

iPilltm Dispenser

A Digital Health + Hardware innovation to:

- Control opioid dispensing
- Securely store opioids
- Destroy unused opioids



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The Problem: Uncontrolled Access to Controlled Substances

Hospitals - Secure

Nurses control dispensing
Omniceil/Pyxis Dispenser
<800 die/year in 6,250 hospitals



Homes - NOT Secure

Self-Medicate
No security
Many accidental deaths

Over prescribing makes 3.3 billion pills¹ available for abuse

The Consequences:



Drug overdoses in children rose 268.2% in last 6 years¹



More than 47,600 adults died of a drug overdose in 2017²



An additional \$635 Billion in healthcare costs and loss of worker productivity per year³

3

The iPiltm Solution: Active Controlled Dispensing



3 Key Features:

1. Active Controlled dispensing
Authentication: 2-point biometrics
Only the prescribed patient can access pills
2. Automatic destruction of pills if tampered
3. Automatic destruction of unused pills after 90 days

The iPilltm Impact

The estimated impact of a **10% reduction**¹ in surgery-related opioid prescribing could:

1. Save lives



332 million fewer unused pills per year for misuse

2. Improve care



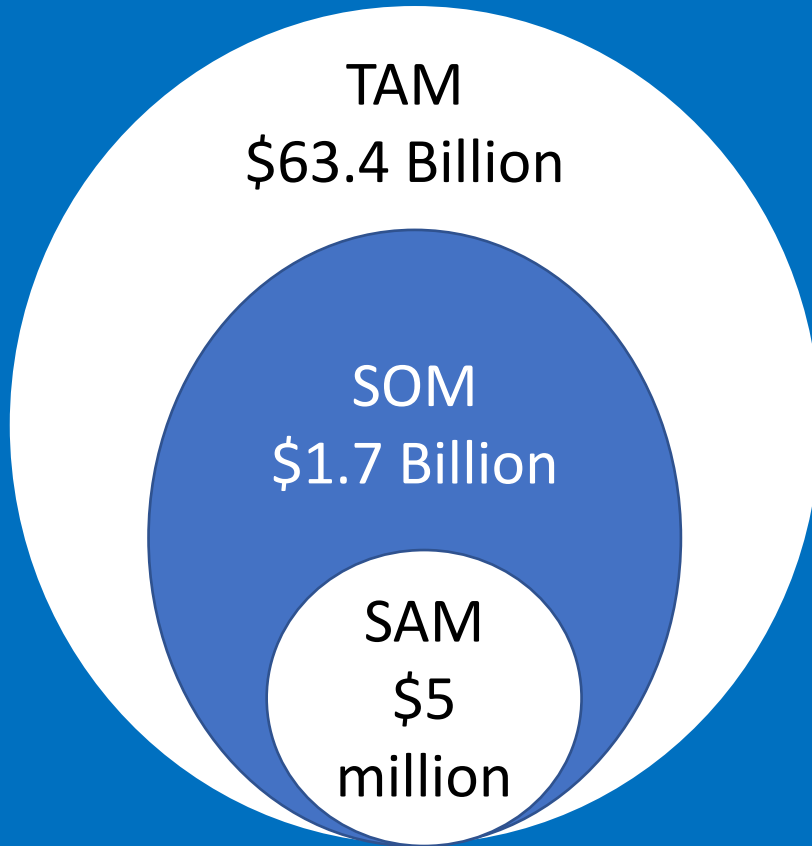
300,000 fewer people per year able to abuse opioids

3. Reduce costs



\$830 million saved in drug costs per year

iPilltm U.S. Market Potential



- TAM = 12.7 Billion pills/yr¹
90 pills per iPill
= 317 Million Dispensers
= \$300 Average dispenser²
- US Market \$1.7 Billion³
- 300 dental practices in 20 states



1. https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html

2. <https://www.medgadget.com/2019/10/automatic-pill-dispenser-market-2019-global-industry-analysis-by-size-share-trends-growth-business-opportunities-type-end-user-and-regions-upto-2024.html>

