



SOVE

Systems Orthodontics  
Virtual Esthetics

# The Team



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# Traditional Braces



- A versatile orthodontic appliance that can treat all severities of crowding
- Unaesthetic silver brackets and wires on the front of the teeth
- Brackets cause irritation to the inside of the lips and cheeks

Braces have never been comfortable or attractive, therefore there has been a large movement in the market towards invisible braces.



# Invisible Braces: Ceramic



- Visible on the front of the teeth
- Unaesthetic silver wires
- Hardness of the brackets can cause damage to opposing teeth when biting
- Brittle material easily fractures when debonding
  - Can damage enamel



# Invisible Braces: Lingual



Incognito



Inbrace

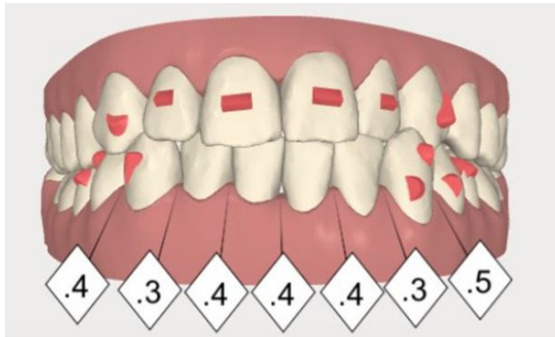
- Ex: Incognito, Inbrace
- Not indicated for all malocclusions
  - Ex: open bites
- Bulky brackets with hooks and tie-wings on the tongue side of the teeth are very uncomfortable for the patient
  - Irritating to the tongue
  - Hinders speech
- Difficult wire ligation
- Longer appointments
  - 60-120 minutes (4-8 times longer than a regular appointment)



# Invisible Braces: Clear Aligners

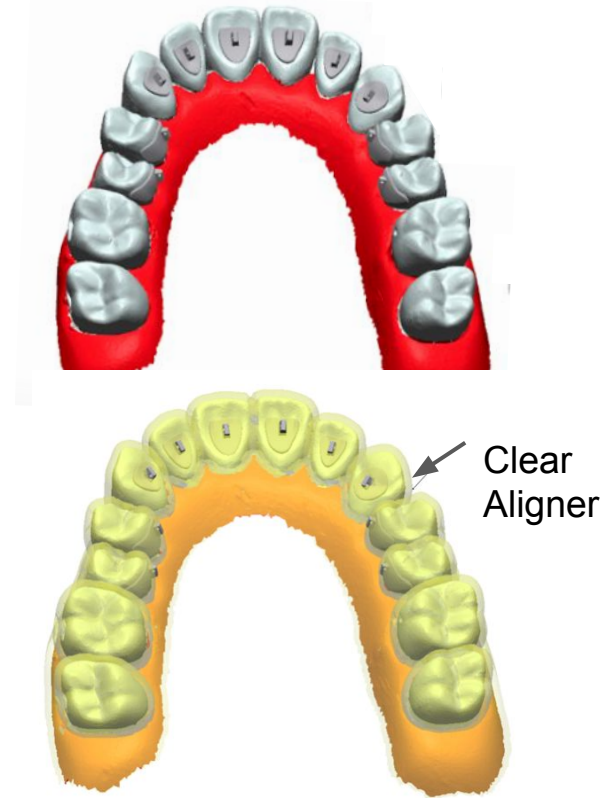


- Ex: Invisalign, Clear Correct
- Require attachments on the front of the teeth
- Attachment formation and placement are subject to error by the orthodontic assistant
- Excessive reduction of healthy enamel is often required when aligning crowded teeth (pictured)
- Not suitable for severe levels of crowding



# Solution: 2Insight

- Developed by our founders to eliminate the problems associated with esthetic orthodontic appliances
- Two-stage orthodontic system that utilizes custom, 3D metal printed lingual attachments and a lingual archwire in conjunction with clear aligner therapy
  - Initial alignment with a lingual archwire
  - Finishing and detailing with clear aligners
- Incorporates the benefits of archwire alignment with the comfort and esthetics of clear aligners



