



BioLum  
S C I E N C E S

*Innovating Chronic Disease Treatment and Management*

with  
*chemiluminescence*



# Problem: Chronic Inflammatory Diseases

Reactive **oxygen** and **nitrogen** species (RONS) are linked to several inflammatory diseases; yet, **measuring RONS in both lab and clinic requires expensive instruments, time, and expertise.**

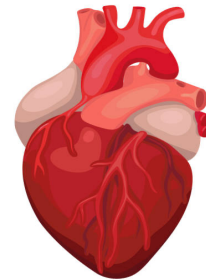
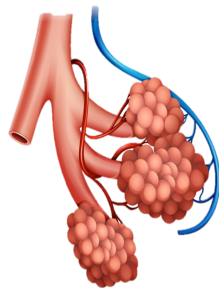
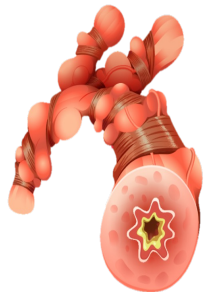
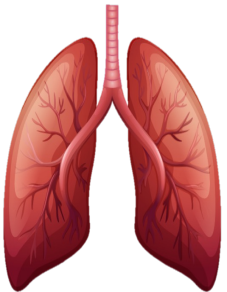
## Respiratory Diseases

- COPD and Asthma – affect millions globally
- Hydrogen Peroxide ( $H_2O_2$ ) is a marker of neutrophilic and eosinophilic airway inflammation
- Exacerbations are the largest cost burden

## Cardiovascular Diseases

- Cardiovascular disease - leading cause of death
- Nitric Oxide (NO) is a marker of endothelial dysfunction and regulates cardiovascular health
- NO has been an impactful therapy target for over a century with different therapies for varying levels of NO

***Urgent need to identify & predict diseases early, monitor progression, and ultimately personalize treatment.***





# R&D Solutions: Services and Assay Kits for Precision Medicine

**Novel, highly-sensitive chemiluminescent techniques to accelerate pharmaceutical development.**

## Expertise and specializations

- World-class chemiluminescent methods
- Biomarker measurements
- Determine efficacy of novel compounds
- Identify mechanism of action

Powered By  
Tunable  
**Chemiluminescent  
Technology**

## Biomarker Testing

- Custom Assays
- Reactive Oxygen and Nitrogen Species (RONS)
- $H_2O_2$  Hydrogen Peroxide Testing
- NO** Nitric Oxide
- Peroxynitrite
- Reactivity and activity of compounds
- Clinical studies

