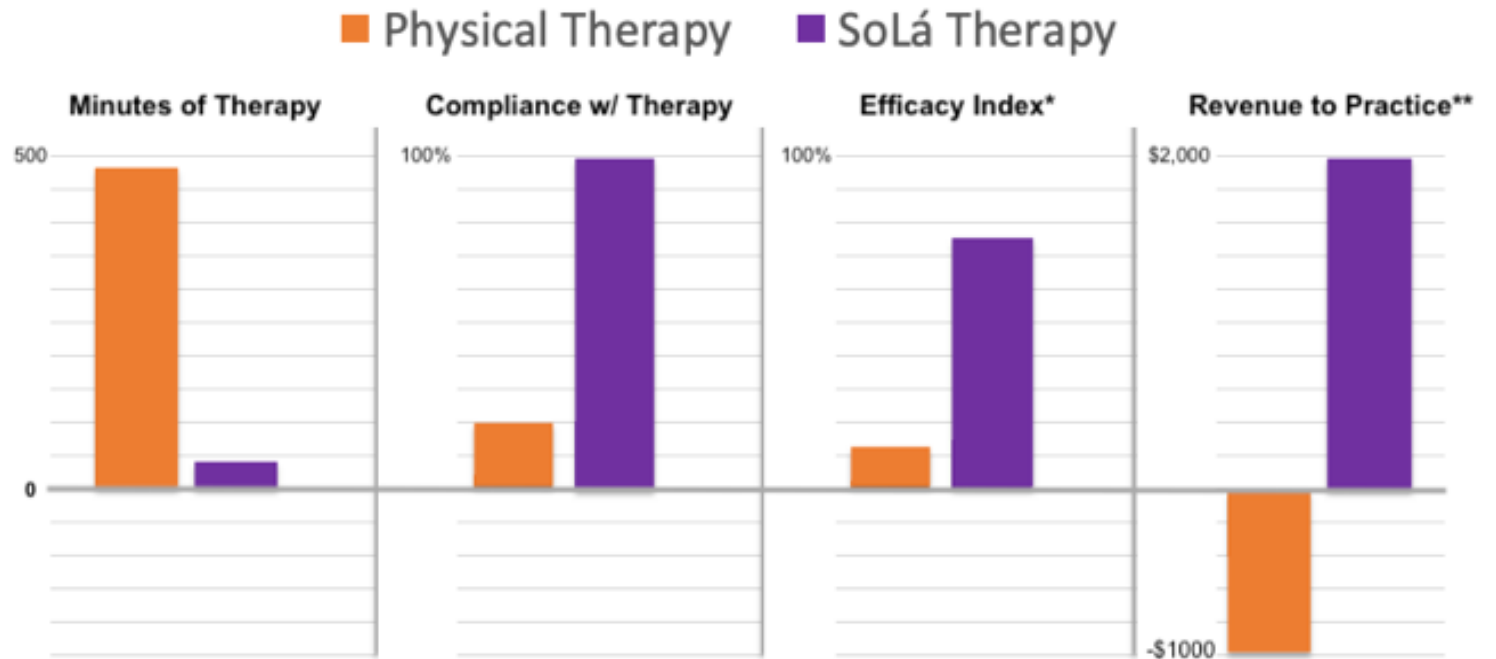
***Whereas many energy devices are illegally marketed for treatment not cleared or allowed by the FDA (aka “off-label marketing), SoLá Therapy is marketed legally (on-label).**

Market Condition and Competitive Challenges

The standard of care in the treatment of chronic pelvic pain is transvaginal pelvic floor physical therapy. Sadly, it has provided very disappointing results.