3. <https://www.top5reviewed.com/automatic-pill-dispensers/>

Competitive Analysis

iPill Class I device



iPill dispenser
\$50



Child Resistant
Cap \$0.001



Hero Pill Dispenser
\$129.95 +\$29/mo



MedSmart Dispenser
\$789.95

Secure opioid storage	✓			✓
Safe disposal	✓			
Drug destruction	✓			
Reduce unused opioids	✓			
Reduce healthcare cost	✓			
Reduce provider liability	✓			
Reduce manufacturer liability	✓			
Improve prescription adherence	✓		✓	✓

iPill_{tm} Regulatory Status



Prototype Built
US Patent no.
10,426,707

For Class I iPill_{tm} FDA registration

- Q1 2020 iPill_{tm} APP and dispenser QMS tested
- Q1 2020 FDA Class I registration
- Q2 2020 employ the Team
- Q2 2020 Injection mold tooling
- Q2 2020 Logistics, distribution, marketing
- Q2-3 2020 Launch



iPill Traction

- a winner 2018 FDA Innovation Challenge for the Prevention and Treatment of Opioid Use Disorder
- a FDA designated breakthrough medical device. Eligible for 3 years of market exclusivity by the Hatch-Waxman Act¹
- a winner of the Hartford InsurTech Hub (Nov 2019)
- Granted patents



1. <http://open.mitchellhamline.edu/cgi/viewcontent.cgi?article=1589&context=wmlr>

iPilltm Customers

CROs/ ATCs

- Approached by CROs and ATCs in a trend away from costly inpatient therapy to more profitable outpatient setting

Dentists

- Approached by a coalition of dental practices and Rutgers Dental school

Physicians

- Approached by a group for remote physician monitoring

Insurers

- Winner of the Hartford Insurtech hub to work with insurers on a financial model for the iPill