## Breath Analysis Services

- Airway Inflammation and Oxidative Stress

**3 active pharmaceutical customers**

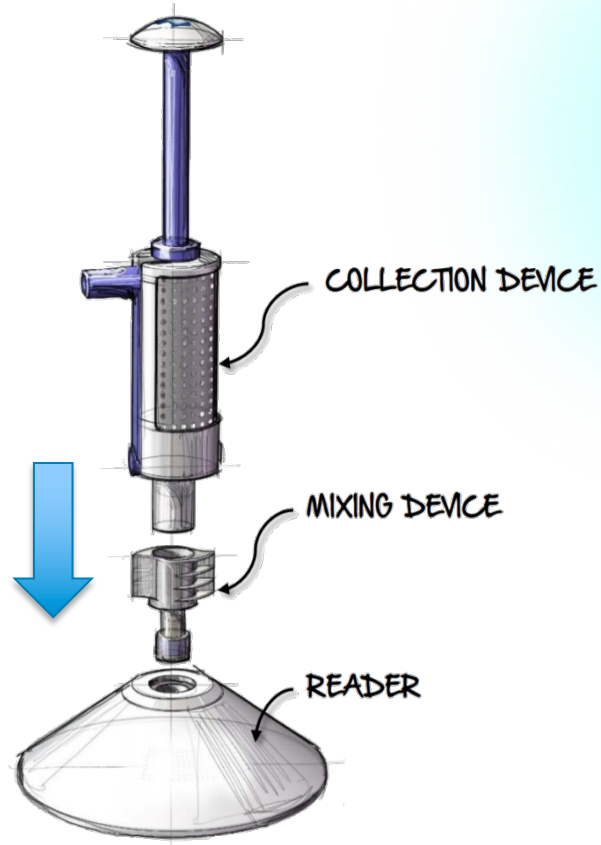


**NITRASE**  
THERAPEUTICS



# Clinical Solutions: Biomarker Platform for Disease Management

## Respiratory Asthma, COPD

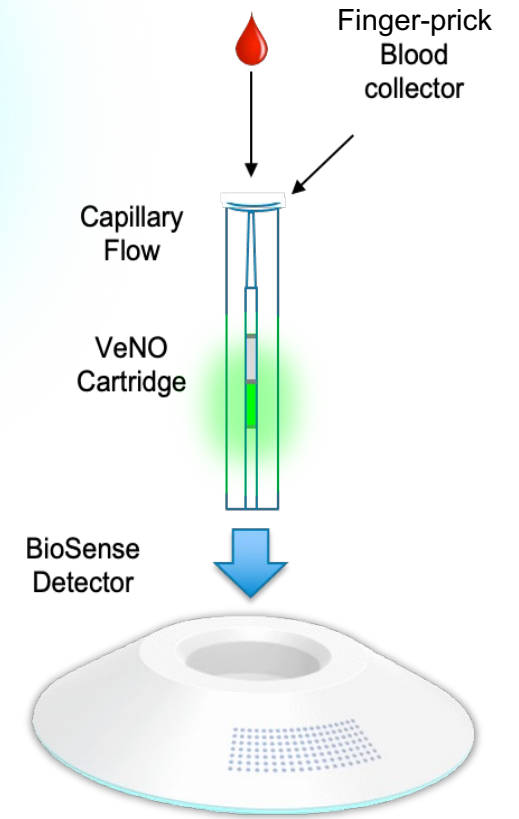


BioSense H<sub>2</sub>O<sub>2</sub> – EBC

Long-term  
Clinical & RPM Product Vision

1. Identify
2. Monitor
3. Predict
4. Personalize

## Cardiovascular PAH, HF



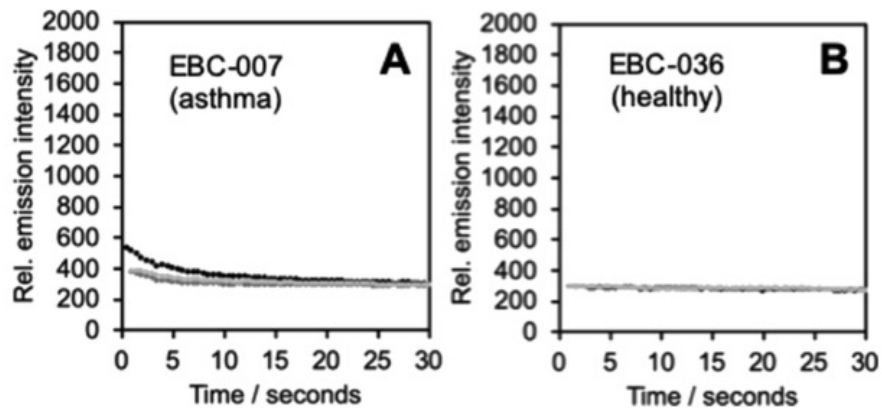
BioSense VeNO – Blood



# Proof of Concept: Feasible and Validated

## Respiratory

- **Clinical Study** with John Peter Smith Hospital
- **Validated** in 60 asthma patients and healthy participants
- $H_2O_2$  higher in asthma patients
- $H_2O_2$  lower with use of rescue inhaler



## Cardiovascular

- **Feasibility Study** funded by Bayer Pharmaceuticals
- Assay detects NO in buffer with picomolar sensitivity
- Assay detects NO in plasma with low nanomolar sensitivity
- Current NIH Phase 1 grant to complete VeNO Assay Kit

