

UNC/Duke Case Competition 2020



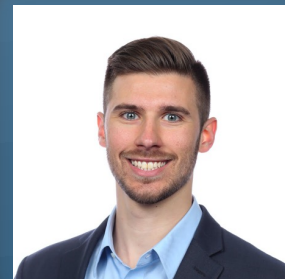
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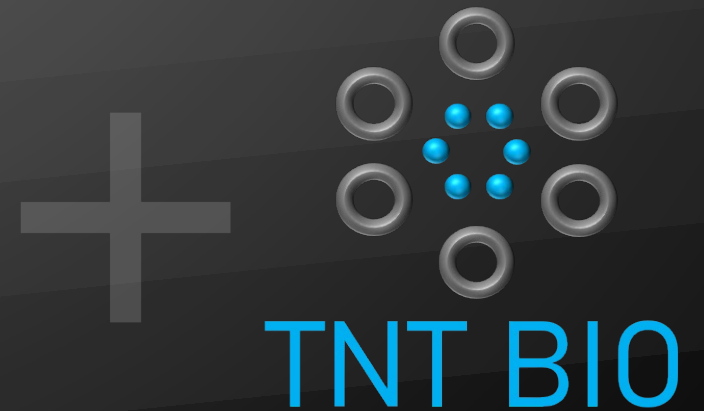
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Blasting away the toughest immune conditions

0 Executive Summary + Introduction

I Competition

II Market size

III Value to stakeholders

IV Likelihood of approval

V Conclusion

Situation

- TNT Bio is a public, small-to-mid sized biopharma company focused on developing immunology medicines
- They are seeking to expand 1 of 2 existing immunology assets into atopic dermatitis (AD)

Recommendation

TNT Bio should focus on TNT-002 for its strategic expansion into atopic dermatitis

Key question

Which one of these two assets should be entered into phase I clinical development for AD?



TNT-013



TNT-002

Impact

Achieve \$1.13 B peak annual sales in the atopic dermatitis space

SCENARIO: TNT Bio is seeking to expand **one** of their existing immunology assets into atopic dermatitis (AD)