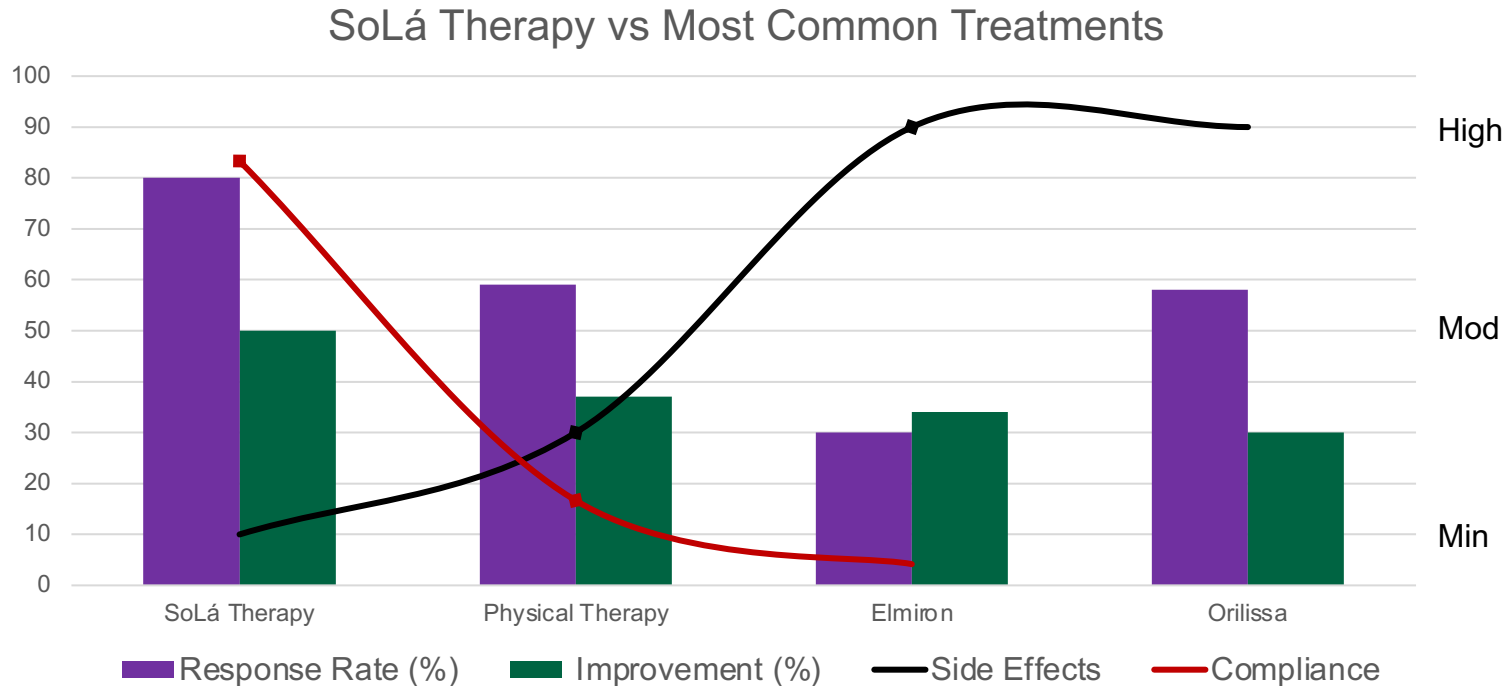
A recent pilot study of physical therapy in women with pelvic pain and hypertonic pelvic floor dysfunction found only a 35% reduction in pain.¹⁸ An earlier randomized control trial that found a similar 36% reduction of pain in 56% of women undergoing physical therapy.¹⁹

Compounding the poor effectiveness, a 2019 report reviewing over 600 referrals to pelvic floor physical therapy for hypertonic pelvic floor dysfunction found compliance to be only 20%.¹³ Only 40% of patients returned to their referring gynecologist.



*Efficacy Index= Fraction of patients improved x compliance

SoLá Therapy vs. Most Common Treatments



- 10M U.S. women suffer from CPP
- Present treatments represent < 1% of CPP market, yet > \$100M in immediately addressable revenue
 - 120,000 PT
 - 25,000 Elmiron
 - 35,000 Orilissa
- Elmiron and Orilissa WAC ≥ \$10,000 per year per patient
- PT referral associated with MD revenue loss and only 20% compliance¹³
- Effective dose of Orilissa limited to maximum 6-month Rx

Treatment	Response Rate (%)	Improvement (%)	Treatment Time	Duration of Response	Compliance Rate	Treatment Limit	Side Effects
SoLá Therapy	80	50	27 Minutes	6 Months	95%	None	Min
Physical Therapy	59	37	10 Hours	3 Months?	20%	None	Min-Mod
Elmiron	30	34	365 Days	6 Months?	5%	Yes	High
Orilissa	58	30	365 Days	6 Months	?	Yes	High