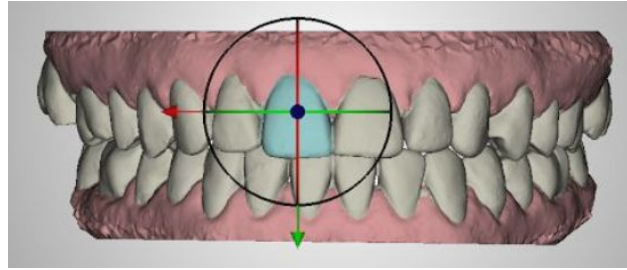


# 2Insight: Stage 1

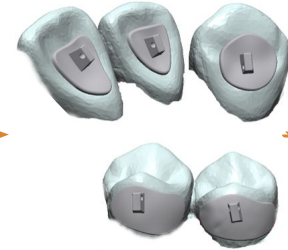
Stage 1: A lingual archwire is incorporated through the attachments to enhance alignment and leveling and reduce the need for interproximal reduction of healthy tooth enamel.



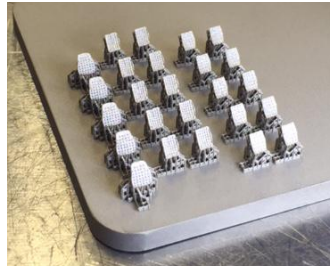
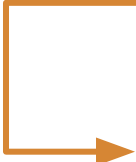
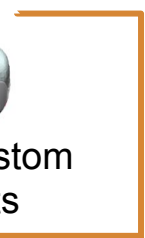
Intraoral Scan



Digital tooth setup



CAD/CAM Custom attachments



3D printed in Stainless Steel



Archwire placed through bonded lingual attachments



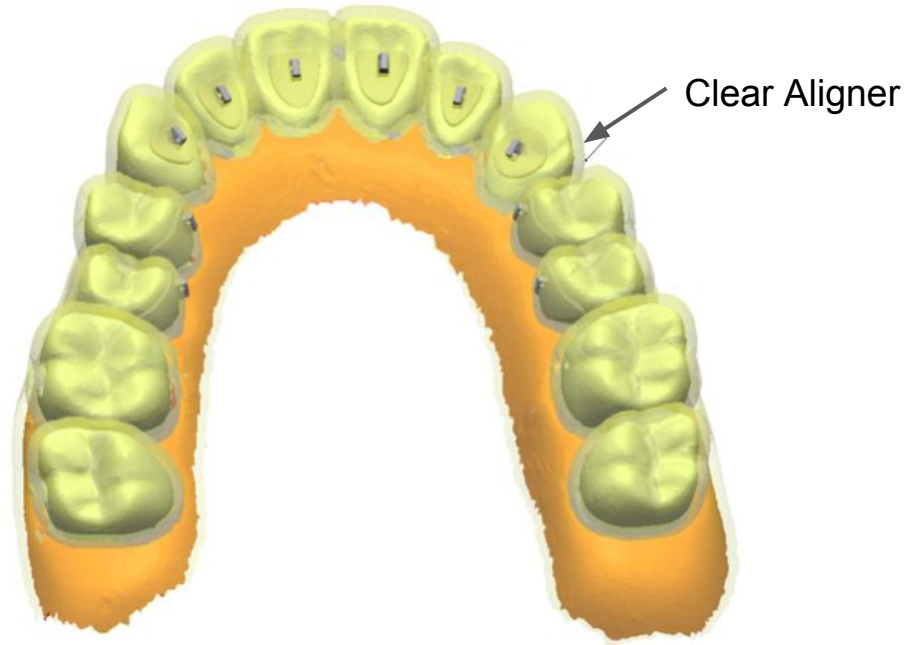


## 2Insight: Stage 1 Summary and Benefits

- Attachments are custom designed from a virtual alignment of the patient's digitally scanned teeth
  - Enables precise, personalized appliance for enhanced treatment efficiency
- Attachments are 3D metal printed in biocompatible, corrosion-resistant Stainless Steel and transferred to the back of the teeth via a bonding template
  - Lower fabrication cost than other custom appliances
  - Not subject to fabrication or placement error by the assistant
  - No visible attachments on the front of the teeth
- A lingual archwire is easily threaded through the holes in the attachments
  - Simple, fast archwire ligation
  - Only one or two archwires are used
  - Small and smooth attachments are more comfortable to the patient than lingual braces
  - Archwire alignment reduces the need to remove healthy enamel
- The archwire is removed after initial tooth alignment and remains out for Stage 2
- Approximate time in Stage 1: 3-6 months



