



MASSACHUSETTS
LIFE SCIENCES CENTER



2014 Accelerator Loan Winner



T1D Exchange®

2016 Diabetes Challenge Winner



windgap
medical

ANDI™ Autoinjector for
Anaphylaxis and Beyond

CAUTIONARY LANGUAGE

We caution that the above statements contain forward-looking statements that reflect our plans, goals, next steps, estimates, assumptions and beliefs as of the date of this communication. Such forward-looking statements can be identified by terms such as “will”, “could”, “expect”, “may”, “believe”, “continue”, “become”, “potential”, “anticipate”, use of the future tense or similar expressions. Actual results could differ materially from those discussed in the forward-looking statements, due to a number of important factors, which include, but are not limited to, the following: changes in the financing, production, partnering or generics marketplace; regulatory changes affecting exclusivity or ability to obtain regulatory approval of our products or similar products; ability of the Company to prosecute, protect or defend its intellectual property portfolio or maintain the Company’s freedom to operate against third parties’ rights; changes in the pharmaceutical reimbursement landscape; changes in regulation affecting drug pricing; appetite for financing or licensing deals by potential investors or licensees and their willingness to offer and negotiate terms of any potential agreements or withdrawal or termination of any or all offers or discussions; and failure to obtain agreement or approval by our or their management, stockholders or board or directors or other third parties to such deals. We have no assurance that any potential agreements are achievable on terms attractive to Windgap, or at all.

MISSION & PRODUCT

- Windgap's novel autoinjector enables the transformation of complicated drug delivery problems into patient-convenient solutions
 - It reduces complicated reconstitution steps and improves drug delivery for patient
 - It increases shelf life and thermal stability

This creates new products for patients and expands markets for pharma partners

MANAGEMENT TEAM

Christopher Stepanian | Chief Executive Officer

- 30 years of experience in management, finance, and operations;
- Founding Team, Aspen Aerogels (NYSE: ASPN Business strategy, finance, management, and engineering)
- Chief engineer for manufacturing plant
- Successfully raised angel and venture capital
- MIT Sloan Fellow



Brent Buchine | Chief Technology Officer

- 15 years of R&D experience and 14 patents issued
- Founder & President of Custom Nanotech, LLC
- Technology strategy, IP prosecution, and business development
- Contracts, Supply Chain, and IP portfolio management



Adam Standley | Director of Product Development

- Engineer with extensive product design experience
- 15 years of experience developing mechanical systems
- Med device and semiconductors
- Manufacturing scale up



Evan Sherr | VP of Operations

- Operations, development, quality and regulatory experience with drug/device combination products
- 25 years of experience in drug and device products
- Successful 505(b)(2) approval
- Built regulatory/quality organizations



EXPERIENCED BOARD

Mel Engle

Chairman & Investor



Former CEO, EpiPen
Dey LP, Allergan

John Conley

Series Seed & Investor



Co-Founder &
Finance VP Alnylam

Tim Krochuk

Series A & Investor



Named Partner,
SKK

Reading Wilson

Series B & Investor



SKK, BoA, First
Union

Richard Gabriel

Outside BOD Member



COO, GLG
Pharma

John Cadigan

BOD Observer & Investor



Former GM, Philips HC

Rob Manning

BOD Observer & Investor



BOD Smart Cells &
Cherrystone Angel Group

Carla (Haslauer) Reimold

BOD Observer



MLSC Observer,
Boston Children's

WINDGAP IN SUMMARY

- Innovative technology
- Epinephrine partnership
- Platform opportunities
- Low-risk regulatory
- Strong IP
- World-class partners
- Experienced team
- Financial opportunity

EPIPEN: THE PROBLEM

Large

Expensive

Confusing

Thermally Unstable



THE SOLUTION



Small
Lower-cost
Easy to use
Thermally stable

EASY TO USE



**Small for
portability**

**Rehydration
upon activation**

Intuitive injection

ANDIPEN[®] AUTO-REHYDRATION

Dry Drug (not visible)

Liquid diluent



ANDI can be operated upside down, sideways or at 45 degrees

The injection can not be made until mixing is complete (safety measure)