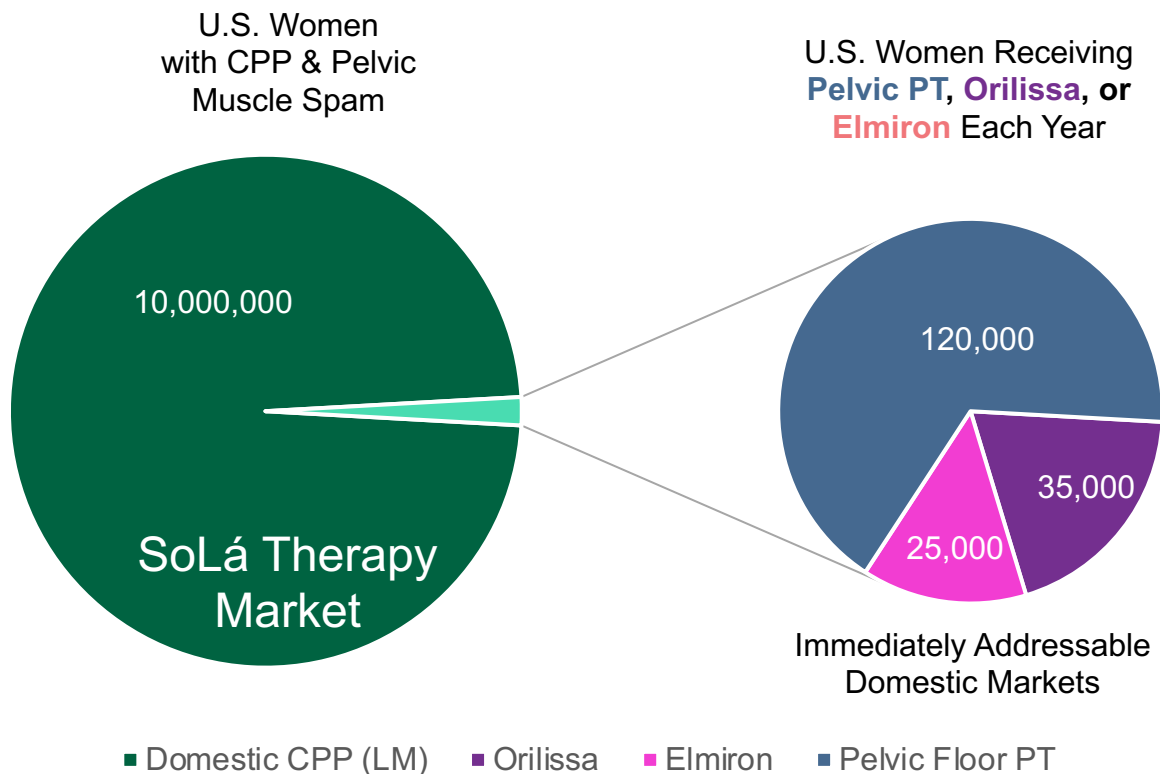
Protected Intellectual Property

Publication Number	Legal Status	App Date	Issue Date	Expiry Date
US8795264	Granted	2009-07-01	2014-08-05	2032-01-25
US8574177	Granted	2011-03-09	2013-11-05	2031-12-27
US10743929	Granted	2010-01-15	2020-08-18	2032-01-25
US8882685	Granted	2008-05-27	2014-11-11	2031-12-30
US8968221	Granted	2008-04-16	2015-03-03	2031-05-17
US9358403	Granted	2014-11-10	2016-06-07	2028-05-27
US9649506	Granted	2016-06-06	2017-05-16	2028-05-27
US10238889	Granted	2015-03-02	2019-03-26	2030-05-29
CN101687100	Granted	2008-04-17	2013-07-13	2028-04-17
US20170172658A1	Examining	2017-03-08	-	TBD
WO2018164676A1	N/A	2017-03-08	-	NA
EP3592423A1	Published	2017-03-08	-	TBD
CN109069857A	Examining	2017-03-08	-	TBD
US20190125448A1	Examining	2018-10-25	-	TBD
62939080 EFID 37831762	Provisional	2019-11-22	-	TBD

Claims are prohibitive to any entity that would seek to commercialize a transvaginal or transrectal photobiomodulation device

Immediately Addressable Domestic Markets

10 million U.S. women who suffer from CPP with muscle spasms.



