



# **4B HealthCare**

**Better Breathing Solutions**

*AS PRESENTED ON 11/06/2025*

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## Brannon Mangus, MD

### Co-Founder & Chief Executive Officer

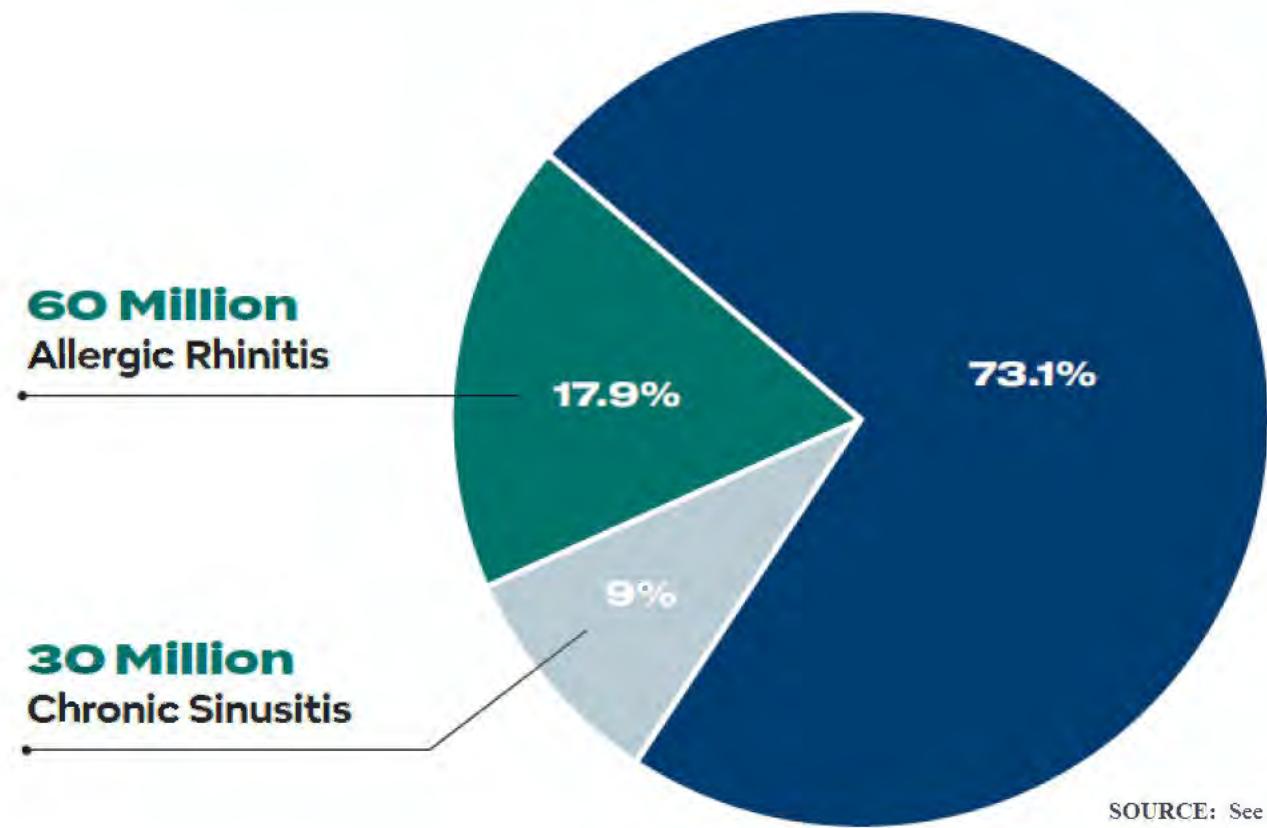
- 15+ years practicing surgeon in the ENT/Sinus/Allergy fields (*active*); treated 40,000+ patients
- Residency training in Otolaryngology, Head and Neck Surgery @ Vanderbilt University; in 2025 VUMC was rated by Doximity Residency Navigator the #1 residency program in its field in the US, by reputation, for the 5th consecutive year
- President of the Board of Directors of Murfreesboro Medical Clinic, Inc. (“MMC”) from 2021-24; MMC is a multi-specialty, multi-site healthcare provider organization with 100+ physicians, \$150 million+ revenue, and 1,000+ employees
- In 12 years at MMC, served multiple terms on Board of Directors, served as Chair and Member of Finance Committee, served on various other standing Committees that govern the affairs of the organization, and served as Department Chair of ENT Department and current acting senior physician in the department of 13 providers.