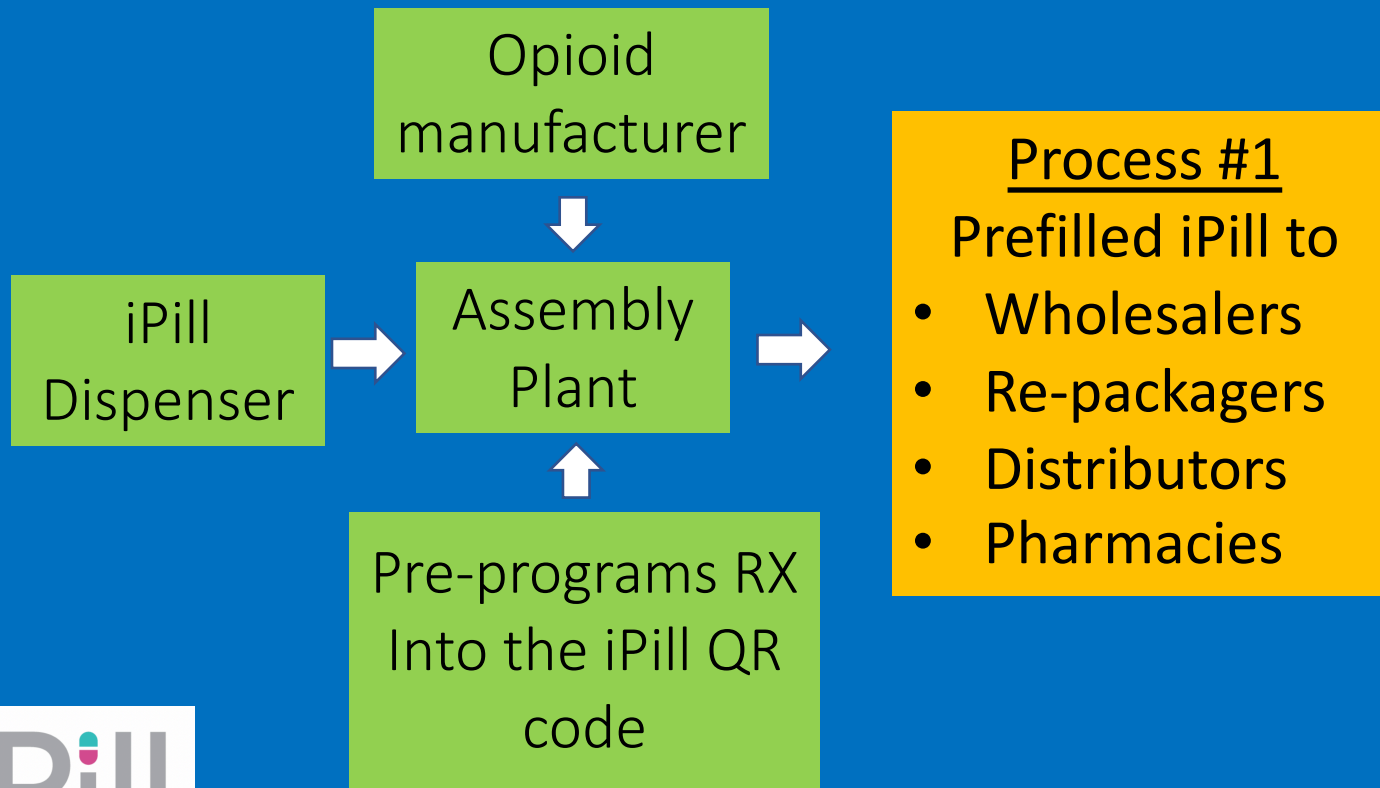
Distributors

- Working with a drug distributor on the distribution model

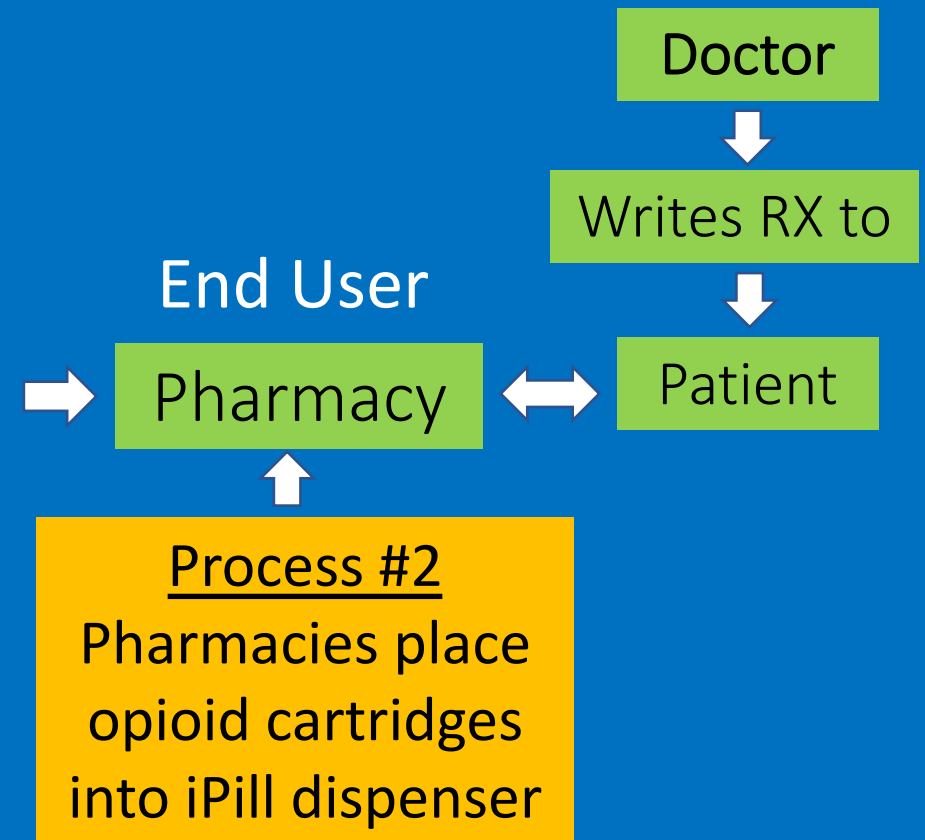


iPill Business Model

Opioid manufacturing and Supply Chain



Prescription flow not changed



Who pays for the iPill

iPill will apply for a HHS¹ HCPCS² code as a reimbursable medical device to decrease opioid usage