Endometriosis Addressable Market²⁸ (6-10% of reproductive age women)

- 35,000 new patients treated with Orilissa in its first year of commercialization (2018-2019).
- Sixteen percent of SoLá patients to date carry an endometriosis diagnosis

Interstitial Cystitis Addressable Market²⁹ (3% of women)

- 25,000 new patients treated with Elmiron annually
- Sixty percent of SoLá patients to date carry an IC diagnosis

Pelvic Floor Physical Therapy³⁴

- 120,000 PT referrals for the treatment of chronic pelvic pain each year
- Fifty-four percent of SoLá patients have been treated with PT

Immediately Addressable Domestic Market

- **180,000 patients equates to \$180M in SoLá Therapy top line revenue**

Each treated patient represents \$1,000 in SoLá Therapy top line revenue.

A Business Plan That Mitigates Risk & Maximizes Reward

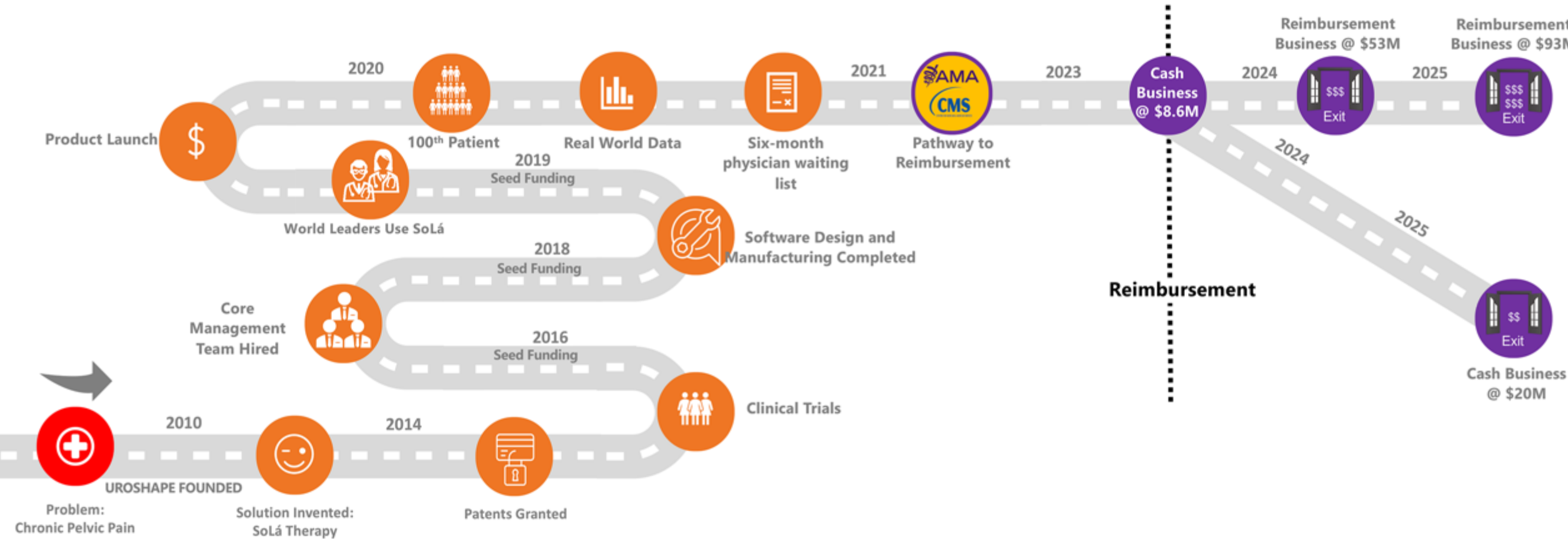
CPP: a multi-billion-dollar problem in search of a solution



SoLá Therapy has been successfully commercialized as a cash-pay procedure with clinical validation and is generating annually recurring revenue.

SoLá Therapy is now on a pathway to reimbursement.