## Matthew Stearns, MBA/JD

### Co-Founder & Senior Advisor

- 10+ years in healthcare executive management as Chief Financial Officer (CFO); 2x private equity (PE) CFO for healthcare PE portfolio companies (*active*)
- B.A. in economics @ Harvard University; MBA/JD from Vanderbilt University
- 10+ years working with PE and VC firms in the healthcare industry; transacted \$600 million+ in total capitalization (equity & debt) in M&A and corporate financings
- Prior to finance, worked 7 years in operations senior management in high-growth, publicly-traded capital construction services company
- Attorney licensed to practice in Tennessee; since 2019 engaged in small boutique practice focused exclusively on select corporate work in Middle Tennessee

Prevalence of Allergic Rhinitis & Chronic Sinusitis  
in the United States



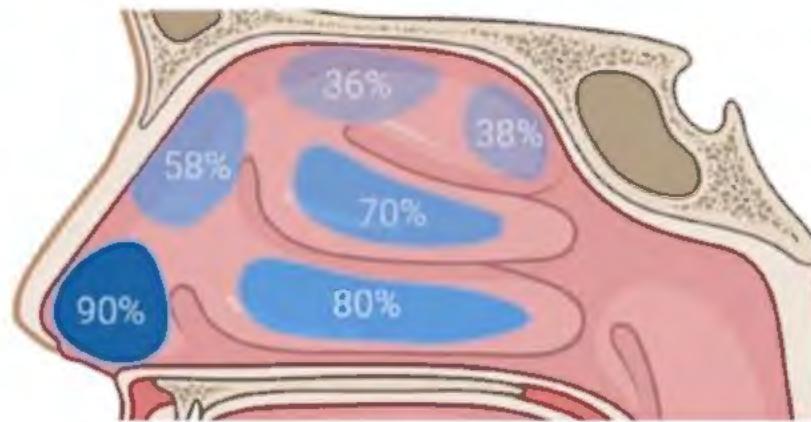
SOURCE: See later slide "Sources," S6.1

## Treatment Options for Allergic Rhinitis



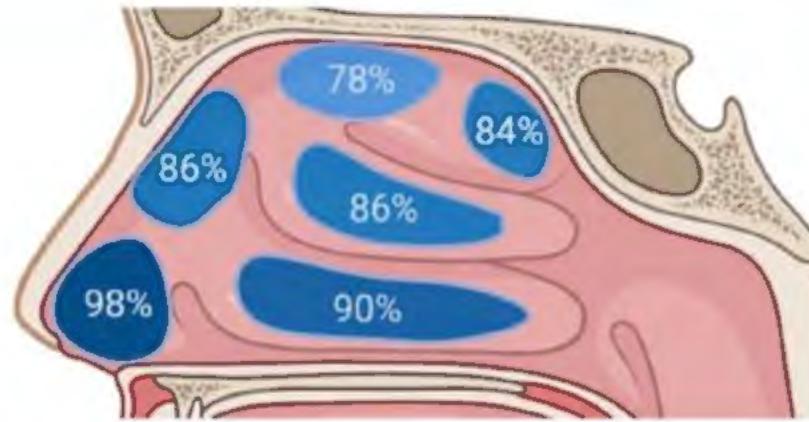
Allergic Rhinitis market to reach \$14 Billion globally due to widespread adoption of nasal steroid sprays

SOURCE: See later slide "Sources," S7.1



## NASAL SPRAY EFFECTS

SOURCE: See later slide "Sources," S8.1



## NASAL IRRIGATION EFFECTS

- **STEROID NASAL SPRAY** – (1) Contain the steroid medication needed to treat inflammation and other symptoms of Allergic Rhinitis, BUT (2) are INEFFECTIVE at delivering the steroid to the entire nasal cavity and furthermore the volume and mass of the spray liquids is INEFFECTIVE at producing enough force to dislodge and rinse away pollen and other irritant particles.

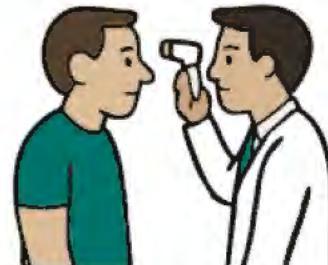
### VERSUS

- **SALINE NASAL RINSE** – (1) Effective at reaching the entire nasal cavity and the volume and mass of the rinses is effective at producing enough force to dislodge and rinse away pollen and other irritant particles, BUT (2) do NOT contain the steroid medication needed to treat inflammation and other symptoms of AR.