TNT-013

Injectable anti-IL-13 monoclonal antibody
Completed Phase II testing for asthma



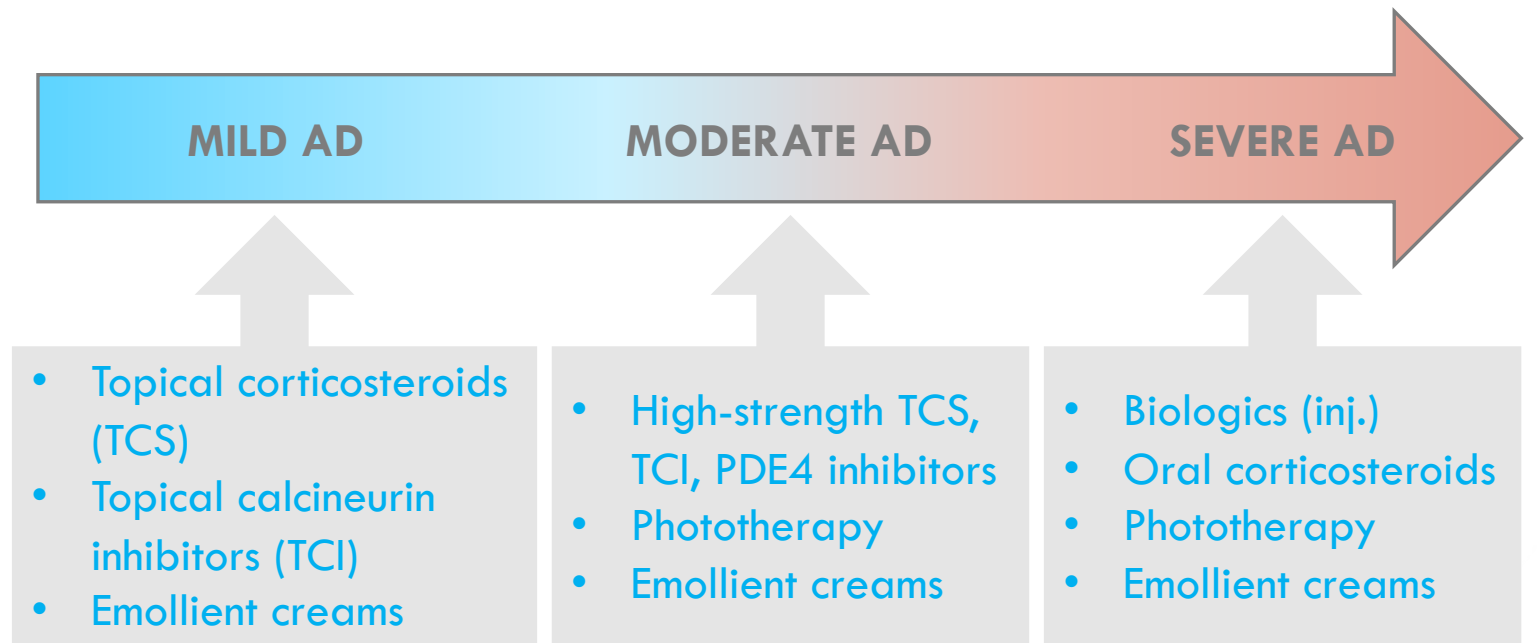
TNT-002

Topical TYK2 inhibitor
Currently in Phase I testing for RA

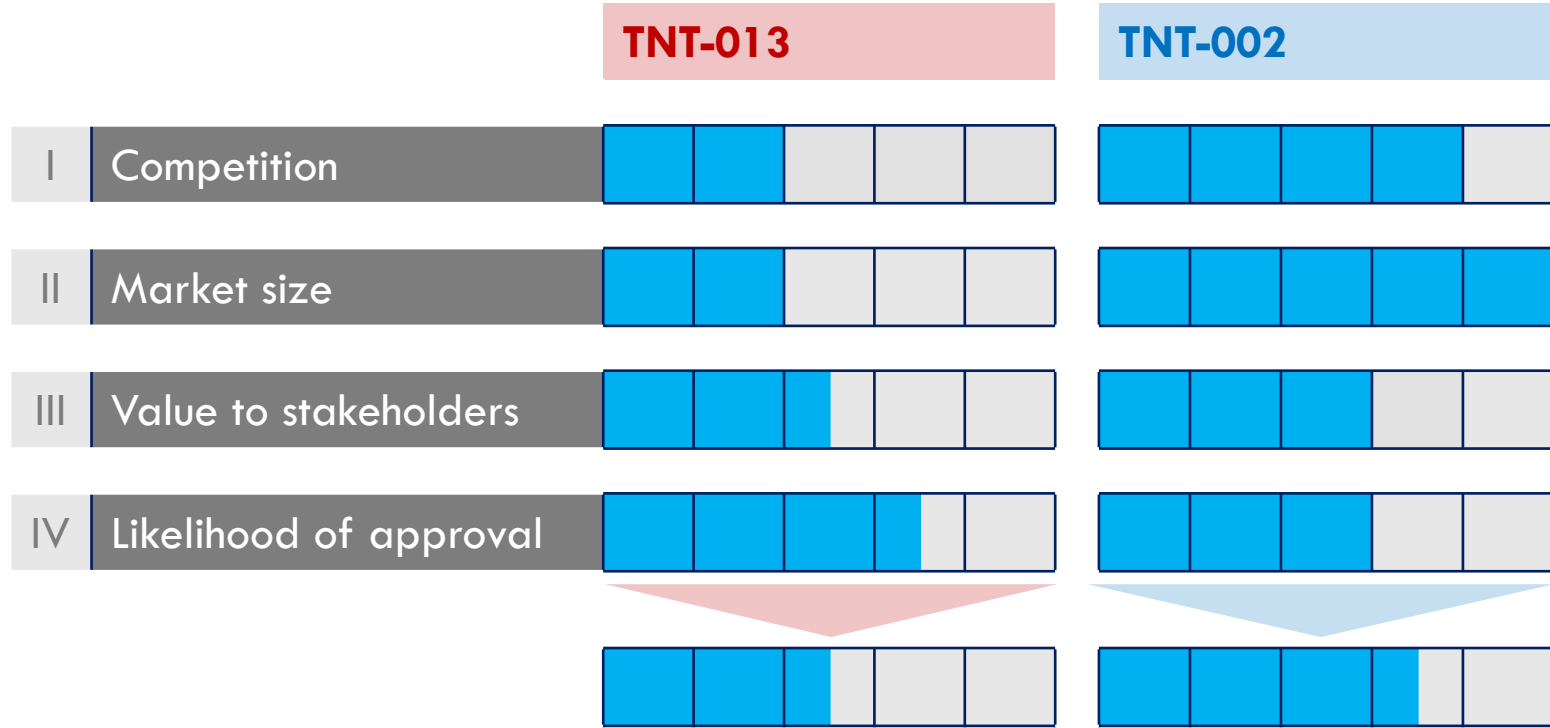
GOAL: Evaluate the opportunity for each program and recommend one agent to develop in AD