Milestones

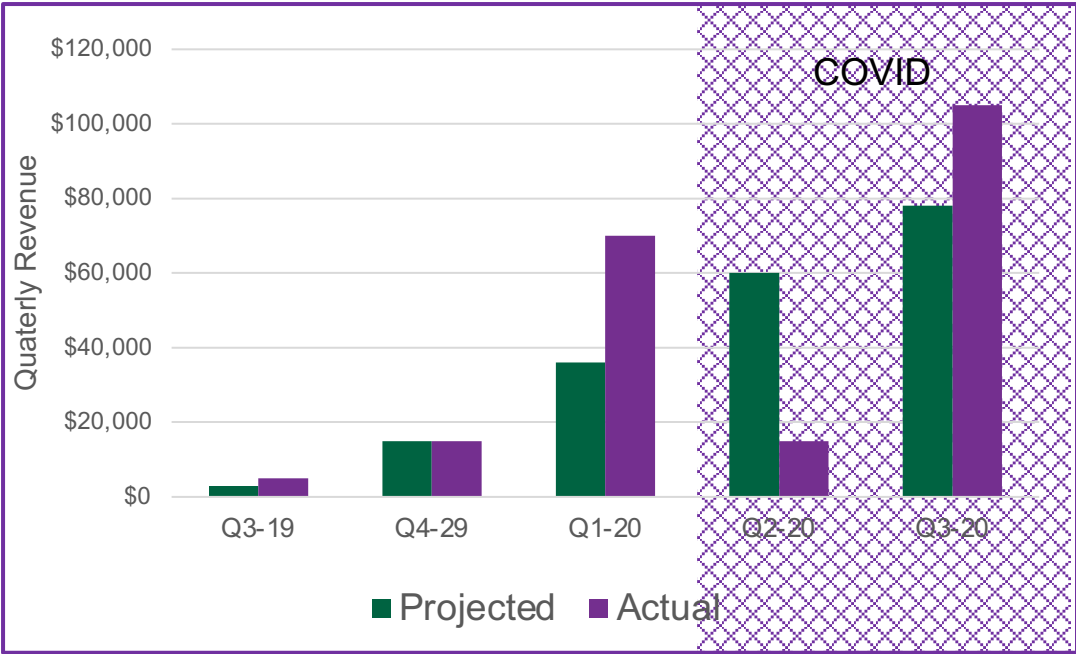


Cash Business Revenue Details



Single Sales Representative Performance

	Q3-19	Q4-19	Q1-20	Q2-20	Q3-20
Marketing Strategy	Initial Launch (MAB)	Limited Launch (MAB)	Launch	COVID	COVID
Sales Output					
Active Providers	6	7	9	5	7
Free Trial Patients	37	3	4	0	0
Paying Patients	5	18	31	28	40
Total Patients Treated	42	21	35	28	40
Patient Treatments-Total	378	286	389	295	360
Patients per provider per month	2.3	1.5	1.3	1.9	2.0
Revenue	\$5,000	\$15,000	\$70,000	\$15,000	\$105,000



Cash Business Model

Patient Pays \$699 to Provider

Provider Profitable on Patient #1

- Provider signs no risk, no cash outlay, 3-year laser subscription agreement @ \$700 per month (\$25,200 Total)
- Provider collects \$699 from patient for treatment series
- Provider nets approx. \$499 per patient treatment series
- Provider Wand inventory autonomously managed by the SoLá Laser user interface

UroShape Has No Accounts Receivable

- ✓ \$25,200 Subscription Value paid to UroShape by way of provider secured financing
- ✓ \$200 Wand Kit fee charged to provider's credit card by laser for each 3 wands used (treatment series).
- ✓ Big data is collected as patients respond to medical questionnaires on the laser's touch-screen at the time of every treatment (Data sent via WiFi to SoLá server).

Reimbursement Business Model

Insurance Pays Provider \$699

Provider Profitable on Patient #1

- Provider signs no risk, no cash outlay, 3-year subscription agreement
- Insurance pay providers \$699 from patient for treatment series
- Provider nets approx. \$499 per patient treatment series
- Provider Wand inventory autonomously managed by the SoLá Laser user interface