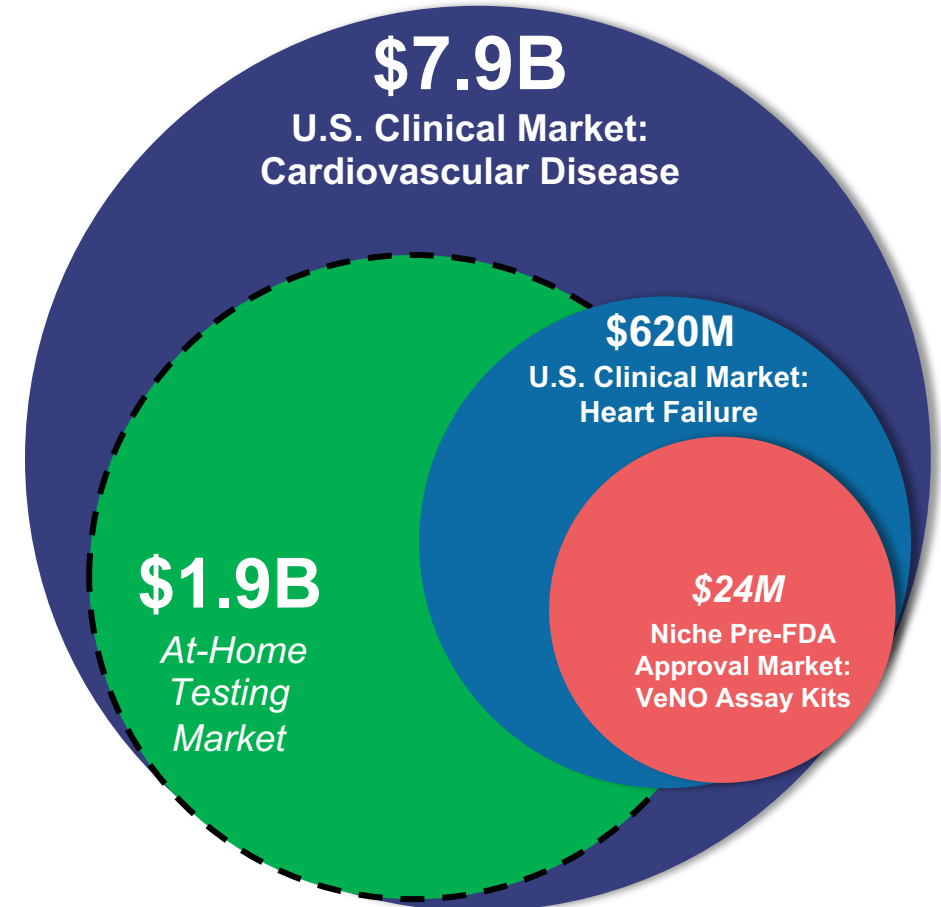
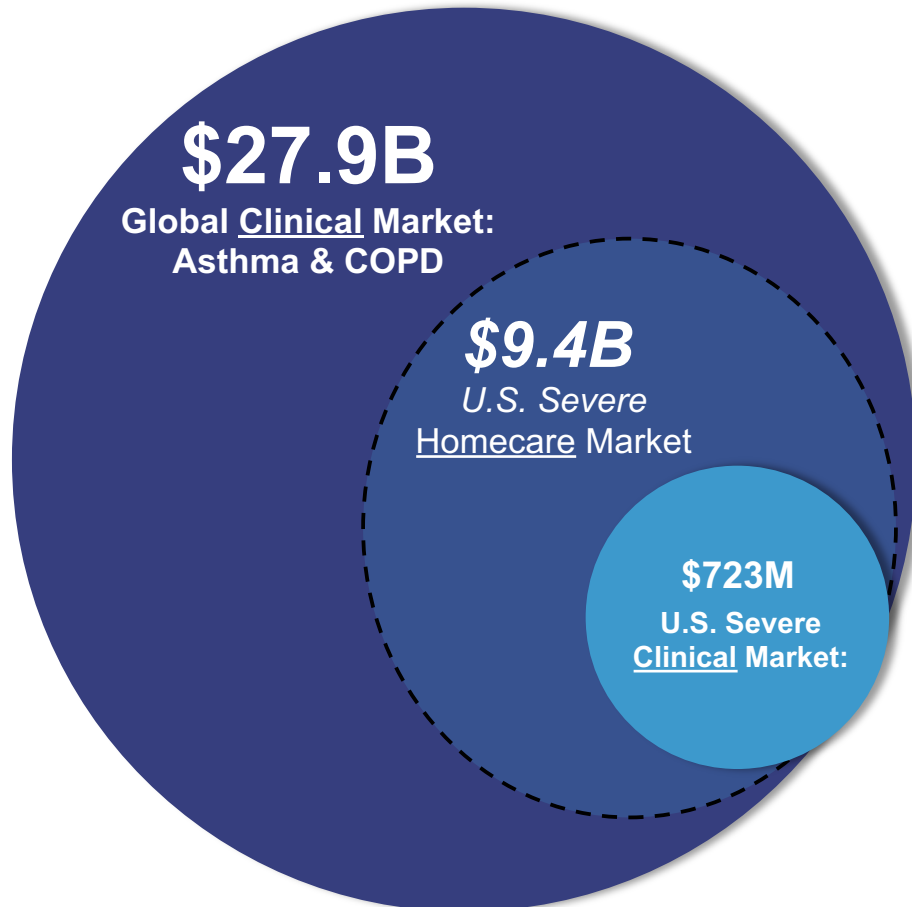
Limit of Detection (LoD) of the chemiluminescent assay formulations.