7.3% US adult AD prevalence

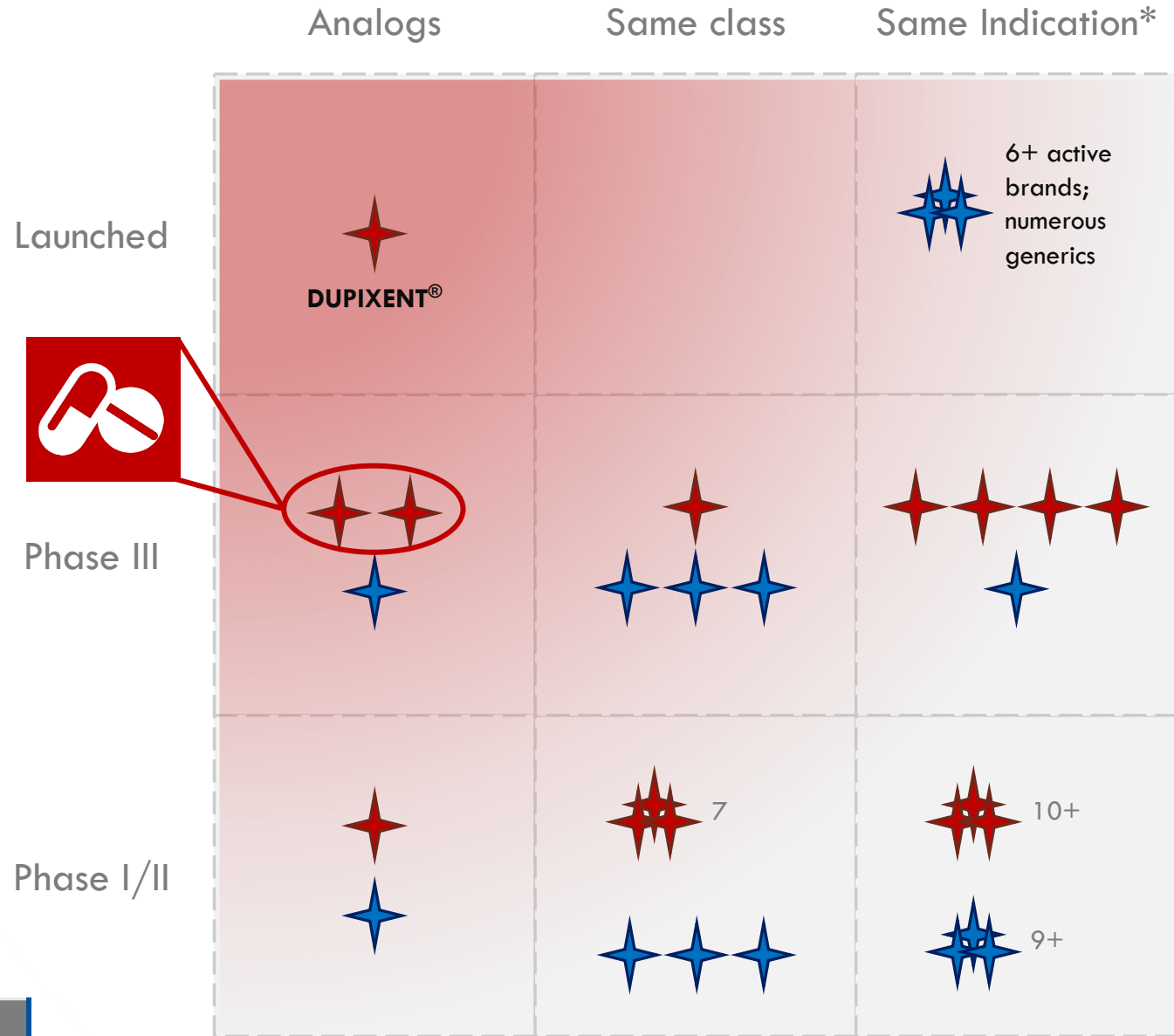
10.7% US child AD prevalence





TNT Bio should focus on developing TNT-002 for atopic dermatitis based on performance across 4 categories:



Current competitive dynamics heavily favor TNT-002



- DUPIXENT® is an entrenched competitor for **TNT-013**
- **TNT-013** is threatened by ph. III analogs that boast oral routes of administration
- Despite a saturated topical market, **TNT-002** does not yet have any launched class competitors

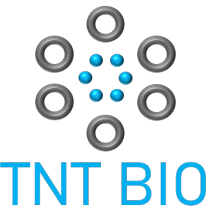
 TNT-013 comparator, moderate-to-severe AD
 TNT-002 comparator, mild-to-moderate AD

Color intensity = threat of competition (illustrative)