UroShape Has No Accounts Receivable

- ✓ \$25,200 Subscription Value paid to UroShape by way of provider secured financing
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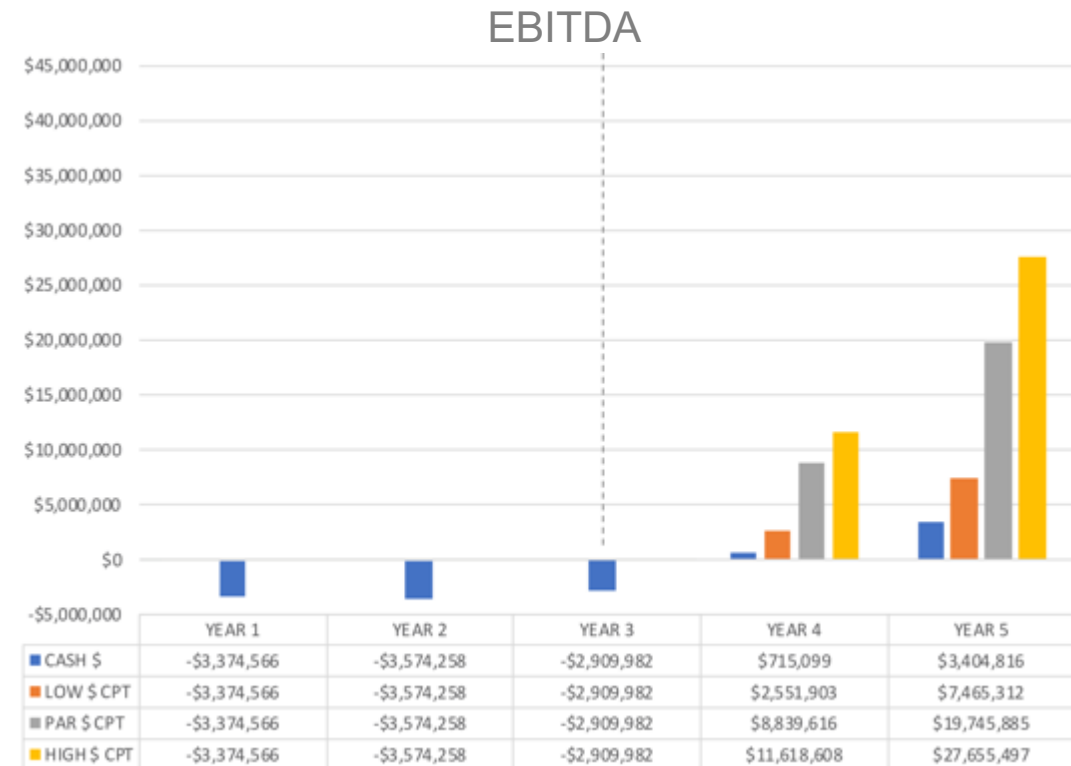
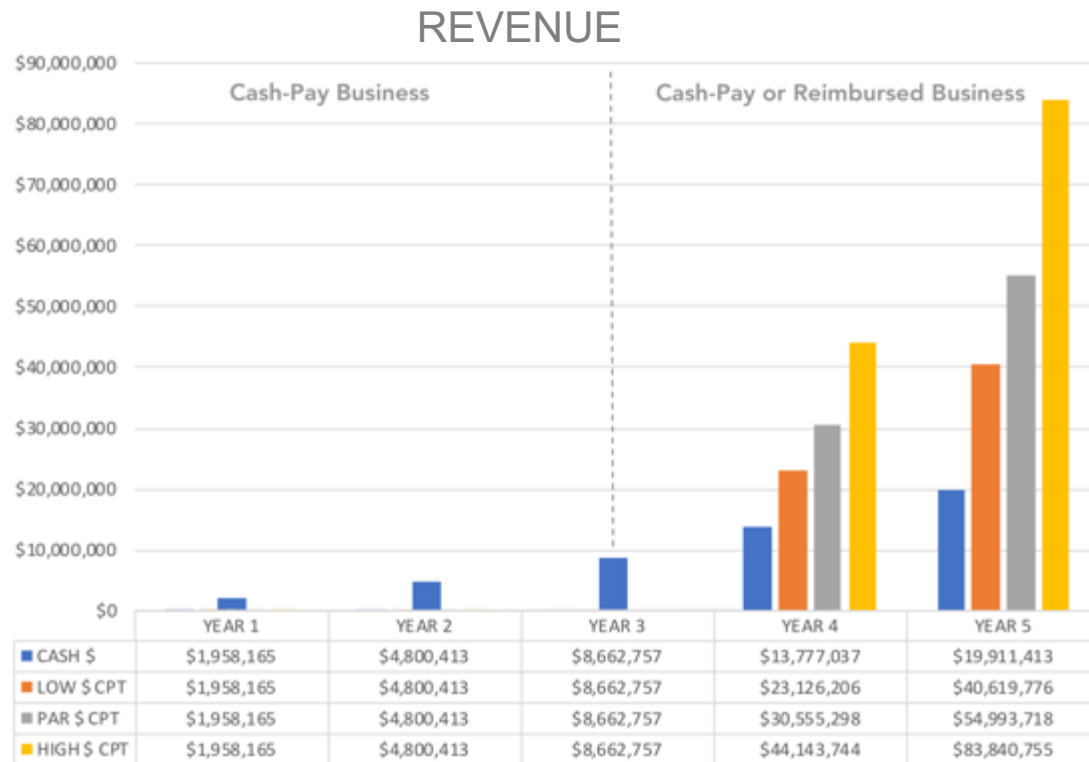
Pathway to Reimbursement