## 2Insight: Stage 2



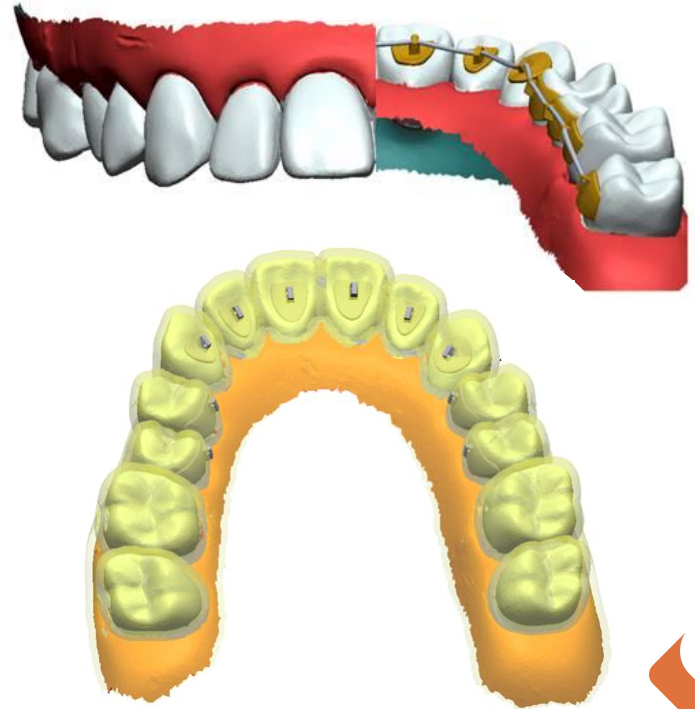
## 2Insight: Stage 2 Summary and Benefits

- The teeth are scanned after initial alignment with the lingual archwire is completed
- Additional desired tooth movements are virtually performed to fabricate a series of clear aligners
- Clear aligners perform the finishing tooth movements without the archwire
  - Finishing bends in large-dimensioned archwires are not needed, saving time during office visits
- The aligners engage the custom attachments to induce precise tooth movements
  - The metal lingual attachments will have more effective mechanical retention and biomechanics than traditional composite attachments
- Approximate time in Stage 2: 6-12 months



# Value Proposition

- Combination lingual appliance with clear aligner system
  - Treat all malocclusions
  - More esthetic
  - Increased comfort
  - Decreased need for enamel removal
  - Decreased chairtime at each visit
  - Custom appliance
  - Shorter treatment time with fewer office visits