Treatment Modality	Contains Steroid Medication?	Effective at Reaching Entire Nasal Cavity?	Enough Force to Dislodge Irritant Particles?
Nasal Spray	 YES ✓	NO ✗	NO ✗
Nasal Rinse	 NO ✗	YES ✓	YES ✓



- In response to the complementary deficiencies of the Steroid Spray versus the Saline Rinse, approximately 20-25 years ago, ENT physicians developed a workaround by instructing patients to combine the two therapies.
- Specifically, the ENT physician would write an off-label Rx prescription for the patient for Budesonide capsules, which would then be filled by a Specialty compound pharmacy.
- Separately, the patient would purchase a nasal saline rinse kit OTC from Walgreens or CVS, and then, at home, the patient would prepare the saline rinse and then, by hand, crack open the Budesonide capsules and pour the steroid powder into the prepared saline rinse.
- The end result was a **STEROID NASAL SALINE RINSE** treatment therapy.
- This method of procedure is allowed under the laws that govern the practice of medicine by duly-licensed physicians, but, to be clear, **this treatment has NOT been studied or approved by the FDA**.

**SEE ENT****HAND MAKE  
BUDESONIDE CAPSULE****SEND VIA FedEx****EMPTY SALT  
PACKET****OPEN  
BUDESONIDE  
CAPSULE****ADD  
DISTILLED  
WATER****RINSE  
NOSE**

**Over 40 Studies Concerning the Efficacy and Safety  
of Nasal Steroid Rinses**

There is a compelling market opportunity to develop and commercialize an FDA approved, high-volume, steroid-based nasal irrigation product.

High-volume, low-pressure steroid nasal irrigations (especially budesonide-based) are superior to nasal sprays:

- Drug delivery to the olfactory cleft, ethmoid, and paranasal sinuses
- Symptom control in chronic rhinosinusitis (CRS), nasal polyposis, and allergic rhinitis (AR)
- Safety, with minimal systemic absorption, even with long-term use

FEATURE	IMPLICATION
Scientific Consensus	Strong, consistent evidence across >40 studies supports safety and efficacy of budesonide nasal irrigation
Clinical Gap	No FDA-approved, branded steroid irrigation product exists - current use is all off-label
Device Innovation	Delivery method (high-volume, low-pressure rinse) is as important as the drug
IP Opportunity	New formulations, combinations (e.g., budesonide + azelastine), and delivery systems are patentable
Market Readiness	ENTs and allergists already prescribe budesonide irrigation off-label - pre-validated market
Unmet Need	Many patients fail nasal sprays and don't want or qualify for surgery - large underserved segment

### We Have A Rare Convergence Of:

STRONG CLINICAL EVIDENCE

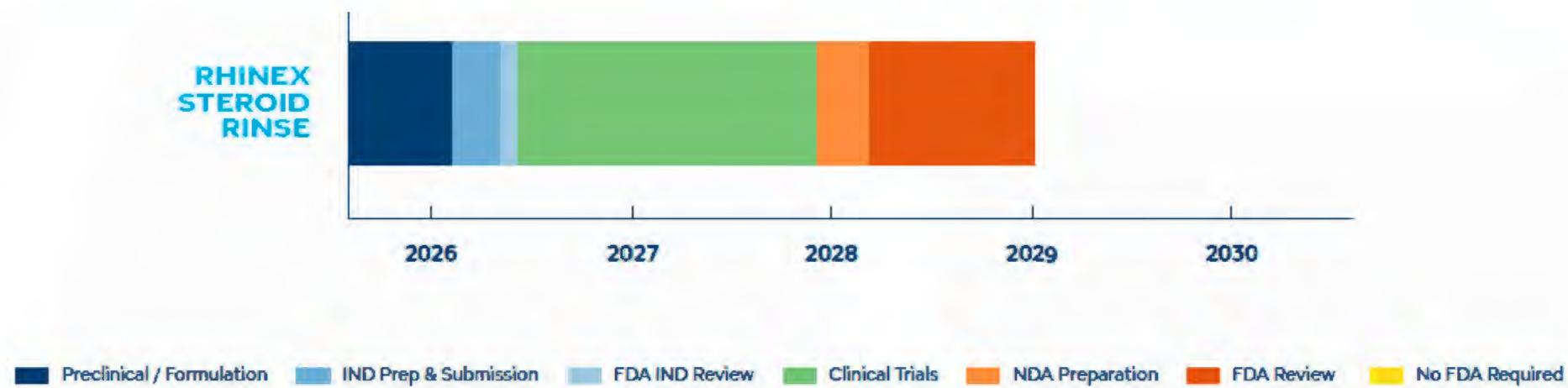
PROVEN MARKET DEMAND

NO FDA-APPROVED COMPETITOR

FAVORABLE REGULATORY PATHWAY

Textbook example of new venture “product-market fit” in the Pharma start-up space presenting opportunity for investment returns in the top 5% across all asset classes.