*“Analog” = overlapping indication + mechanism of action

* Pipeline drugs without a disease severity focus were excluded

TNT-002 can achieve >5x the market share of TNT-013



Competitor	2020	2021	2022	2023	2024	'25 – '29
TNT-013 Competition	DUPIXENT®	Pediatric expansion		Infant expansion		
	Lebrikizumab		Approval (65%)			
	Tralokinumab			Approval (68%)		
	ASLAN004					Approval (16%)
	Other class comparators		Approval (68%)			Approvals x7 (16 – 24%)
	Indication competitors			Approvals x4 (61 – 71%)		Approvals x10 (16 – 24%)
TNT-002 Competition	Ruxolitinib Cream	Completing ph. III	Approval (62%)			
	PF-06700841			Approval (24%)		
	Other class comparators		Approvals x3 (68 – 71%)		Approvals x3 (16 – 27%)	
	Indication competitors		Approval (71%)		Approvals x7 (16 – 24%)	

Projected competition:

- 2 analogs
- 2 class competitors
- 4 other competitors

Adjusted market opportunity for **TNT-013: 7.2% market share**

Projected competition:

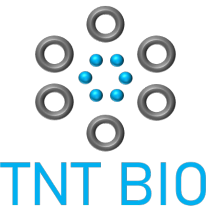
- 1 analog
- 3 class competitors
- 2 other competitors

Adjusted market opportunity for **TNT-002: 40.3% market share**

(xx%)—likelihood of approval. Analog—overlapping indication + mechanism of action.