Activity	2020	2021	2022	2023
Build specialty society support and regular engagement				
Establish and operate Patient Access Program (PAP) for reimbursement support providers for Cat III/Unlisted CPT code and long-term coverage strategy				
Develop and execute evidence generation and publication plan with input from payers, (includes economic and clinical data)				
Develop clinical and economic value proposition and positioning with input from key stakeholders- payers, providers, Medicare consultancy				
Establish and operate Patient Access Program (PAP) for reimbursement support providers for Cat III/Unlisted CPT code and long-term coverage strategy				
Engage with Commercial Payers to establish coverage as additional evidence is generated				
Submit CPT coding application for physician Category III procedure code				
Submit application for CPT Category III conversion to Category I (assuming all criteria is met: evidence, market penetration, society support)				

NO ACTIVITY	
LOW ACTIVITY	
MODERATE ACTIVITY	
FULL ACTIVITY	

The Projections

Reimbursement w/in 36 Months



Cash projections for years 3-5 represent a continuation of cash business in the event of non-reimbursement.

Uroshape Management



Chief Executive Officer: Ralph Zipper, MD, FPMRS, has over 22 years of experience in both the clinical and medical device sides of pelvic medicine. Dr. Zipper has taken multiple products from conception to commercialization. His scope of experience includes IP development, product development, labeling, regulatory affairs, evidence generation, and DTC marketing. Ralph is fellowship trained in gynecology and obstetrics at the Johns Hopkins Hospital. He is a trained over 1,000 surgeons and hundreds of sales representatives.



Chief Operating Officer & President: Kevin Richardson, MBA has over 20 years of global commercial and operational leadership experience in healthcare technology. Mr. Richardson is the former CEO of the Americas for Sirtex Medical where he grew North American sales from a stagnant \$30 MM to over \$140 MM. Kevin has extensive medical device experience with companies such as Boston Scientific and St. Jude Medical. He has a masters degree in Finance from the University of Texas at Arlington.



Chief Scientific Officer: Georgine Lamvu, MD, MPH received her Masters of Public Health in epidemiology and completed a fellowship in Advanced Laparoscopy and Pelvic Pain at UNC. Dr. Lamvu served as a fellow scholar in the NIH T-32 Training in Epidemiology and Clinical Trials Program. She is a Professor in Obstetrics and Gynecology at the UCF and Director of the Fellowship in Advanced Minimally Invasive Surgery at the Orlando VA Medical Center. Dr Lamvu is Chairwoman of the International Pelvic Pain Society.



Chief Medical Officer: Charles Butrick, MD FPRMS is a former president of the International Pelvic Pain Society and a former President of the International Society of Pelvic Neuromodulation. Dr Butrick is one of the most recognized and enjoyed key opinion leaders in the areas of Chronic Pelvic Pain and Pelvic Medicine. Charles is the author of multiple publications and keynote presentation on chronic pelvic pain.



Vice President of Sales & Marketing: Steve Bowers is a former U.S. Army Blackhawk pilot with over 21 years of experience in the women's healthcare market. Steve was a national sales manager for American Medical Systems (Gyn & Urology), TAP Pharmaceuticals, Influence Medica. He has been a key figure in multiple product launches in which he planned and built a bench of sales and marketing.