**Development Timeline for FDA Regulatory Pathway (505(B)(2)**

## START @ INITIAL IDEA (July 2024)

Product Concept Development



Scientific Research- Initial



Market Research- Initial



Preclinical Formulation



Marketing- Product Design &amp; Branding- Initial



Legal- Corporate Formation



Financing- Seed Stage



FDA SME Consultant



Legal- Intellectual Property- Patent &amp; Trademark



Advisory Board (KOLs &amp; SMEs)



FDA Pre-IND- Company Preparation &amp; Submission



FDA Pre-IND- FDA Review &amp; Feedback (Approval)



Scientific Research- Final



Market Research- Final



FDA- Contract Research Organization (CRO)



FDA- Contract Manufacturing Organization (CMO)



Financing- Series A

FDA Clinical Trials- Phase I

FDA Clinical Trials- Phase II

FDA Clinical Trials- Phase III

FDA NDA- Preparation &amp; Submission

FDA NDA- FDA Review &amp; Feedback (Approval)

CMS &amp; Commercial Insurance- Access &amp; Coverage

Marketing- Pre-Commercialization- Final

Manufacturing

Logistics &amp; Distribution

YOU ARE HERE ! →

## FINISH @ COMMERCIALIZATION ACHIEVED (Fcst 2029)

## CURRENT STATUS:

- All of the work required before FDA Clinical Trials is now **COMPLETE**
- Now **READY TO BEGIN** Clinical Trials (Phase I)
- Following slides will highlight some of the **KEY POINTS** from the milestone schedule

					
<b>TURNER</b> <i>Birmingham, AL</i> ENT PRACTICE, RESEARCH, TEACHING & KEY OPINION LEADER	<b>SAIN</b> <i>Murfreesboro, TN</i> RETAIL PHARMA SPECIALITY PHARMA; VENTURE GROWTH, LEADERSHIP & EXIT	<b>PATEL</b> <i>Murfreesboro, TN</i> INTERNAL MEDICINE PRIMARY CARE; ORGANIZATIONAL GROWTH & LEADERSHIP	<b>AYER</b> <i>Murfreesboro, TN</i> FINANCE & PRIVATE INVESTMENT; EXTERNAL CAPITAL FORMATION; VENTURE GROWTH & LEADERSHIP	<b>MAYNARD</b> <i>Clarksville, IN</i> FINANCE & INVESTMENT; EQUITY ANALYSIS; PHARMA & BIOTECH BUY-SIDE ANALYSIS	<b>MCRACKAN</b> <i>Charleston, SC</i> ENT PRACTICE, RESEARCH & TEACHING



## Rodney Schlosser, MD

Director of Rhinology and Sinus Surgery at The Nose & Sinus Center and Professor at Medical University of South Carolina (MUSC)

- **Academic and Clinical Leadership:** Dr. Rodney Schlosser is a Professor at the Medical University of South Carolina (MUSC) and serves as Director of Rhinology and Sinus Surgery at The Nose & Sinus Center, where he leads one of the Southeast's foremost programs for complex sinus and nasal disorders.
- **Specialized Expertise:** The only fellowship-trained adult and pediatric sinus surgeon in South Carolina, Dr. Schlosser's clinical focus includes advanced endoscopic sinus and skull base surgery, nasal obstruction, sinonasal tumors, cerebrospinal fluid leaks, and revision sinus procedures.
- **Education and Training:** A West Point graduate and former U.S. Army officer, he earned his M.D. from the Mayo Clinic, completed his ENT residency at the University of Virginia, and pursued advanced fellowship training in rhinology and sinus surgery at the University of Pennsylvania under Dr. David W. Kennedy, one of the premier sinus surgeons in the world.
- **Scholarly and Global Contributions:** Author of a major textbook and over 340 peer-reviewed publications and book chapters, Dr. Schlosser is an internationally recognized educator who lectures worldwide on innovations in endoscopic sinus and image-guided surgery.
- **Research and Academic Impact:** His work has significantly advanced understanding and treatment of chronic sinus and nasal disease, making him one of the most widely published and respected figures in modern rhinology.