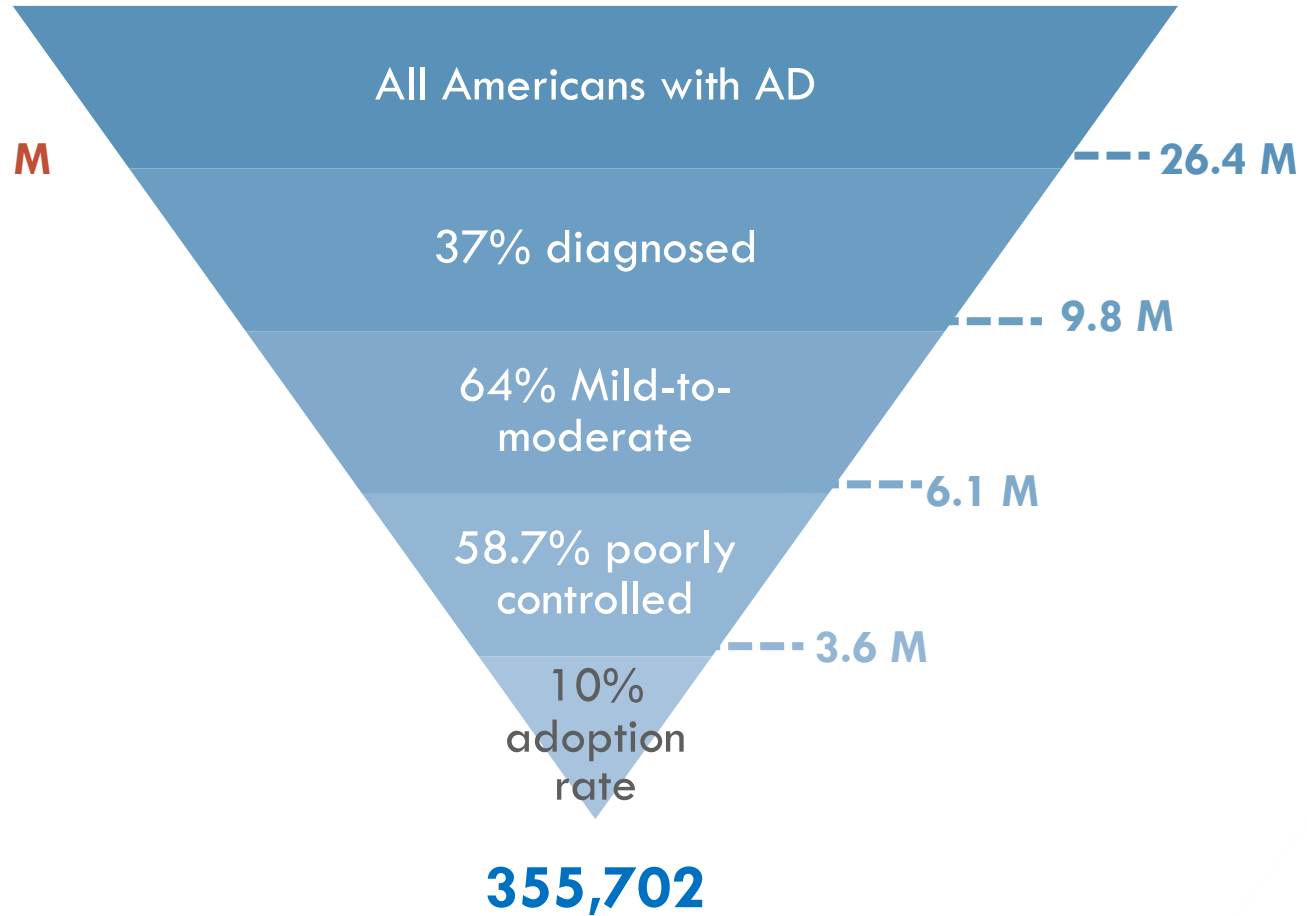
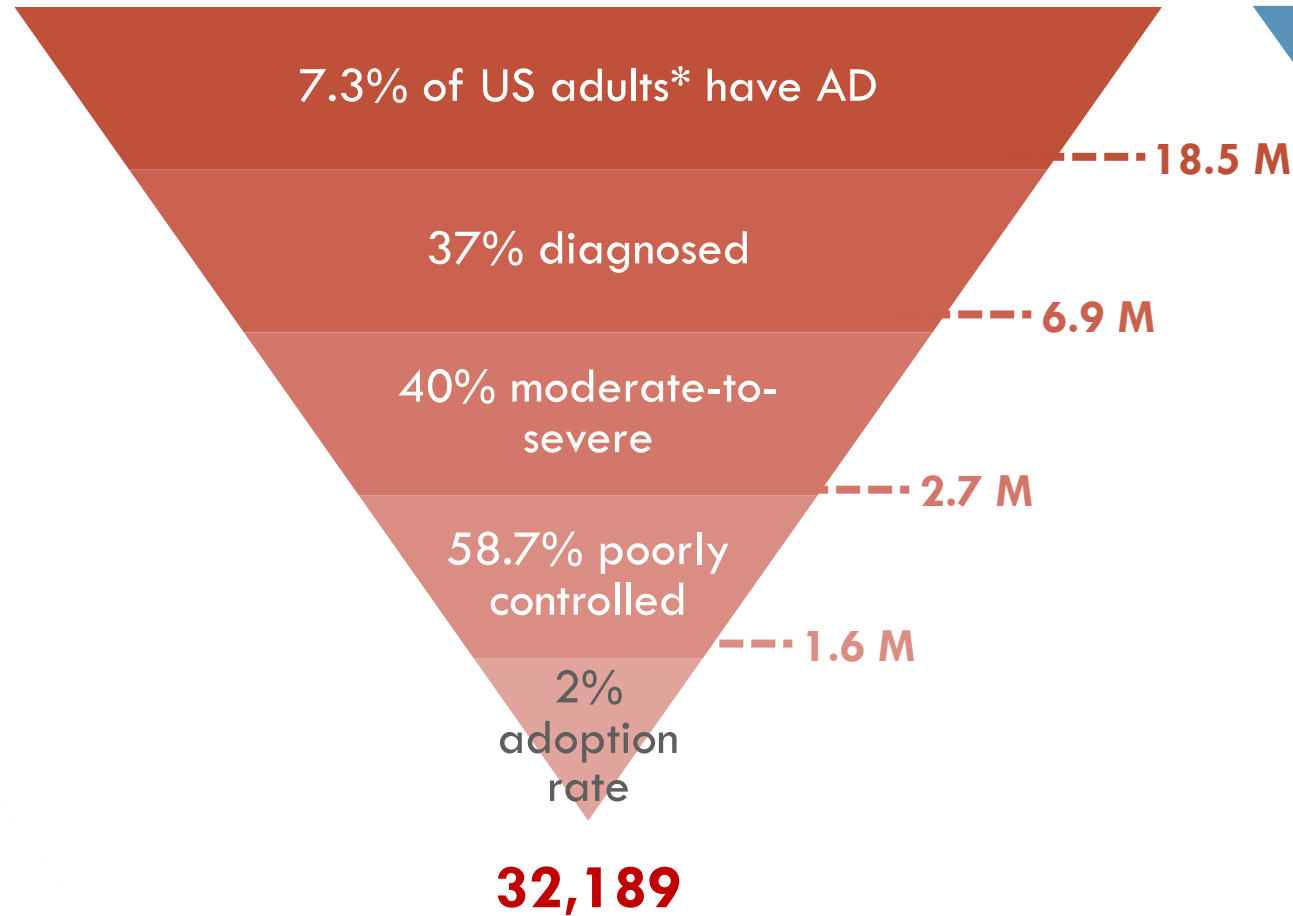