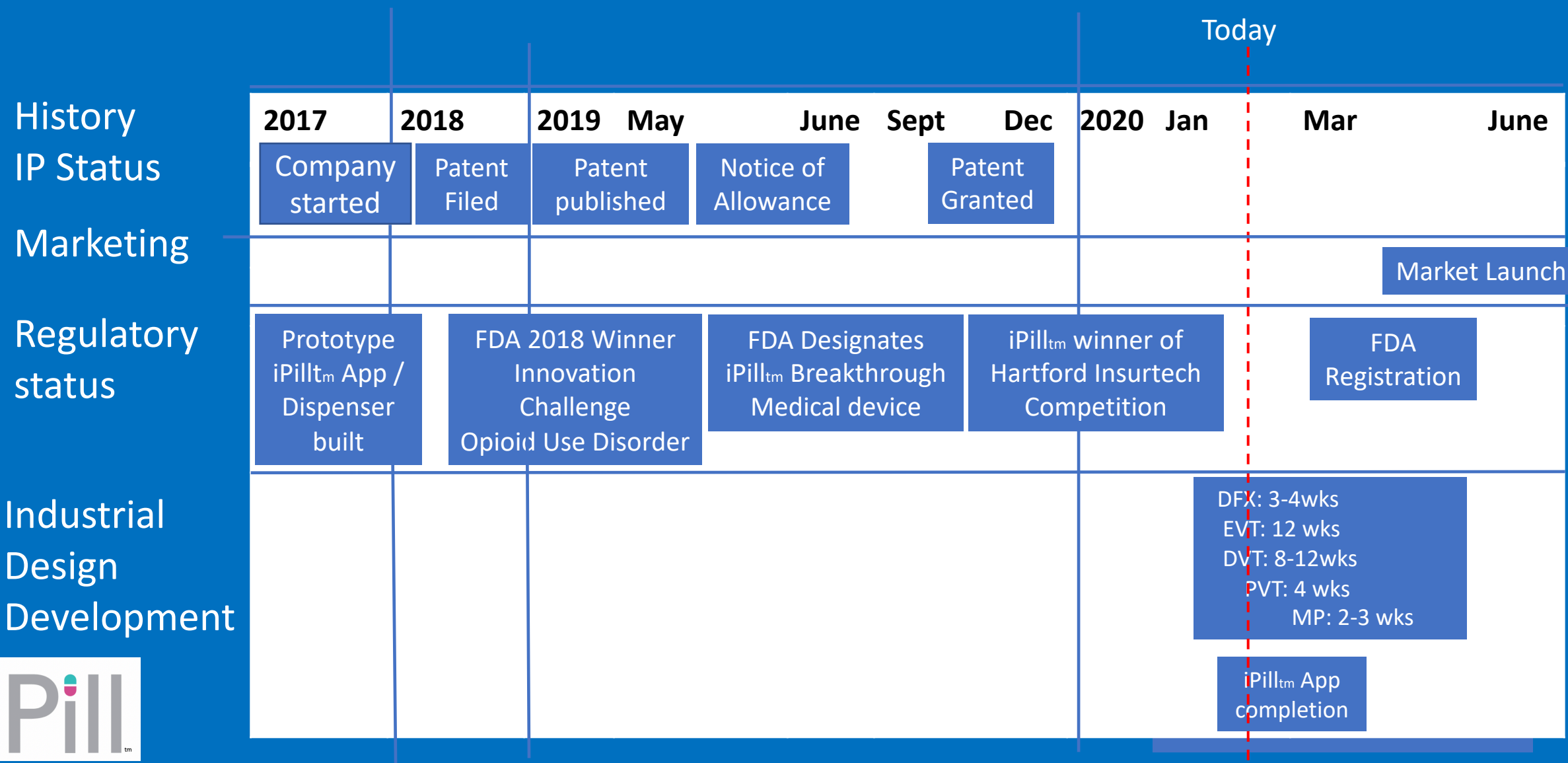
iPill will follow Pacira

- Pacira's **EXPAREL®** is a \$300 drug with a \$10 dollar generic competitor
- Exparel's HCPCS code C9290 makes it a reimbursable medical device