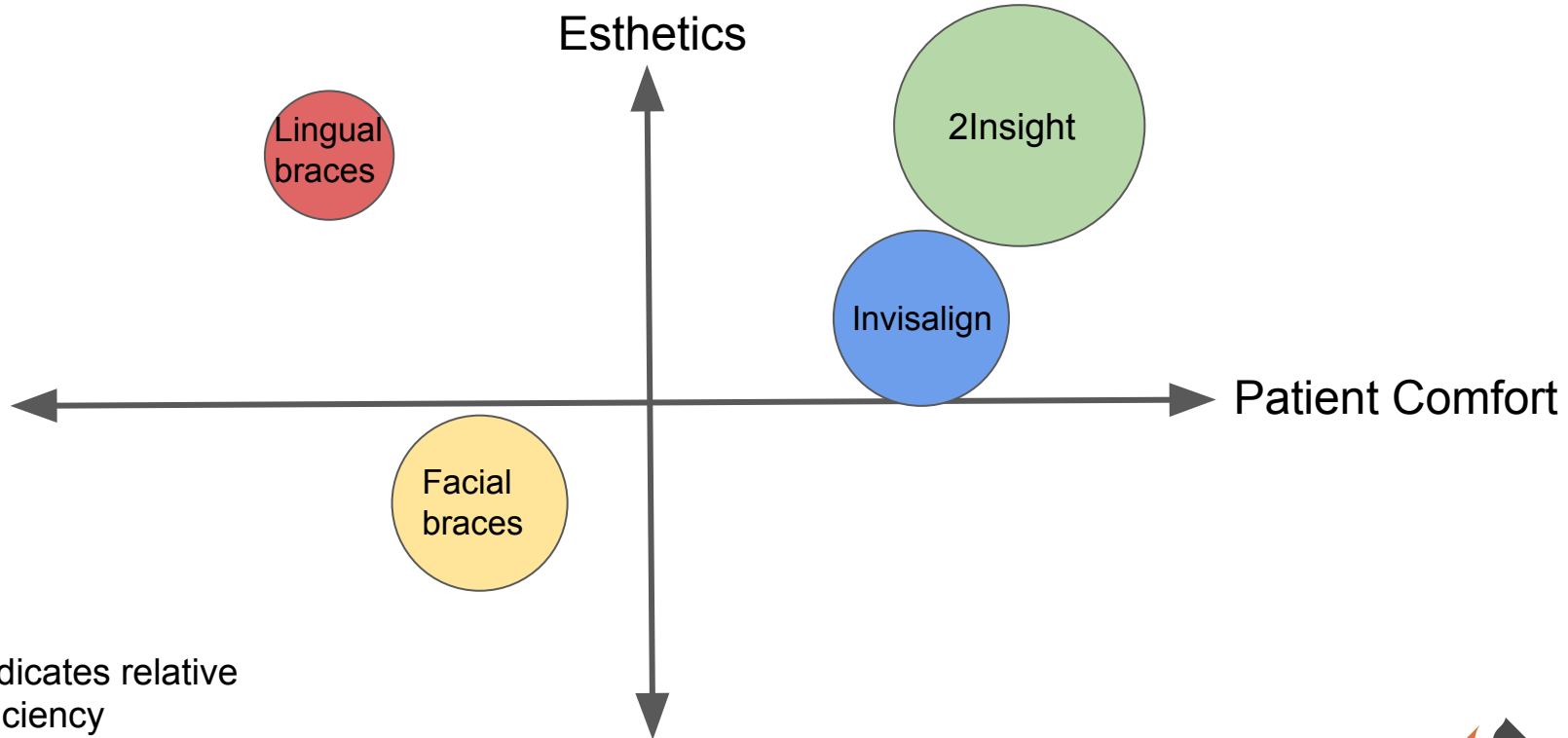


# Competitor Analysis

	2Insight	Invisalign	Facial Braces	Lingual Braces
<b>Cost to provider</b>	\$1,200	\$1,600	\$500	\$1,600
<b>Time per visit</b>	15 minutes	15 minutes	30 minutes	60-120 minutes
<b>Treatment Duration</b>	.75-1.5 years	1.5-2 years	2 years	2 years
<b>Breadth of Utility</b>	Highest	Nominal	Broad	Nominal
<b>Tooth Reduction</b>	Low	Highest	Low	Low
<b>Esthetics</b>	Optimum	Favorable	Low	Favorable
<b>Patient Comfort</b>	High	High	Moderate	Low



# Competitor Comparison

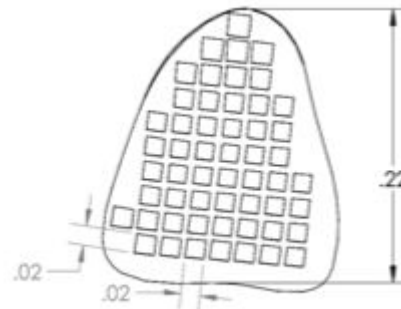
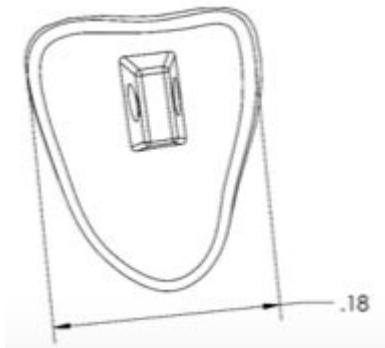