Assay	Donor	Analyte	Limit of Detection	Calibration Range	Reaction Media
Reagent Set 1	DEA NONOate	NO	3–12 $\mu$ M	0–25 $\mu$ M	PBS (pH 7.4)
Reagent Set 2	DEA NONOate	NO	0.4–5.5 nM	0–50 nM	PBS (pH 7.4)
Reagent Set 2	DEA NONOate	NO	40–95 nM	0–1000 nM	10% plasma (v/v)



# Market Opportunity

- **Total Addressable Market:** 1, 4, or 12 annual tests (\$15) for controlled (75%), moderate (20%), or severe patients (5%).
- **Homecare Market:** Severe patients take 2-4 weekly tests for early warning of exacerbation. **1,600 Patients = \$5M revenue**
- **U.S. Total Addressable Clinical Market:** 1 annual test (\$50) for at-risk patients (47% of Americans).
- **Niche Market:** Pre-FDA sales of research assay kits. 12,000 VeNO studies/year x 4 kits (\$500) per study.

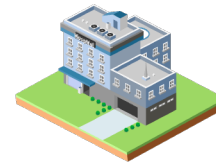





# Business Model & Pricing



Interviews with 70+ Healthcare Specialists



<b>Pharmaceutical Partnerships</b> (Bayer, Novo Nordisk, others)	<b>Specialist Physicians</b> (Dr. Pristas, Leon, Davis)	<b>Hospitals &amp; Primary Care Physicians</b> (JPS Hospital, Texas Children's)	<b>Homecare</b> (Severe, Frequent Exacerbators)
<p><b><u>Stage 1: Initial R&amp;D revenues</u></b></p> <p>Generate revenues developing custom assays for pharma research partners</p> <ol style="list-style-type: none"> <li>1. Provide attractive <u>research kits (\$550-\$950/kit)</u> to measure Reactive Oxygen and Nitrogen Species (RONS) for drug discovery, development, studies.</li> <li>2. Establish clinical evidence and acceptance of biomarkers.</li> <li>3. Identify patients who will benefit from specific therapies.</li> </ol>	<p><b><u>Stage 2: Commercial Clinical Sales</u></b></p> <ol style="list-style-type: none"> <li>5. <b>Commercialize</b> BioSense clinical tests with 'razor and blades' business model through sale of platform sensor (\$1,500, 10% margin) and single-use disposable test cartridges (\$15-\$50, 67% margin).</li> <li>6. Majority of early profits will be driven through high volume clinics</li> </ol>	<p><b><u>Stage 3: Clinical Sales Growth</u></b></p> <p><b><u>Most asthma treatment occurs in the primary care setting</u></b></p> <p>Inclusion in GINA, GOLD, ACC/AHA guidelines for treatment &amp; management:</p> <ol style="list-style-type: none"> <li>7. Expand BioSense usage in hospital and ER settings, providing significant cost savings for healthcare system.</li> <li>8. Repeat disposable test sales</li> </ol>	<p><b><u>Stage 4: At-Home Sales</u></b></p> <p>Early diagnosis &amp; monitoring with frequent, objective measurements of disease control.</p> <p><b><u>At-home Testing &amp; Long-term Monitoring</u></b> </p> <p><b>9. Recurring sales</b> from severe, exacerbation-prone patients that require frequent home monitoring.</p> <p>Patients can monitor disease progression &amp; predict exacerbations <i>before</i> they occur.</p>