TNT-002 has the largest eligible patient population



TNT-013

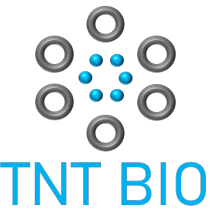
TNT-002





*Upon indication expansion, TNT-013 could additionally be used in a population of 11,258 children with uncontrolled moderate-to-severe AD



TNT-002 offers the largest commercial opportunity



Attribute			TNT-013 	TNT-002 
Revenue potential per patient			\$43,542/year*	\$7,827/year**
Patient Segment	Mild-to-moderate	Children	-	355,702 patients
		Adults	-	
	Moderate-to-severe	Adults	32,189 patients	-
Market size			\$1.4 B/year	\$2.8 B/year
Market share			7.2%	40.3%

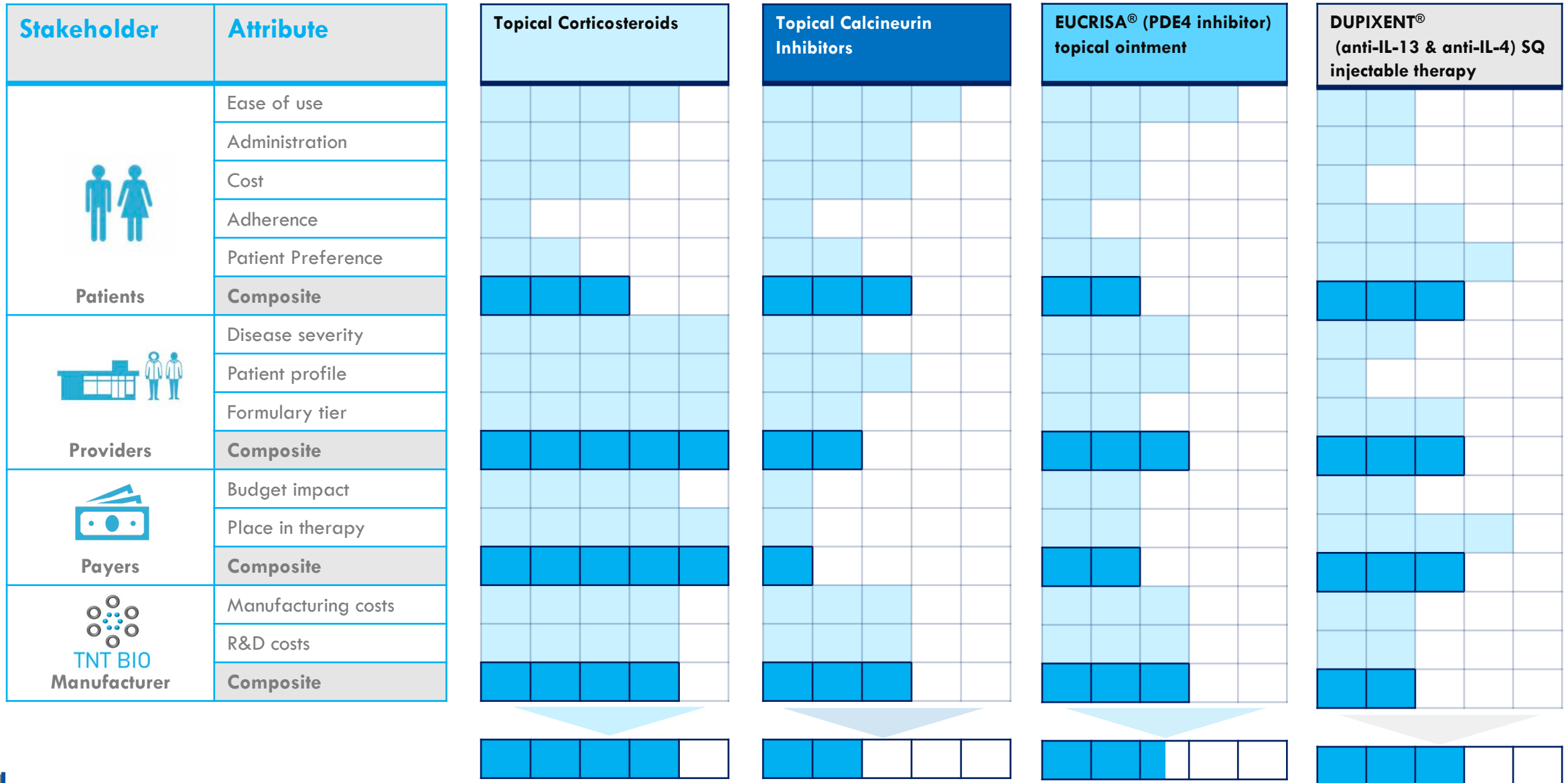
Peak annual sales	\$101 M/year	\$1.13 B/year
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*Based on wholesale acquisition cost of leading marketed competitor Dupixent