PRODUCT OPPORTUNITIES

Unstable liquids

**Epinephrine
(Anaphylaxis)**



**Benzodiazepine
(Seizure)**



**Emergency treatment
(Opioid Overdose)**



**Etanercept (Enbrel)
(Rheumatoid Arthritis)**



Awkward rehydration

**Glucagon
(Hypoglycemia)**



**Clotting Factor (VII,VIII)
(Hemophilia)**



**Sumatriptan
(Migraine)**



**Human Growth Hormone
(Pituitary Disease)**



Long-acting drugs

**GLP-1 (exenatide, liraglutide)
(Diabetes, weight loss)**



**Naltrexone
(Opioid addiction)**



**Resperidone
(Anti-Psychotic)**



**Sandostatin
(Antidiarrheal, Acromegaly)**



PRODUCT PIPELINE

- **Epinephrine**
 - \$1,300 billion + ex-US growth
 - Strong partner with international reach
- **Emergency Treatment, Opioid Overdose**
 - \$245 million + growing potential
 - Transition from vials -> delivery devices resulting in 30% YoY unit growth
 - Active term-sheet negotiations with intl. pharma partner
- **Glucagon**
 - \$250 million + growth to \$1 billion w/ autoinjector
 - Strong need for portable, easy-to-use version
- **Benzodiazepines**
 - DoD opportunities
 - Treatment for chemical weapon exposure