4B HealthCare



**DRUG DEVICE**  
CONSULTING



#### WRITTEN RESPONSES

**Meeting Type:** Type B  
**Meeting Category:** Pre-IND (PIND)  
**Application Number:** PIND 178247  
**Product Name:** Budesonide powder (1 mg) for nasal irrigation solution  
**Indication:** Treatment of nasal symptoms of seasonal or perennial allergic rhinitis in adults and children twelve years of age and older  
**Sponsor Name:** 4B Healthcare Inc.  
**Regulatory Pathway:** 505(b)(2) of the Federal Food, Drug, and Cosmetic Act

#### 1.0 BACKGROUND

On July 22, 2025, 4B Healthcare Inc. submitted a meeting request to seek input from the Division regarding the acceptability of development plan for the planned NDA. The Division determined that written responses would be the most appropriate means for responding to the meeting request and granted the meeting in a letter dated August 4, 2025.

The questions from the briefing package are listed below in ***bold italics*** font followed by FDA responses in normal font.

#### Introductory Comment

A PIND meeting was held with the Division of Nonprescription Drugs I (DNPDI) on June 18, 2025 (refer to meeting minutes dated June 18, 2025) to discuss budesonide powder for nasal irrigation solution for nonprescription use for temporary relief of symptoms of hay fever or other respiratory allergies (nasal congestion, runny nose, itchy nose, and sneezing). The meeting package and questions submitted for this PIND meeting are similar to those submitted for the PIND meeting with DNPDI. Consequently, responses reference the previous PIND meeting minutes dated June 18, 2025, with additional responses provided where relevant.

- **KEY MILESTONE:** This response letter from the FDA provides the authorization for 4B Healthcare to proceed with its Phase I Clinical Trials.



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ALTA SCIENCES



- **CRO (Contract Research Organization)** is an external partner hired by a drug sponsor to manage or conduct clinical trials, regulatory submissions, and related research activities on behalf of the sponsor under FDA Good Clinical Practice (GCP) regulations.
- **CMO (Contract Manufacturing Organization)** is a third-party company contracted by a drug sponsor to manufacture clinical or commercial drug product and ensure it complies with FDA Good Manufacturing Practice (GMP) standards and Chemistry, Manufacturing, and Controls (CMC) requirements.

## 4B HEALTHCARE INC.

USES OF PROCEEDS | RhineX Rinse #2 from Preclinical through FDA Regulatory Approval, FY26-28, est.

Prepared on November 02, 2023 by MCS for the Company | Version control: 20251102.v02mcs

## ANALYSIS- SOURCES &amp; USES, est.

Total SOURCES, proceeds est.	\$ 17,000,000
<u>Total USES, budget est.</u>	<u>\$ 16,664,400</u>
% of Total, Cumulative	98%

## ACTIVITY- USES, est. FY26 FY27 FY28 Total, FY26-28

## FDA/Regulatory

FDA Consultant	\$ 54,000	\$ 54,000	\$ 54,000	\$ 162,000
Phase I Clinical Trials	2,700,000	-	-	2,700,000
Phase II Clinical Trials	2,000,000	-	-	2,000,000
Phase III Clinical Trials	-	4,000,000	4,000,000	8,000,000
NDA Submission & Review	-	-	100,000	100,000
<u>Subtotal- FDA/Regulatory</u>	<u>4,754,000</u>	<u>4,054,000</u>	<u>4,154,000</u>	<u>12,962,000</u>
ADD: Comingency @ 20%	950,800	810,800	830,800	2,592,400
<u>Total- FDA/Regulatory</u>	<u>5,704,800</u>	<u>4,864,800</u>	<u>4,984,800</u>	<u>15,554,400</u>
% of Total, Annual	94%	93%	93%	93%

## SG&amp;A

Insurance	75,000	75,000	75,000	225,000
Legal Fees	50,000	50,000	50,000	150,000
Marketing	50,000	50,000	50,000	150,000
Business Travel	15,000	15,000	15,000	45,000
Accounting & Tax	10,000	10,000	10,000	30,000
Information Tech (IT)	5,000	5,000	5,000	15,000
Other General & Admin	165,000	165,000	165,000	495,000
<u>Total- SG&amp;A</u>	<u>370,000</u>	<u>370,000</u>	<u>370,000</u>	<u>1,110,000</u>
% of Total, Annual	6%	7%	7%	7%

<b>TOTAL- All USES, est.</b>	<b>\$ 6,074,800</b>	<b>\$ 5,234,800</b>	<b>\$ 5,354,800</b>	<b>\$ 16,664,400</b>
% of Total, Annual	36%	31%	31%	98%
% of Total, Cumulative	36%	67%	98%	98%