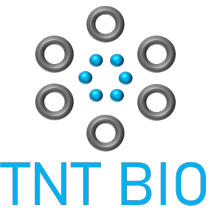
**Based on wholesale acquisition cost of leading marketed competitor Eucrisa




Across current AD therapies, topical corticosteroids provide greatest value




Regulatory approval odds of co-developing indications



TNT-013 may allow for greater efficiency in atopic dermatitis launch over TNT-002

 TNT-013: Asthma Clinical Development			
<i>Phase 1</i>	<i>Phase 2</i>	<i>Phase 3</i>	<i>Approval</i>
Completed (100%)	Completed (100%)	71.1%	94.6%

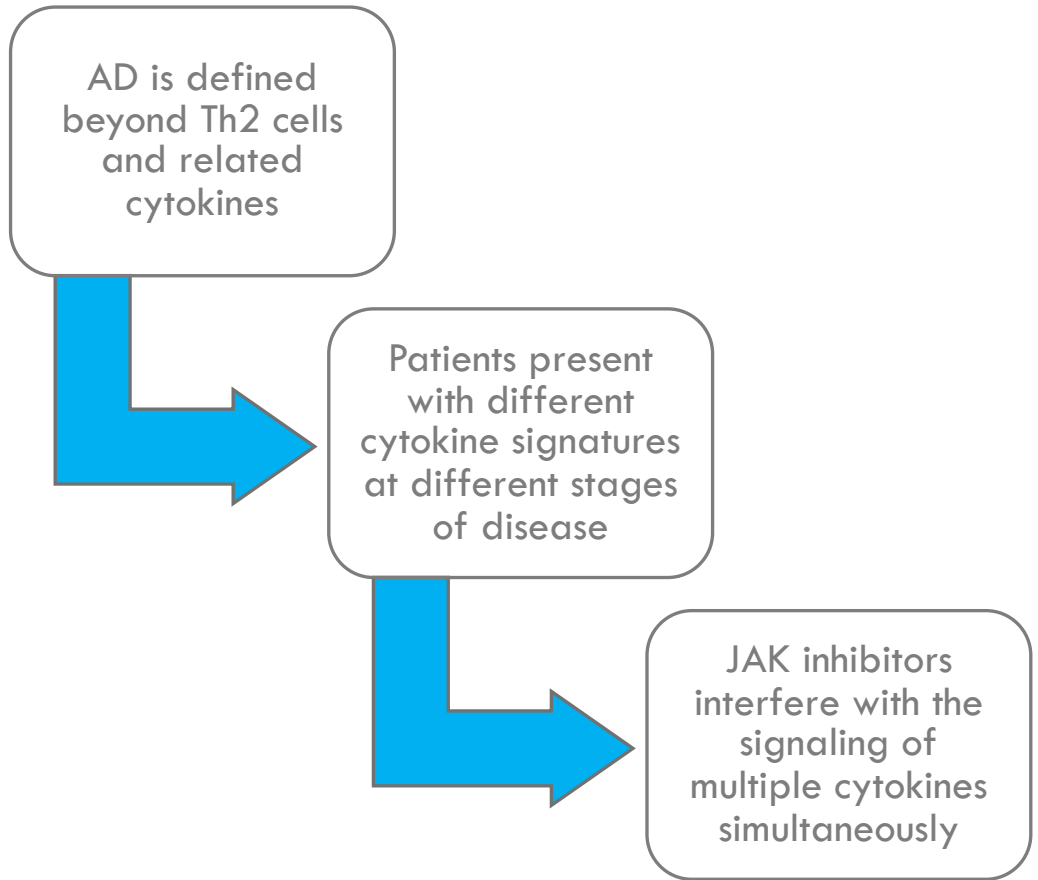
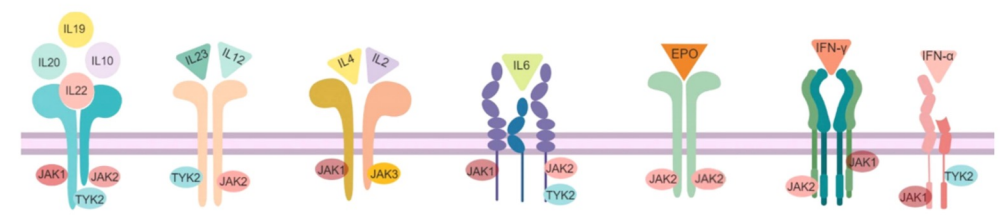
67.2% chance of approval