# IP Strategy

## Novel IP Portfolio

Unique combination of chemistry, biological sample collection devices, and hardware that allows for protection and significant value.

Core patent and trade secrets fully owned by BioLum.

## Validated Differentiation

Our attorneys have determined path is clear, International Searching Authority (ISA) recognized all 53 claims as novel.

## Patent Strategy

Freedom-to-operate complete

Filed large initial patent and will file supporting patents as we continue to develop our IP portfolio, alongside our trade secret formulas.







# Respiratory & Cardiovascular Competitive Landscape

## Company

## Description

## BioLum's Advantage

### Aerocrine

First to Market device for exhaled fractional nitric oxide. Acquired by Circassia for \$215M with \$25M revenue.

- Neutrophilic asthma & COPD
- Simple breathing maneuvers
- Differentiate smokers



Homecare breath nitric oxide device. Acquired by Caire for undisclosed amount with \$1.5M revenue.



Developed technology for H<sub>2</sub>O<sub>2</sub> measurement in COPD patients. EU, UK market.

- Specificity of chemiluminescence
- Focused on U.S. market
- Established clinical evidence



Measures nitric oxide in liquid samples with toxic ozone gas.


- Simpler method
- Direct measurement
- Clinical viability



Electrochemical real-time measurements in liquid samples.




# Biomarker Assay Pipeline and Status

Product Pipeline	Concept	Feasibility	Prototype	Validation	FDA Pre-sub	Finalized Device	Clinical Trials	Commercial Sales
<i>H<sub>2</sub>O<sub>2</sub></i> (Hydrogen peroxide)							cortex  design	Clinical Sales >\$5M for M&A
<i>NO</i> (Nitric oxide)					Research Sales \$550-\$950/kit			
<i>ONOO-</i> (Peroxynitrite)				Research Sales \$550-\$950/kit				


## Business




- Jack Reynolds, CEO 
- Startup experience
- Finance & marketing expertise

## Science



- Dr. Alex Lippert, CSO 
- Leading Expert in Luminescence
- 20 years, 50 papers, >\$3M federal funding

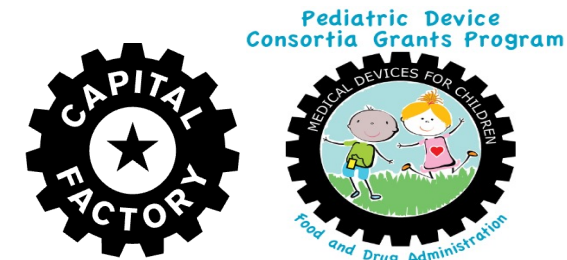
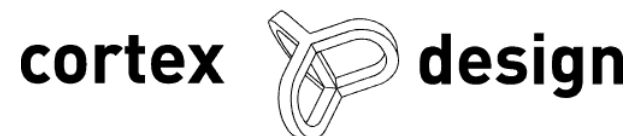


- Dr. Husain Kagalwala 
- CTO
- 20 papers, 2 patents

## Key Advisor/Potential Officer



- Tom Sundelin
- Sales Director at Aerocrine 2000-2009
- Proven record of commercialization, growth, and profitability relating to respiratory medical devices
- Distribution & sales channels