## 01- "Proven" Market (*Fcst*)

### MANAGEMENT ANALYSIS

*Current/existing/as-is market in the US for Steroid Nasal Irrigation prescribed by ENT physicians (the "Proven" market)*

#### 01- Fact Assumptions

ENT physicians in the US (#)	13,000
Average weeks worked per year (#)	46

## 02- Expanded Market (*Fcst*)

### MANAGEMENT ANALYSIS

*Estimated market in the US for Steroid Nasal Irrigation prescribed by All licensed PCPs (adult) (the "Expanded" market)*

#### 01- Fact Assumptions

Licensed PCPs (adult-care) in US	400,000
Average weeks worked per year (#)	46

## 01- “Proven” Market (*Fcst*)

### 02- Utilization Analysis Table

% of ENT Physicians who actively prescribe Steroid nasal rinses

# scripts/week	50%	60%	70%	80%
4	1,196,000	1,435,200	1,674,400	1,913,600
5	1,495,000	1,794,000	2,093,000	2,392,000
6	1,794,000	2,152,800	2,511,600	2,870,400
7	2,093,000	2,511,600	2,930,200	3,348,800
8	2,392,000	2,870,400	3,348,800	3,827,200



### Table Stats

Minimum	1,196,000
Average (Mean)	2,332,200
Maximum	3,827,200

## 02- Expanded Market (*Fcst*)

### 02- Utilization Analysis Table

% of Licensed HCPs (adult care) who actively prescribe Steroid nasal rinses

# scripts/week	5%	15%	25%	35%
0.5	460,000	1,380,000	2,300,000	3,220,000
1.0	920,000	2,760,000	4,600,000	6,440,000
1.5	1,380,000	4,140,000	6,900,000	9,660,000
2.0	1,840,000	5,520,000	9,200,000	12,880,000
2.5	2,300,000	6,900,000	11,500,000	16,100,000



### Table Stats

Minimum	460,000
Average (Mean)	5,520,000
Maximum	16,100,000

01- “Proven” Market (*Fcst*)03- Financial Analysis, Scenarios x 3, *Pro Forma*

Conservative- Low Estimate		Base- Average Estimate		Optimistic- High Estimate	
Activity	Amt	Activity	Amt	Activity	Amt
Volume	1,200,000	Volume	2,300,000	Volume	3,800,000
Price per unit	\$ 75.00	Price per unit	\$ 75.00	Price per unit	\$ 75.00
Revenue	\$ 90,000,000	Revenue	\$ 172,500,000	Revenue	\$ 285,000,000
EBITDA %, adj.	20%	EBITDA %, adj.	20%	EBITDA %, adj.	20%
EBITDA, adj.	\$ 18,000,000	EBITDA, adj.	\$ 34,500,000	EBITDA, adj.	\$ 57,000,000
Valuation Ratio	2 x Revenue	Valuation Mult.	2 x Revenue	Valuation Mult.	2 x Revenue
Valuation, est.	\$ 180,000,000	Valuation, est.	\$ 345,000,000	Valuation, est.	\$ 570,000,000

02- Expanded Market (*Fcst*)03- Financial Analysis, Scenarios x 3, *Pro Forma*

Conservative- Low Estimate		Base- Average Estimate		Optimistic- High Estimate	
Activity	Amt	Activity	Amt	Activity	Amt
Volume	500,000	Volume	5,500,000	Volume	16,100,000
Price per unit	\$ 75.00	Price per unit	\$ 75.00	Price per unit	\$ 75.00
Revenue	\$ 37,500,000	Revenue	\$ 412,500,000	Revenue	\$ 1,207,500,000
EBITDA %, adj.	20%	EBITDA %, adj.	20%	EBITDA %, adj.	20%
EBITDA, adj.	\$ 7,500,000	EBITDA, adj.	\$ 82,500,000	EBITDA, adj.	\$ 241,500,000
Valuation Ratio	2 x Revenue	Valuation Mult.	2 x Revenue	Valuation Mult.	2 x Revenue
Valuation, est.	\$ 75,000,000	Valuation, est.	\$ 825,000,000	Valuation, est.	\$ 2,415,000,000