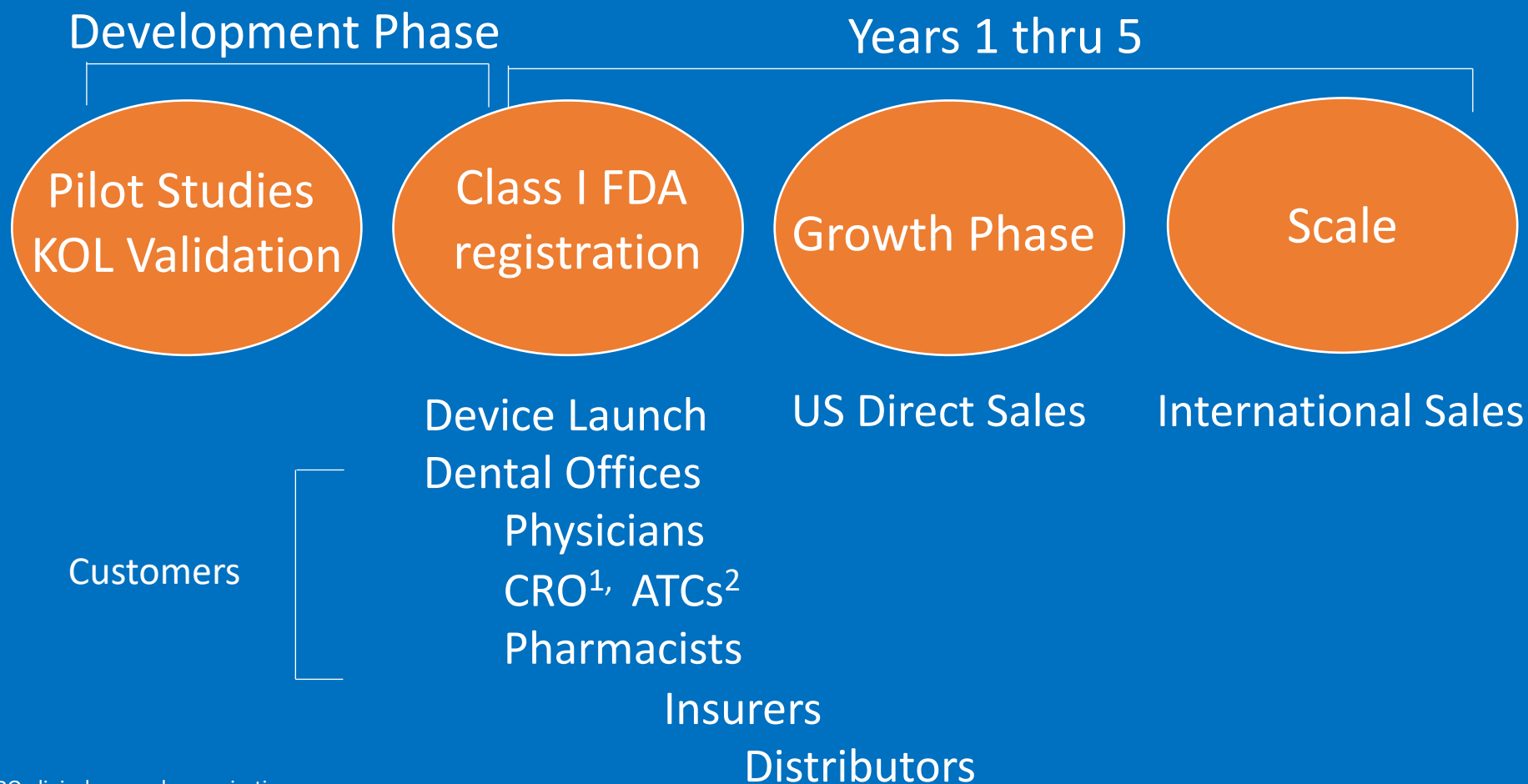


1. HHS Health and Human Services
2. Healthcare Common Procedure Coding System

iPilltm Timelines & Milestones



iPilltm: Go to Market Strategy

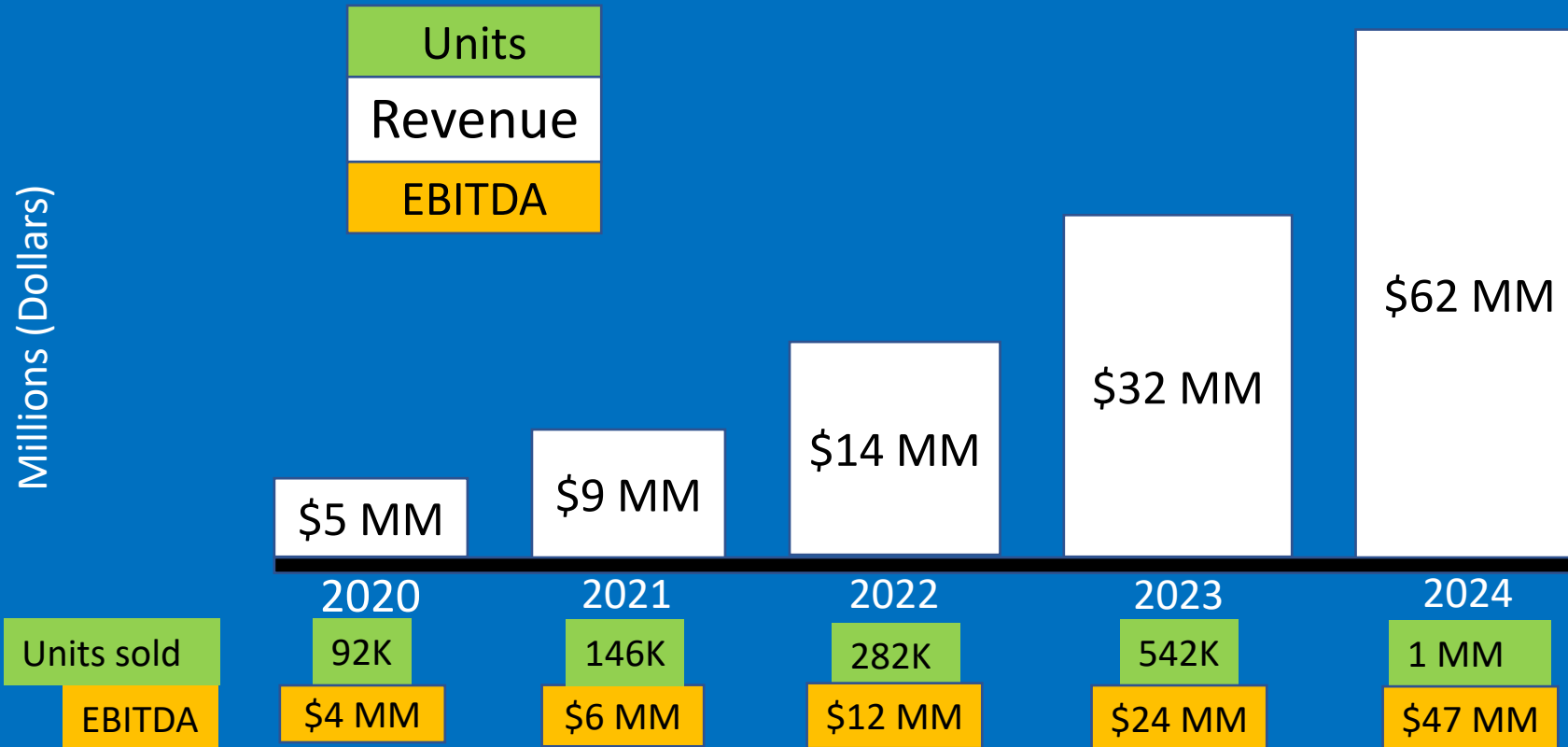


1. CRO-clinical research organization
2. ATC-addiction treatment centers

iPilltm 5 year Projection Summary

Gross
Revenue
\$62 MM

EBITDA
\$47 MM



2020

Launch iPill Class I at DCA 300
Dental practices in 20 states

2021

Launch iPill with CROs and ATCs

2022

Launch to Launch to insurers

2023-2024

Insurance mandate
Federal Mandate



iPill™ Investment Opportunity

We are seeking \$3 Million in early stage financing

- We have Bootstrapped iPill™
- We have invested \$500K of our own money
- With this round we will use the money for:
 - Finish development and perform QMS testing
 - Apply for Class I iPill FDA registration
 - Apply for a HHS HCPCS and CPT code for the iPill
 - Tool injection molding
 - Establish a warehouse
 - Establish an assembly plant
 - Establish a distribution network



iPilltm Management



CTO

Software Engineer

James Yang BS was the principal developer for Ticketmaster and Hilton Hotel Mobile app



CEO

Dr. Hsu practiced anesthesia pain management for 28 years



CSO

Hardware Engineer

Bruce Sargeant BSEE was the principal developer of Velodyne which was sold to Schwin

iPilltm Team

iPilltm Board

Experienced business executives



John Hsu MD
CEO, Co-Founder,

Practiced anesthesia
pain management for 28 years



Sherie Hsieh, BS Co-Founder
International real estate
investment investor



Nick Spring
Founded and exited from a
medical device and a
biopharma company



Peter Weinstein, PhD, JD
IP Attorney and former patent
reviewer for the US Patent Office



iPilltm Scientific Advisory Board



Scientific
Clinical
Advisor

Daniel I. Sessler, MD, Professor Cleveland Clinic was the editor of *Anesthesiology* and 7 other editorial board in 2012.