PARTNERSHIP VALIDATION

Epinephrine Autoinjector

Platform



Worlds Largest
Allergy Practice

“THE” Allergy
Company

Leading Producer
in Drug Delivery

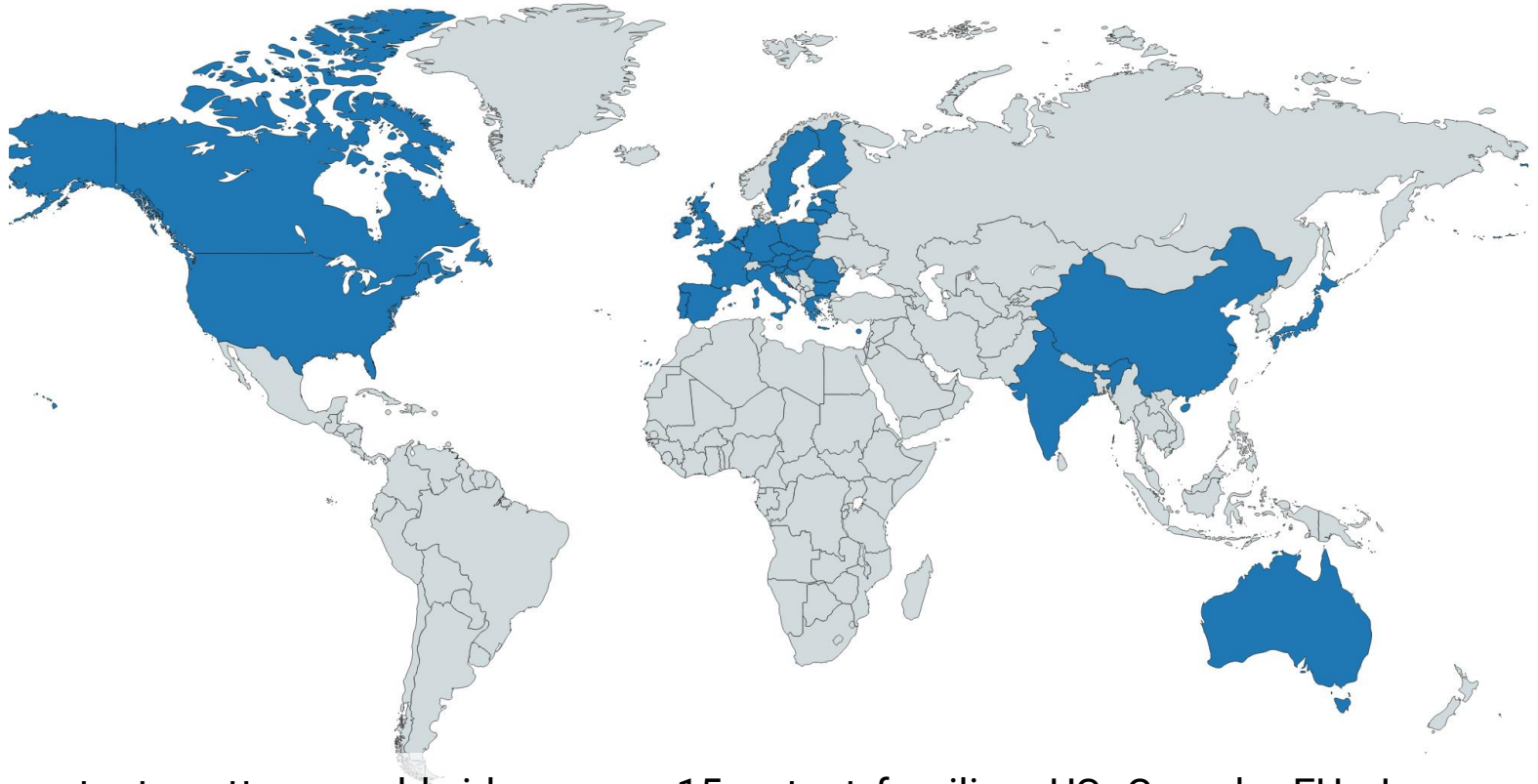


Series A



Series B

INTELLECTUAL PROPERTY



- 80+ live patent matters worldwide across 15 patent families: US, Canada, EU, Japan, Australia, India, China
- 13 patents issued (7-US, 5-International, with 11 additional notice of allowances pending issuance)
- Three patentability studies: **patentable**
- Freedom-to-Operate: **unobstructed**

REGULATORY: 505(b)(2)