## 01- “Proven” Market (*Fcst*)

### 04- Key Conclusions

- Therefore, the size of the current/existing/as-is market yields following financial metrics ranges (from average to high scenarios):
  - Revenue: ~\$170-285 million
  - EBITDA: ~\$35-57 million
  - Valuation: ~\$350-570 million
- To reiterate, with **emphasis**, this is the **CURRENT** market; this does **NOT** assume any growth due to insurance coverage approval & provider marketing
- Consequently, Management views the above amounts as the **FLOOR** of the expectations of the opportunity (*\*if FDA approval is granted\**)

## 02- Expanded Market (*Fcst*)

### 04- Key Conclusions

- Therefore, the size of the current/existing/as-is market yields following financial metrics ranges (from average to high scenarios):
  - Revenue: ~\$400 million - 1.2 billion
  - EBITDA: ~\$80-240 million
  - Valuation: ~\$800 million - \$2 billion+

- **FUTURE EXIT/LIQUIDITY:** While it is impossible to see far enough into the future for Management to know with certainty what the Exit/Liquidity plans will be, Management's belief remains that, by far the most likely scenario for exit/liquidity for a successful scenario is for the Company to be bought by an acquirer in a private-markets corporate merger or acquisition within 3-8 years from the present time.
- **TERM SHEET:** See the Terms slide later in this section for the normal key financial and legal terms provided in a standard-form Terms Sheet for a private placement equity investment.
- **GUIDANCE FOR INTERESTED POTENTIAL INVESTORS:** See the Next Steps slide later in this section to see the list of actions that will be required in order for you to execute an investment into the current round.
- **QUESTIONS FROM INTERESTED POTENTIAL INVESTORS:** Finally, if you have any questions related to the Company, then please email Brannon and Matt and cc Tiffany; similarly, if you have any technical questions about the investment details or mechanics, then please email Matt and cc Brannon.
- **DISCLAIMER NOTICE RE HIGH-RISK, HIGH-REWARD NATURE OF THE INVESTMENT:** And, once again, please note that, even in the calmest and most favorable view, this situation is much more inherently risky than many other types of common investments available to the public, so please exercise full prudence and diligence over your investment decisions.

## MANAGEMENT ASSESSMENT OF KEY INVESTMENT CRITERIA

## Method of Exit:

- **Success** = 100% of the Company is acquired by another pharmaceutical company
- **Non-success** = Shutdown of the Company & return all remaining cash to the shareholders

## Probability of Success:

- At present, all factors considered, **Probability of success** = ~20-33% (which is ~1-in-5, 1-in-4, 1-in-3)
- IF FDA approval is granted, then **Probability of success** instantaneously jumps to ~80%+

## Return on Investment (ROI):

- **Success (High)** = Original investment amount will multiply by ~8-10x+ (which is +800% to +1,000%)
- **Success (Medium)** = Original investment amount will multiply by ~5-7x (which is +500% to +700%)
- **Success (Low)** = Original investment amount will multiply by ~2-4x (which is +200% to +400%)
- **Non-success** = Loss of ~50-100% of original investment (which is loss of half to all of cash invested)

## Timeline to Exit:

- **Quick** scenario = ~2-4 years
- **Moderate** scenario = ~4-7 years
- **Slow** scenario = ~7-9 years

## Key Risk Factors:

- **FDA regulatory approval risk** (\*\*\* this risk factor is ~80% of the total risk in the investment\*\*\*)
- **Competitor risk**
- **Patent/IP approval risk**
- **Funding risk** (for pre-commercialization & commercialization)
- **Commercialization risk**

**IMPORTANT DISCLAIMER:**  
THESE STATEMENTS ARE  
MANAGEMENT BEST ASSESSMENTS  
OF OUTCOME RANGES BASED ON  
ALL INFORMATION THAT THEY HAVE  
REVIEWED THROUGH 11/06/2025;  
THESE STATEMENTS ARE FORWARD  
LOOKING AND UNCERTAIN AND THE  
FUTURE MIGHT DEVIATE  
MATERIALLY FROM THESE  
ASSESSMENTS.

## Series A Preferred Stock – Term Sheet

4B HEALTHCARE INC.

*(Confidential – For Discussion Purposes Only)***1. Overview**

Item	Description
<b>Offering</b>	Series A Preferred Stock (private placement)
<b>Total Raise</b>	\$17 million
<b>Pre-Money Valuation</b>	\$45 million
<b>Price per Share</b>	\$6.6033
<b>Minimum Investment</b>	\$100,000.00 (15,144 shares)
<b>Closing Target</b>	January 2026
<b>Use of Proceeds</b>	90%+ proceeds to be used to pursue FDA Approval for Nasal Steroid Irrigation Rinse under 505(b)(2) regulatory pathway pursuant to that separate certain FDA IND Letter

**2. Capitalization & Ownership**

- Post-financing ownership:** Series A Preferred Stock Investors approx. 27.4%; Founders, ESOP and other equityholders approx. 72.6%.
- Securities offered under Regulation D Rule 506(c) exemption.