Circle size indicates relative treatment efficiency



# Intellectual Property, Incorporation and Regulatory

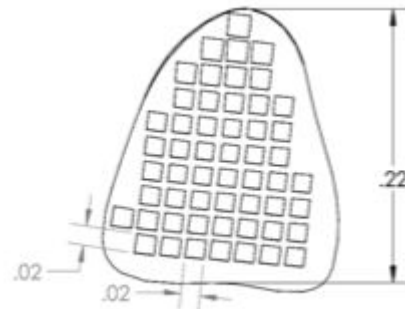
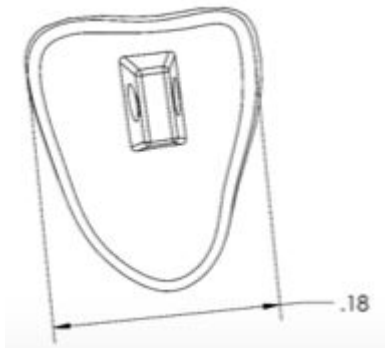
- International filing date: January, 2018
- PCT/US2018/015515 “Orthodontic Brackets, Systems, and Methods”
- SOVE, Inc. incorporation date: February, 2018
- Expected US Regulatory Path: Class I
  - Pre-IDE submission in process for a clinical trial





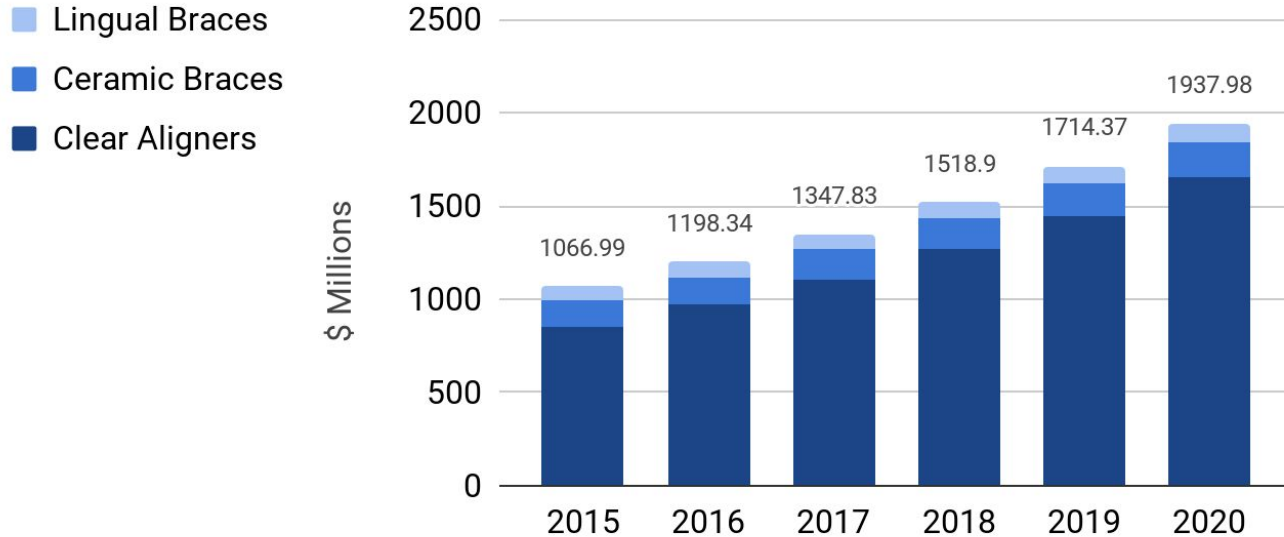
# SOVE's Proprietary Technology

- One-piece bracket with retentive features in the base
- Lingual attachment with archwire hole
- Clear aligner interaction with lingual attachment
- 2Insight method of “Archwire first, aligner second”
- In negotiations with UNC-CH for a Carolina Express License Agreement



# Market Analysis

## Global “Invisible” orthodontic market projection by product type



Source: Technavio

2020 Global addressable market projection: \$1.94B (12.68% CAGR)

Target population size: 2.8MM patients annually



# Market Trends



- Adults are increasingly seeking esthetic orthodontic treatment
  - Growing awareness of oral health
  - Relapse from previous orthodontic treatment
  - Tooth alignment to address periodontal concerns
  - Pre-prosthetic orthodontic treatment for veneers, bridges and implants
  - Increased social media influence
- Increase in global demand for orthodontics along with rise in disposable income
- Patients are willing to pay more for custom, faster, esthetic treatments