Reference drug

YES

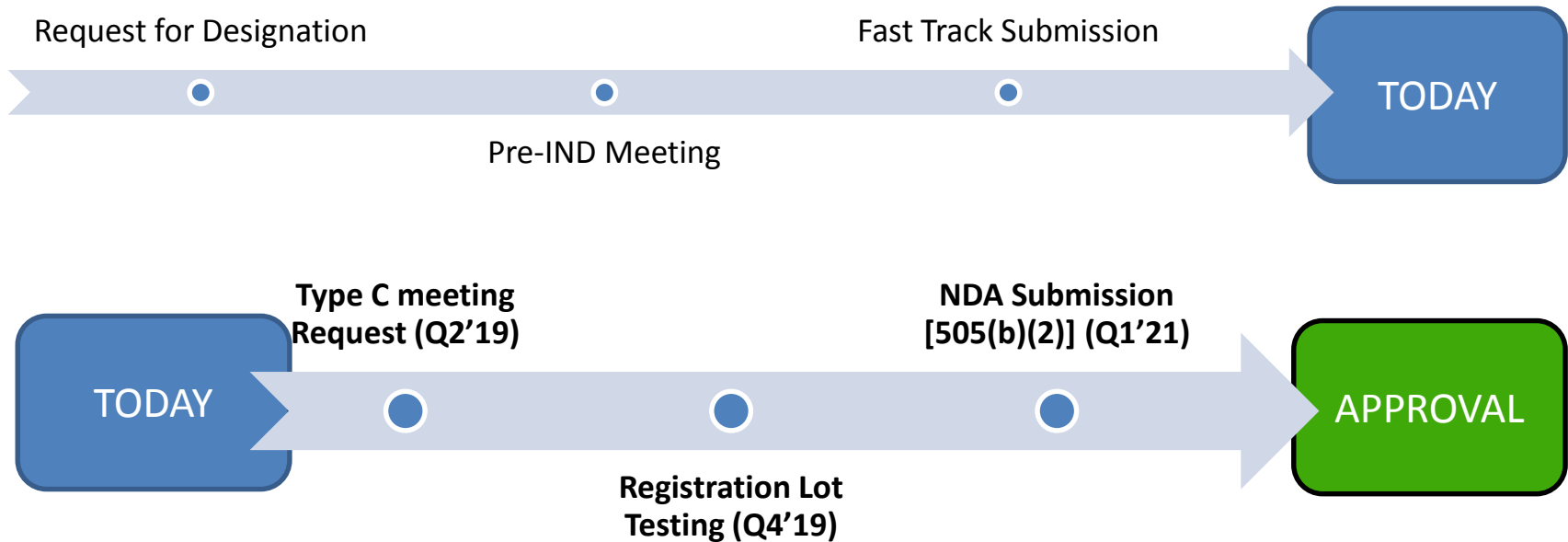
Same route of
administration

YES

Human clinical trials

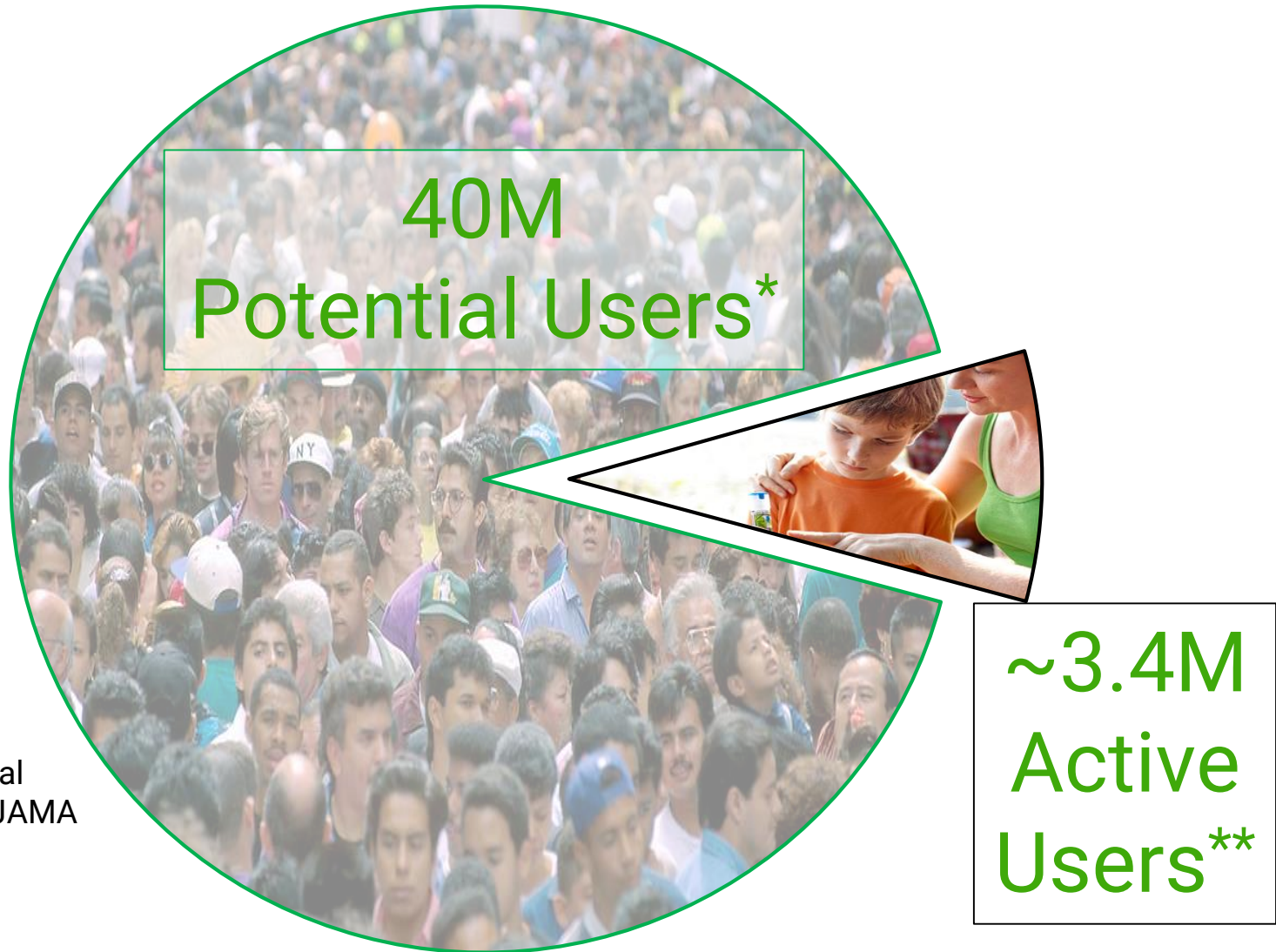
NO

REGULATORY HISTORY & FUTURE



- Fast track impact: potential 3-6 month savings
- Approval range: Q2'21 – Q4'21
 - Impacted by Fast Track, FDA feedback, and CMC test results