CBT
Scientific
Advisor

Jared Adams, MD, PhD is the Dir. Of research at SelfCareCatalysts which currently has 60,000 users



Scientific
Regulatory
Advisor

Brian Harvey MD, PhD, was a former CDRH Dir. of FDA



Pharmacy
Regulatory
Advisor

Robert Nickell, PharmD Pharmacy and taught FDA pharmacy Regulations at USC School of Pharmacy



iPilltm Consultants



Consultant FDA regulatory



Ginger Cantor RAC, MBA 25 years in regulatory affairs



Legal Counsel



Peter Weinstein PhD, JD, former USPTO reviewer and was senior patent counsel at Baxter Healthcare



Consultant Corporate Finance



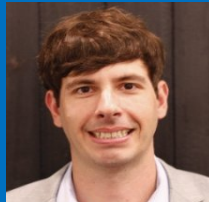
Lacarya Scott, MS, MBA 18 years in finance, M&A



Consultant Pharma Distribution



Chris Baker, MBA, former VP at McKesson, 25 years managing \$200 billion in healthcare-related transactions



Consultant Quality Management



Kyle Rose, MBA 15 years in medical device as a Certified Quality Auditor (CQA)



Consultant Cybersecurity HIPAA Compliance



Matthew Clark, BS, 19 years in IT systems in cybersecurity and HIPAA compliance



Consultant Bio-Sensor Engineer



Alfonso Limon, PhD has over 17 years in medical device design



Consultant Commercialization



Chris Buckley, BA, 20 years in pill dispenser industry, Pyxis then with Livi

iPilltm Consultants

Business Development Consultants



Nick Arjomand
Founder of Simpligene, Head of
Investment outreach, Wellesley
Pharmaceuticals



iPill_{tm} Summary

- We are seeking \$3 million to:
 - Complete development
 - Register with the FDA
 - Get market ready

- ## iPill_{tm} Future Steps
- Class II FDA de novo Approval for the iPill_{tm}
 - Bidirectional physician remote access
 - Cognitive behavioral therapy
 - Wearable respiratory bio-sensor set up to call 911 through the iPill_{tm} App
 - Data collection for predictive analytics and population health management



iPilltm 5 year Projection

Key Assumption	2020	2021	2022	2023	2024
iPill Market Share (%)	0.50%	0.73%	1.27%	2.22%	3.89%
Number of prescriptions issued in iPill Dispenser	91,857	146,512	282,036	542,920	1,045,120
Income					
US Accessible Market Volume (Rx/year)	91,857	146,512	282,036	542,920	1,045,120
US iPill Market Price	\$60	\$60	\$60	\$60	\$60
US iPill Market Income	\$5,511,420	\$8,790,720	\$16,922,160	\$32,575,200	\$62,707,200
Total number of Prescriptions	229,000,000	229,000,000	229,000,000	229,000,000	229,000,000
iPill Volume % penetration of total market	0.040%	0.064%	0.123%	0.237%	0.456%
iPill Units sold	91,857	146,512	282,036	542,920	1,045,120
iPill Cost per unit	\$15	\$15	\$15	\$15	\$15
iPill Cost per unit x volume	\$1,377,855	\$2,197,680	\$4,230,540	\$8,143,800	\$15,676,800
iPill Operating Profit EBITDA	\$4,133,565	\$6,593,040	\$12,691,620	\$24,431,400	\$47,030,400
Expenses Total	\$8,203,000	\$8,594,000	\$9,566,400	\$10,680,240	\$9,580,564
iPill Net = Gross Profit - Expenses	-\$4,069,425	-\$2,000,948	\$3,125,226	\$13,751,139	\$37,449,841



A Digital Health + Hardware innovation to:

To save lives
To improve care
To reduce costs



Thank you

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