**3. Governance**

- Board of Directors:** 2 Members (which shall be the 2 Founders/Common Stockholders)
- Information Rights:** Quarterly and annual financial statements; annual budget.

**4. Key Investor Protections**

Term	Summary
<b>Liquidation Preference</b>	1x non-participating (Series A paid back first).
<b>Conversion</b>	Convertible into common at any time; automatic on qualified IPO.
<b>Anti-Dilution</b>	Standard broad-based weighted average.

**5. Founder & Management Matters**

- Key Person Insurance:** Company to maintain policies on key people, as appropriate.

**6. Exit & Liquidity**

Scenario	Investor Return
<b>M&amp;A / Liquidation</b>	Return of 1x investment before common stock participates.
<b>IPO</b>	Automatic conversion to common at IPO.

**7. Registration & Future Rounds**

- Pro-Rata Rights:** Series A Preferred Stock Investors may participate in future financings.

**8. Legal & Closing**

- Company Counsel:** Matthew C. Stearns, attorney-at-law
- Investor Counsel:** [Investor selected and retained]
- Governing Law:** State of Delaware

**Disclaimer**

This term sheet is for discussion purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities. Any offer or sale will occur only through definitive agreements and in compliance with applicable securities laws.

## TIMELINE OF STEROID NASAL SPRAY DEVELOPMENT

Year	Event
~1962–1965	ENT and allergy physicians begin in-office compounding of hydrocortisone/dexamethasone nasal suspensions.
1972	Betamethasone dipropionate introduced as an inhaled steroid (for asthma).
1974–1975	Beconase® / Vancenase® approved as first commercial nasal corticosteroid sprays.
1978–1982	Flunisolide and Triamcinolone (Nasacort) launch; metered pump spray innovation.
1981–1985	Budesonide (Rhinocort) developed with improved safety.
1994	Flonase® (fluticasone propionate) approved by FDA; sets new standard.
2006–2007	Fluticasone furoate (Veramyst) and Mometasone (Nasonex) expand class.
2014	Flonase Allergy Relief becomes the first steroid nasal spray approved for OTC sale in the U.S.
2020s	OTC steroid nasal sprays dominate allergic rhinitis therapy; generic fluticasone available.

**Today:** Flonase and generics dominate both Rx and OTC markets (> \$700 million annual U.S. sales mid-2000s; OTC market now > \$1 billion).



2009

Dr. Schlosser started using off-label compounded steroid nasal rinse



2025

4B Healthcare is primed to start Clinical Trials to seek approval for the **first-ever FDA-approved** commercial steroid nasal rinse

*“History does not repeat itself*

*but it often rhymes”*

thank you

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**S6.1:** <https://www.cdc.gov/climate-health/php/effects/allergens-and-pollen.html#:~:text>Allergic%20rhinitis%20symptoms%20vary%20seasonally,%2C%20runny%20nose%2C%20and%20congestion>

**S7.1:** [https://www.biospace.com/seasonal-allergic-rhinitis-market-to-reach-us-14-1-billion-by-2034-impelled-by-widespread-adoption-of-intranasal-corticosteroids#:~:text=Reach%20US\\$%2014.1%20Billion%20by%202034%2C%20Impelled%20by%20Widespread%20Adoption%20of%20Intranasal%20Corticosteroids](https://www.biospace.com/seasonal-allergic-rhinitis-market-to-reach-us-14-1-billion-by-2034-impelled-by-widespread-adoption-of-intranasal-corticosteroids#:~:text=Reach%20US$%2014.1%20Billion%20by%202034%2C%20Impelled%20by%20Widespread%20Adoption%20of%20Intranasal%20Corticosteroids)

<https://www.futuremarketinsights.com/reports/intranasal-corticosteroids-market#:~:text=Intranasal%20Corticosteroids%20Market%20Outlook%202025,USD%2012%2C025.2%20million%20by%202035>

**S8.1:** [https://www.researchgate.net/figure/The-surface-area-coverage-of-drugs-using-nasal-spray-and-nasal-irrigation-in-the\\_fig2\\_349272183](https://www.researchgate.net/figure/The-surface-area-coverage-of-drugs-using-nasal-spray-and-nasal-irrigation-in-the_fig2_349272183)

( END OF PRESENTATION )