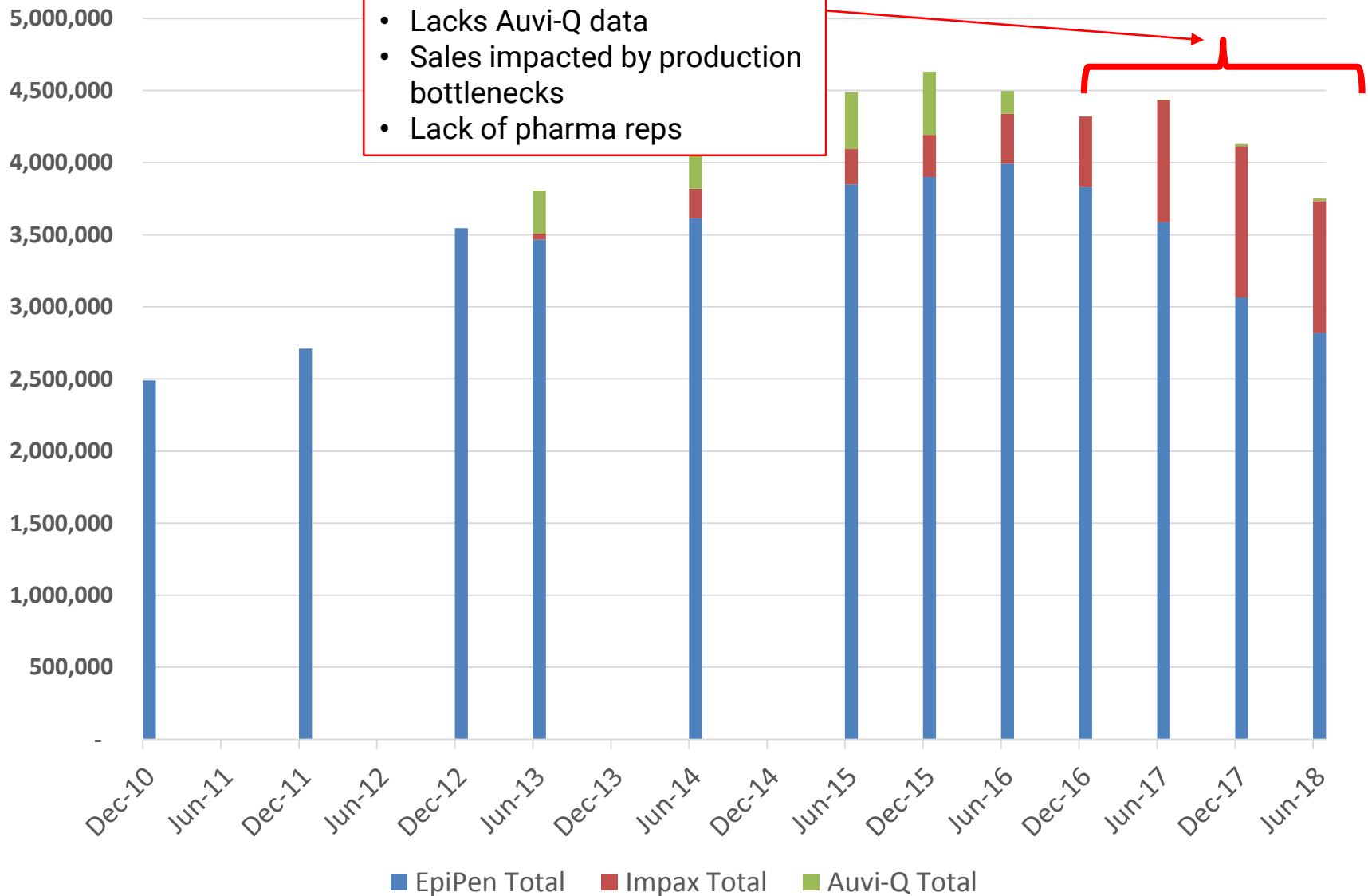
US POPULATION AT RISK OF ANAPHYLAXIS



*Mylan investor presentations; Journal papers: Gupta et.al. JAMA (2019), Gupta et.al. Pediatrics (2019)

