



UTULY™ (NDS1C): A Development Story

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The Bryn Pharma Story



- ▶ Started with an idea in November 2017 – to build a non-needle product that was better than an EpiPen for the treatment of severe allergies including anaphylaxis
- ▶ My two partners – an interesting story:
 - One is a retired PE partner – no life science experience
 - One was a COO of a manufacturing business in the clothing/fashion industry – but is anaphylactic as well as two of her children
 - Connected to me via a network connection to bring on pharma development experience
- ▶ Raised first round of seed capital in December 2017
- ▶ Started pre-clinical work in 2018
- ▶ Filed the IND and started clinical work in 2019
- ▶ Ran the company with three people with input from corporate advisors and outsourcing partners
- ▶ Complete out-sourcing model
- ▶ 2018 – 2022; did five rounds of fund-raising totaling about \$100MM

Starting at the end.....



The current US anaphylaxis market is dominated by auto-injector devices



Epinephrine Auto-Injectors (EAI)

Manual Syringes



Market leader with branded and authorized generic options



Branded EAI alternative with perceived superior form factor to EpiPen



Generic and branded EAI alternative with limited adoption



Syringe and vial kits primarily for hospital use



Branded pre-filled syringe with limited adoption

Current US anaphylaxis market overview

- Auto-injectors account for ~90-95% of anaphylaxis injectable volume market share in 2021, mostly used in the out-patient setting.
- **Branded EpiPen** accounted for **~2% volume share in 2021**, with its low share attributed to launch of generic EpiPen.
- **AUVI-Q** accounted for **~4%** share by volume in the epinephrine market for 2021
- Adrenaclick was discontinued in 2012 by Shiongi and relaunched by Amedra in 2013
- Symjepi accounted for **<1%** epinephrine volume market share in 2021

SOURCES: IQVIA MIDAS, Business Insider, 2016; Gov.info, 2016; FDA.gov; FDA.gov; Forbes, 2017
<https://www.fortunebusinessinsights.com/epinephrine-market-104291>

UTULY™ potential clinical profile based on completed studies¹



Patient-driven solution addressing key barriers associated with EpiPen® and other comparable autoinjectors

- ✓ Potential **best-in-class PK release profile** (T-max, C-max, AUC) compared to EpiPen®¹ which is the current market standard. Works quickly with similar epinephrine concentration levels in first 10 minutes post-dose compared to EpiPen®¹, provides therapeutic levels of epinephrine twice as long as an EpiPen®, and has potential dosing advantages
- ✓ PD response (HR and blood pressure) comparable to EpiPen®¹
- ✓ Congestion improves absorption
- ✓ Safe and well tolerated without added risks of needle injection
- ✓ Convenient and easy-to-use. In HF studies, children as young as 8-years have been able to use the product correctly
- ✓ No difference between nurse and self-administration
- ✓ Faster time-to-treat as patients indicate willingness to use UTULY™ 5-10 minutes sooner than an autoinjector such as EpiPen®

¹All UTULY™ profile attributes are based on numerous completed clinical studies comparing UTULY™ to EpiPen® Authorized Generic (Viatris) and manual syringe injections of epinephrine. Statements relative to competing epinephrine options are based on an assessment of UTULY™ clinical study results and published results for competing products

How did we get here?



A Long Journey



- ▶ Started with an idea based on a clear and recognized unmet patient and medical need – Replacing an EpiPen with a better product
- ▶ Finding funding sources – building value and investors over time in a step-wise manner
 - Develop a realistic plan, time and cost estimate
 - Spend time and money to get realistic inputs, guidance and advice
 - Manage your expectations
 - Starting with like-minded friends, family, angel, foundations, small business grants
 - Can you sell your story?
 - Develop proof of concept
 - Pre-clinical model?
 - Demonstration of feasibility
 - Is there a need?
 - Is there a market that warrants the investment for return?
 - Competition?
 - IP?

Building Value Based Milestones

- ▶ The development plan becomes essential:
 - Focus on the answer to a very basic question: “What do you want to be when you grow up?”
 - Know what you want to do/have to do by when
 - Remember everything will take longer and cost more than you think
 - Develop a realistic budget to achieve that goal + contingencies
 - Ensure that you have the right team (internal and/or external) to accomplish the goal and demonstrate that you have the wherewithal to get things done
- ▶ Focus on the essentials defined in the plan
 - How much money do you need to accomplish that milestone?
 - How long will it take to get there?
 - Manage your cash and burn rate to be able to reach the milestone
 - Easier said than done

Building Value Based Milestones

- ▶ Once you know that, then:
 - What does the end product/data package have to be at each milestone?
 - What is the fastest, cheapest and more expeditious path to that end?
 - Define what do you REALLY need when – don't get distracted with what would be “nice” to have
 - Define what data do you REALLY need to reduce risk?
 - Development risk
 - Clinical, CMC, tox, safety, etc.
 - Regulatory risk
 - Conduit to/from FDA
 - IP risk
 - No/weak IP – skeptical/no investor
 - Investor risk
 - Exit and multiples
- ▶ Meeting milestones translates to higher valuations

Building Value Based Milestones



- ▶ Stage your fund raise:
 - Investors invest in people (management team) with good science and a real opportunity
 - Understand where and how much are you willing to give up in control and/or ownership
 - Dilution and control issues are real and cannot be ignored
 - Raise enough to get you to milestones plus contingency
 - Chose your money sources carefully
 - Not all funding sources are equal or be of strategic value; all have pros and cons
 - Not all funding sources will have money to invest, nor will they be willing to invest in the stage your company is in
 - You will need to kiss a many “frogs” to find your “prince”
 - Remember, you are selling your story to a skeptical investor who is risk averse and looking for a profitable exit
 - How do you stand out over other possible investments they are considering?
 - Can you find their sweet spot?
 - Always raise money when you still have some to spend
 - Don't look desperate
 - Achievement of each milestone increases valuation
 - Achievement of each milestone changes your funding requirements and universe of possible funding sources

It's Doable

- ▶ If it was easy, anyone could do it
- ▶ Science, credibility, value and passion are requirements
- ▶ Patience and tenacity – don't give up
 - You will hear hundreds of “no's” to a few “maybe's” and 1-2 “yes's”
 - Take criticism politely and use what they say to adjust, revise and/or change your message
 - Keep close to all contacts as:
 - People move between investment groups
 - Investment criteria change
 - Funding sources change
 - Relay progress and positive news
- ▶ Lastly, remember the difficult stuff takes a while to do, the impossible a little bit longer.....



Questions & Discussion