Medical Advisory Board



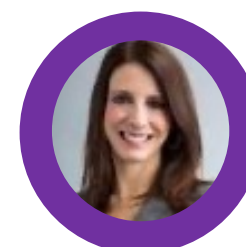
Neeraj Kholi, MD MBA

Boston, MA
Medical Director, Boston Urogyn
**Former Chief Dept Urogyn Brigham
& Women's Hosp**



Kristene Whitmore, MD

Philadelphia, PA
University Urogyn
Extensive researcher CPP and IC



Stephanie Prendergast

Los Angeles, CA
Multi-Center PT
**Past president of IPPS
Board Member IPPS**



Michael Hibner, MD , PhD

Phoenix, AZ
St. Josephs Hosp
Board Member of IPPS



Frank Tu, MD

Chicago, IL
University Gyn
**Past president of IPPS
Board Member IPPS**

SoLá Therapy Evidence



The Best of Both Worlds:

In alignment with the FDA's MDUFA IV agreement, CDRH's creation of the Division of Clinical Evidence and Analysis, and the formation of NEST (National Evaluation System for Health Technology).

SoLá Therapy adopted an evidence generation program that combines clinical trials with real world data collection. This provides evidence that applies beyond the ideal conditions found in clinical trials.

The SoLá Therapy Real World Data Program:

The SoLá Therapy Laser touch screen collects demographic data and ICD 10 data, and utilizes validated medical questionnaires to gather real-world patient reported outcome data on every patient at every treatment. This data is collected, under a data use agreement, in a HIPAA compliant system and coded. Our CRO, under a business associate agreement, performs bimonthly real-world analyses. **Unlike clinical trials, real world evidence (RWE) can be generalized to real women in the real world.**

The SoLá Therapy Clinical Trial Program:

Under the guidance and direction of our Chief Scientific Officer, a multicenter randomized controlled trial (RCT) is scheduled to begin enrollment in Q1 of 2021. The SoLá Therapy Laser touch screen user interface and proprietary data collection software provides an ideal platform for the rapid collection and analysis of RCT data.

SoLá Therapy vs. Most Common Treatments

Treatment	Labeled Indication	On-Label for CPP	CPP Effectiveness Data	Real World Evidence	% who Improve	% Improvement	Duration of Effect	Side Effects
SoLá Therapy	Reduce muscle spasm & pain, increase blood flow	YES	CPP w/ Muscle Spasm	YES	80%	50%	6 Months	Minimal
Physical Therapy	Reduce Muscle Spasm / tension	N/A	CPP w/ Muscle Spasm	NO	59% ¹⁹	36%	3 Months?*	Pain w Treatment
Trigger Point Injections	Multiple. None for Muscle Spasm	NO	CPP w/ Muscle Spasm	NO	0-65% ³⁵⁻³⁷	50%	8 weeks	Minimal
Botox Injections	OAB and eyelid spasm	NO	CPP w/ Muscle Spasm	NO	0-75% ^{23,24}	40%	2-8 weeks	Pain w Treatment
Valium Suppositories	None	NO	CPP w/ Muscle Spasm	NO	17% ^{38,39}	?	?	30% Dizzy
Interstim / Axonics	OAB symptoms and incontinence	NO	CPP without IC	NO	30-50% ^{40,41}	50%	Unknown	17% infection & removal
Urgent PC (PTNS)	OAB symptoms & urinary incont	NO	CPP without IC	NO	25-55% ^{42,43}	55%	12 weeks	Minimal
Gabapentin	Post-herpes nerve pain and epilepsy	NO	CPP without Endo or IBS	NO	70% ⁴⁴⁻⁴⁶	30-40%	24 weeks	30% Dizzy
Elmiron	Bladder pain associated w I.C.	NO	IC	NO	5-30% ²⁶	34%	6 Months	24% retinopathy
DMSO (RiMSO)	Symptomatic relief of I.C.	NO	IC	NO	?	15-50%	?	Minimal
Orilissa	Endometriosis Pain	NO	Endometriosis without Depression, back pain, FM	NO	58% ²⁵	30%-40%	6 months Max	50% Hot flashes, >20% headache & lost bone
Pelvic Vessel Embolization	Embolization in the peripheral vasculature	NO	Pelvic Congestion Syndrome Only	NO	75% ^{47,48}	>50%	12 Months	Minimal

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