**IMS Health; Chua and Conti, JAMA Intern Med. (2017)

EPI AUTOINJECTOR UNITS (US TTM)



FINANCE (HISTORY)

- Series Seed Preferred (2014)
 - \$2.75 million pre, \$2 million raised
- Series A Preferred (2015)
 - \$20.5 million pre, \$4.5 million raised
 - Catalyzed by ≈\$1 million MLSC loan
- 2016 and 2017 Debt Rounds
 - A total of \$8 million raised

SERIES B ROUND

- \$30 million raise, \$60 million pre
 - SKK leading - \$20 million appetite
 - Strategic investor (Molex Ventures) onboard for \$5 million
 - Initial close completed in early January, full completion by late-Q2'19
- ALK announcement pending

SERIES B: SUMMARY USE OF FUNDS

	V&V	Stability	Regulatory Review	Comissioning / Approval	Totals
		full, 12 Months of Stability*	full, 10 months of review		
Number of Months from Funding Date	0-8	9-22	23-33	34	34
Maximum Headcount during Period	16	21	22	22	
Salaries & Benefits	\$1,200	\$3,600	\$3,000	\$300	\$8,100
R&D					
Engineering Test Lots, Testing, and Design Lock-Down, and Lab Expense	\$400	\$200	\$100	\$0	\$800
Verification and Validation of Drug and Device	\$3,000	\$5,500	\$0	\$0	\$8,500
Regulatory Package [NDA-505(b)(2)] Development and Submission	\$0	\$1,300	\$2,100	\$100	\$3,600
NRE Associated with Commercial Mfg. Line (2.5M per annual scale)	\$0	\$2,300	\$2,800	\$0	\$5,100
CapEx Associated with Commercial Mfg. Line (2.5M per year)	\$100	\$5,400	\$6,500	\$0	\$12,000
Product #2 Development and Commercialization	\$100	\$400	\$1,200	\$0	\$1,700
Product #3 Development and Commercialization	\$0	\$0	\$100	\$0	\$200
General OpEx	\$1,200	\$3,200	\$3,700	\$400	\$8,500
Subtotal	\$6,000	\$21,900	\$19,500	\$800	\$48,500
Less Milestone Payments	(\$2,000)	(\$10,000)	\$0	(\$5,000)	(\$17,000)
Total	\$4,000	\$11,900	\$19,500	(\$4,200)	\$31,500