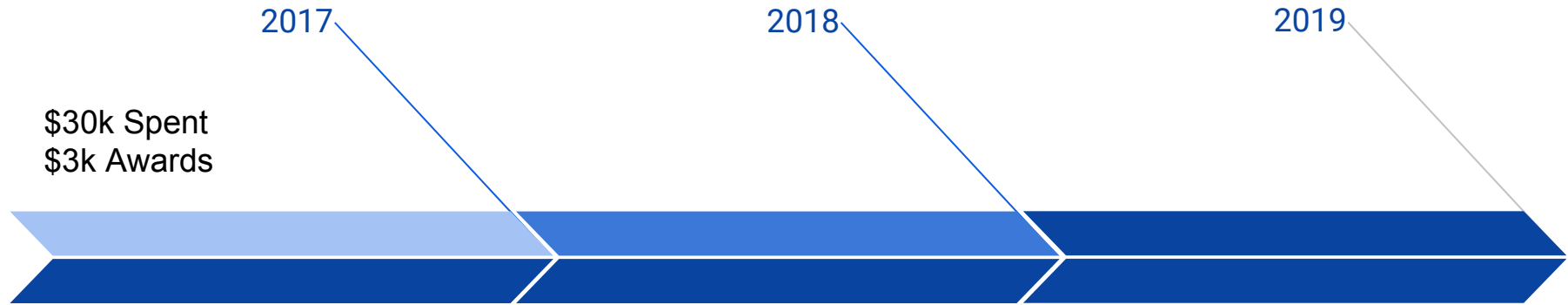
# Go-to-Market Strategy



- Software to align teeth and plan treatment: Smart Check
- 3D metal printing of 2Insight attachments: Protolabs
- Archwires and clear aligner materials: G&H Orthodontics and Xiamen Chaofu Leatherette
- Marketing, Sales and Distribution: FUBURG and G&H Orthodontics
- SOVE will perform activities related to system and protocol design, regulatory approval, and IP/licensing
- SOVE will provide support to the Orthodontist and patient



# Milestones



1. Provisional Patent Filing
2. Preliminary accuracy and bond strength studies of one-piece 3D metal printed brackets
3. Prototype development



# Milestones

2017

2018

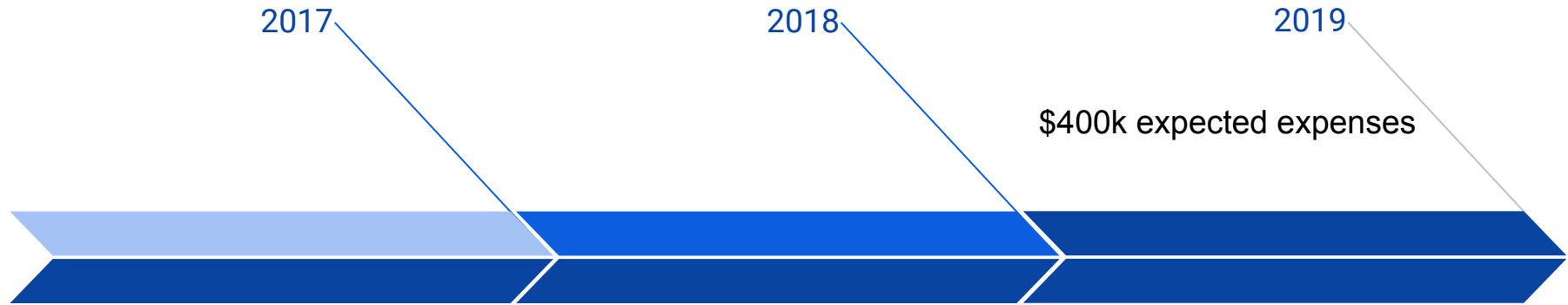
2019

\$12k Spent  
\$280k in awards sought

1. International Patent Filing
2. Incorporation of SOVE, Inc.
3. Prototype development, cont'd
4. STTR grant application
5. Commercialization award applications
6. Initiate regulatory process
7. Identify potential industry partners



# Milestones



1. Further studies on 2Insight® to demonstrate efficacy and biocompatibility
2. Identify additional industry and strategy partners
3. Apply for Phase II funding
4. Complete regulatory process
5. Seek seed investments





# Current Needs

- \$400k in funding from awards and seed investments
  - Advanced prototype development (\$100k)
  - Phase I efficacy and biocompatibility studies (\$100k)
  - FDA approval (\$200k)
- Company Advisors
- Connections to Industry
  - Potential partners, suppliers, and/or distributors





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