 TNT-002: Rheumatoid Arthritis Clinical Development			
<i>Phase 1</i>	<i>Phase 2</i>	<i>Phase 3</i>	<i>Approval</i>
65.7%	31.7%	62.2%	86.0%

11.1% chance of approval



TNT-002 may align more closely with growing rhetoric in the atopic dermatitis space

	IL-10 family receptor	Cytokine sharing the IL-12Rβ1	Cytokine receptor sharing the γ-chain	Cytokine receptor sharing the gp130	Homodimeric cytokine receptor	IFN-γ receptor	IFN-α receptor
PAN-JAK INHIBITORS	+	+	+	+	+	+	+
delgocitinib							
peficitinib							
JAK1 JAK3 INHIBITORS	+	-	+	+	-	+	+
tofacitinib							
ATI-501							
ATI-502							
JAK1 JAK2 INHIBITORS	+	+	+	+	+	+	+
saricitinib							
CTP-543							
ipadacitinib							
ruxofitinib							
JAK1 TYK2 INHIBITORS	+	+	+	+	-	+	+
F06700841							
JAK1 INHIBITORS	+	-	+	+	-	+	+
tacitinib							
PF-04965842							
olicitinib							
INC8054707							
ilgotinib							
JAK2 INHIBITORS	+	+	-	+	+	+	-
iecritinib							
GSK2586184							
JAK3 INHIBITORS	-	-	+	-	-	-	-
F-06651600							
TYK2 INHIBITORS	+	+	-	+	-	-	+
F-06835375							
BMS986165							

Solimani F, et al. Front Immunol. 2019.
 Weidinger S, et al. Lancet. 2016.
 Amano W, et al. J Allergy Clin Immunol. 2015.

Competition	Market size	Value to stakeholders	Likelihood of approval
<ul style="list-style-type: none">• Threat of competition is determined by development stage & overlap in MoA, indication, and route of administration• Competition reduces commercial opportunity by:<ul style="list-style-type: none">• 70% for analogs with more convenient RoA• 50% for other analogs• 5% for class competitors• 3% for indication competitors• TNT-013 will pursue moderate-to-severe AD indication and TNT-002 will pursue mild-to-moderate indication	<ul style="list-style-type: none">• Assumptions and statistics are based on scientific literature and market research:<ul style="list-style-type: none">• 37% diagnosis and treatment rate¹• 40% of adults have moderate-to-severe AD²• 33% of children have moderate-to-severe AD³• 58.7% of patients' AD is uncontrolled (on or off treatment)⁴• 2% adoption rate for TNT-013• 10% adoption rate for TNT-002	<ul style="list-style-type: none">• Stakeholder values extrapolated from current literature on currently-approved medicines	<ul style="list-style-type: none">• Both TNT-013 and TNT-002 gain FDA approval without significant hurdles and/or complications during the drug development process

¹Hanifin JM, et al. *Dermatitis*. 2007

²AD in America PDF. www.aafa.org

³Boguniewicz M, et al. *Ann Allergy Asthma Immunol*. 2018

⁴Wei W, et al. *J Dermatol*. 2018



Recommendation:

TNT Bio should focus on TNT-002 for its strategic expansion into atopic dermatitis



Rationale

- TNT-002 has a more favorable competitive landscape
- TNT-002 has a potential blockbuster market opportunity
- TNT-002 has a novel mechanism of action that brings more value to stakeholders



Risks

- No discernible market advantage over analogs, so market share capture is not guaranteed
- Potentially less workforce synergy when pursuing AD indication for TNT-002 instead of TNT-013
- No commercial roadmap as of yet for medicines in this class in AD



Next steps

- Determine optimal pricing with quantitative market research
- Research global market opportunities
- Consider finding a partner with a global immunology commercial team

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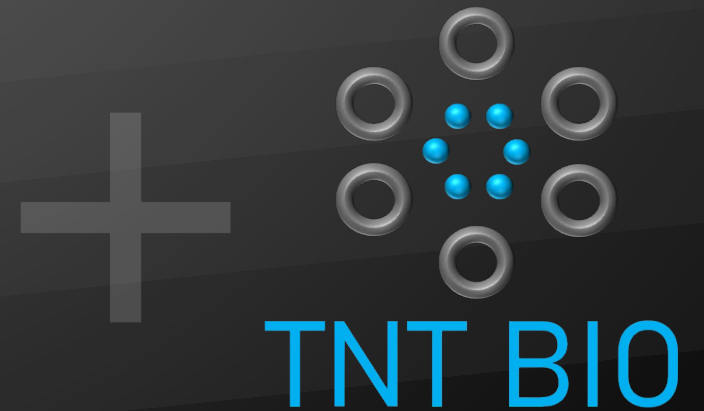
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