Series B initial close: December 2018

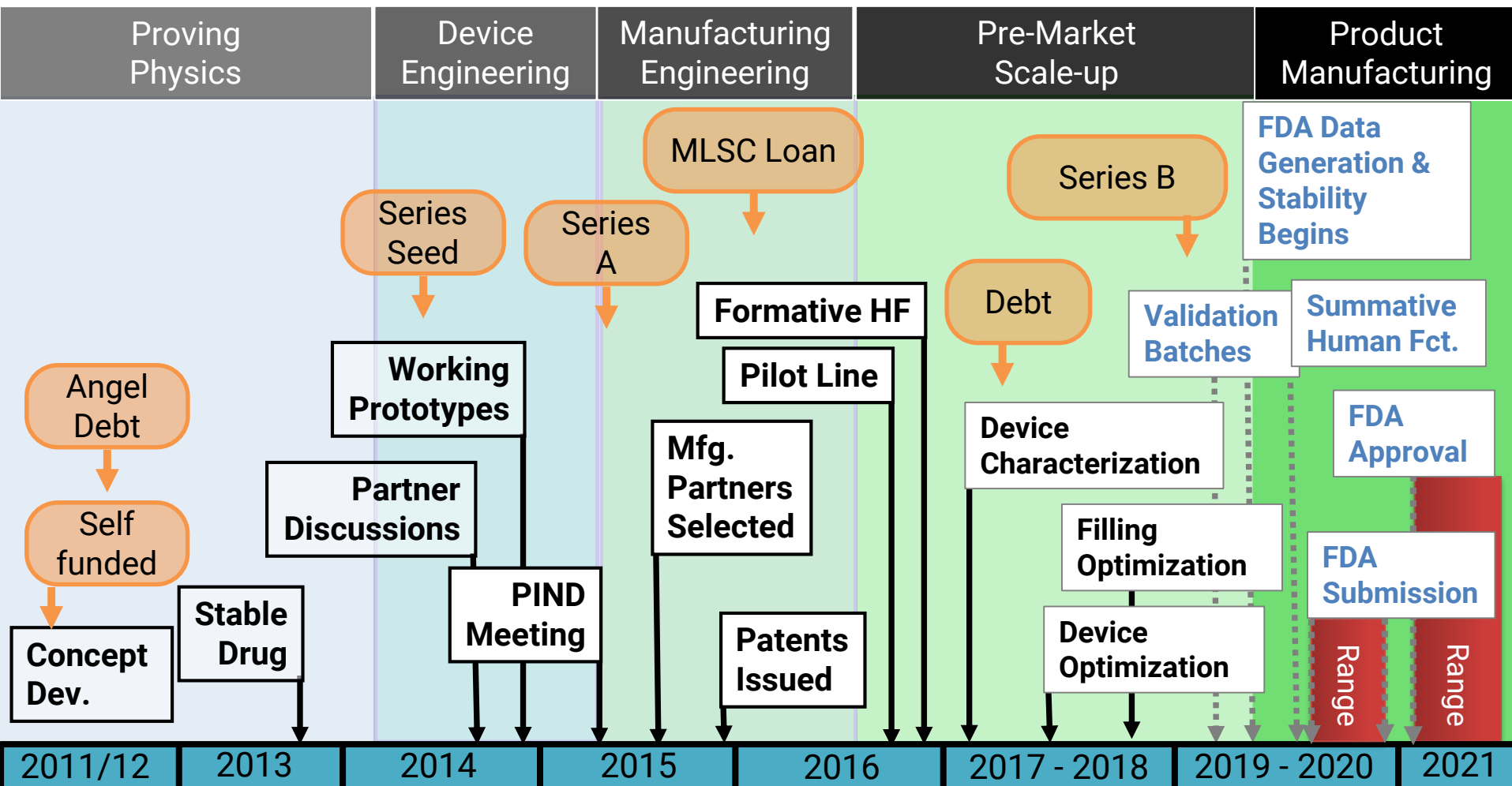
* Opportunity to decrease TTM with 6 months of submission data vs. waiting for 12 months

MARKET SHARE ANALYSIS

- 2017: Mylan's end-of-lifecycle EpiPen strategy
 - End advertising and fired pharma reps
 - Chiral purity and longevity = potency
 - **ANDIEpi targeting 60% market share with strong differentiation, compelling shelf life, and chiral purity**
- 2013: Launch of Auvi-Q led to peak market share (sales \$) in 16 months
 - Strong headwinds by Mylan in US resulted in a 13.4% market share
 - Auvi-Q Canada launch resulted in 30% market share without marketing - no headwinds by Mylan
 - ANDIEpi's worst-case 25% capture of existing + new patients = conservative for a highly differentiated product

<https://www.policymed.com/2017/05/sanofi-and-mylan-are-preparing-to-duke-it-out-in-court.html>

EPI COMMERCIALIZATION TIMELINE



EPINEPHRINE REVENUE MODEL

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END

REGULATORY ATTORNEY



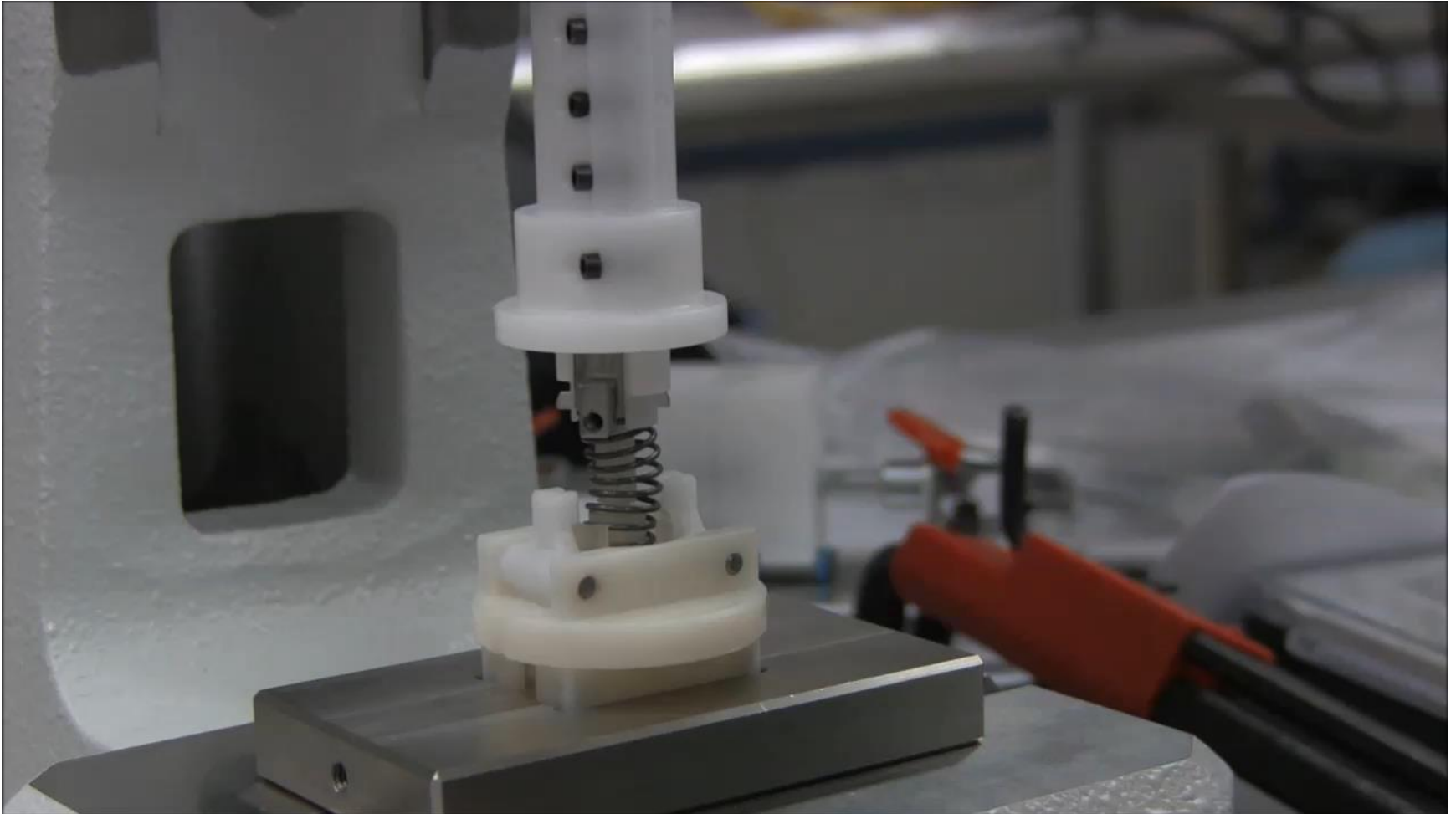
David Rosen

Partner

Foley & Lardner, LLP

- 14 years at the FDA
- Assisted in drafting the orange book
- Combination products expert
- 505(b)(2) filing expert
- Experience working on other epinephrine products for anaphylaxis

ANDIPEN[®] ASSEMBLY



CANNULATION AUTOMATION SYSTEM



POWDER FILL/FINISH



DISSOLUTION TEST STATION

Dissolution Test Station
Test Sample 6
Adam Standley
Dir. Prod. Dev.
MAY 01 2017

FORMATIVE HUMAN FACTORS SUMMARY