# Advisory Team



**Dr. Michael Devoy**  
Chief Medical Officer, Bayer  
EVP Medical Affairs &  
Pharmacovigilance  
for Pharmaceuticals Division



**Elisa Maldonado-Holmertz**  
Clinical Development Lead at  
Aerocrine, Pfizer, Pharmaco



**Scott Giambalvo**  
Former Commercialization  
Specialist at Stryker  
Medical Advisor of NTEC



**Jonathan Crowder**  
\$70M exit, Choose Energy



**Dr. Steven Davis M.D.**  
Head Pulmonologist at  
John Peter Smith Hospital  
Internal Medicine Chairman



**Dr. Artin Atabaki**  
Franchise (COPD) Manager, Bayer



**Kevin Coker**  
CEO at ProximaCRO  
Led 500+ Clinical Trials  
25 Drugs FDA Approved



**Dr. Adrian Pristas M.D.**  
Pulmonologist at  
Hackensack Meridian Health  
Riverview Medical Center



**Dr. Rene Leon M.D.**  
Allergist/Immunologist at  
Methodist Southlake Hospital  
Baylor Scott & White



**Eric Nordstrom**  
Medical Device Sales Manager  
4 Medical Device Exits



# Funding for Platform Development

**Current Raise:** \$1.2M bridge round to hit final respiratory product milestones (*technical co-lead investor/partner secured*) and scale NO research assay kit sales

## **Funding for BioSense AMD**

Product Finalization: \$357,000 (Quote from Cortex Design)

- Breath collection integration, automated sample metering

Initial Manufacturing & Tooling, Quality Management System: \$400,000

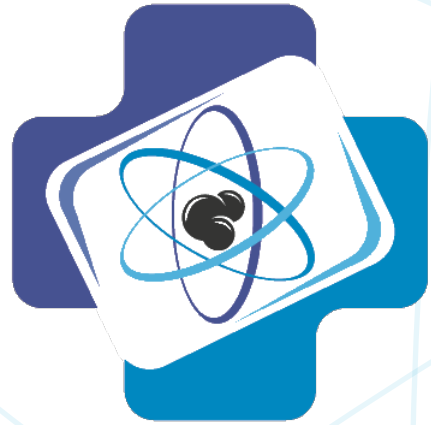
VeNO Assay Kit Commercial Launch: \$400,000

## **Future Funding**

AMD Clinical Trials and FDA: \$1,766,000

***Previous Funding: \$1.09M (non-dilutive prizes & grants, angel, VC, R&D contracts)***

jpreynolds@biolumsciences.com  
(720) 985-3131  
www.biolumsciences.com



**BioLum**  
SCIENCES

***Appendix: Additional Supporting Information***

**CEO Jack Reynolds**  
**[jpreynolds@biolumsciences.com](mailto:jpreynolds@biolumsciences.com)**  
**(720) 985-3131**  
**[www.biolumsciences.com](http://www.biolumsciences.com)**

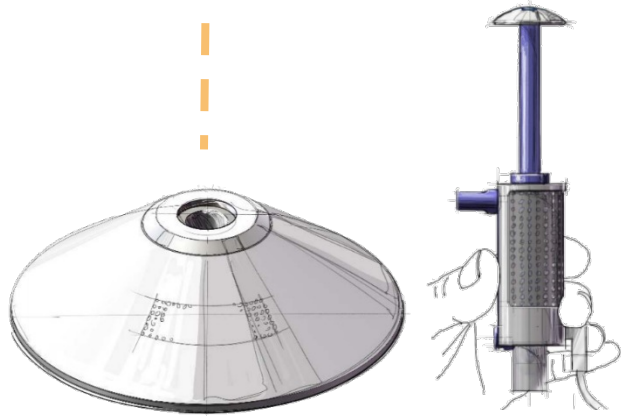


# System Components

## Hardware

## Software

## Data



Diagnostic & Monitoring Platform

- Instant indication of lung function
- Automatic data upload
- Easy-to-use



Desktop Data Platform

- Personalized treatment program
- Comprehensive treatment platform
- Automated patient records



Mobile Application

- Remotely monitor patient health
- Create objective data points
- Identify at risk patients



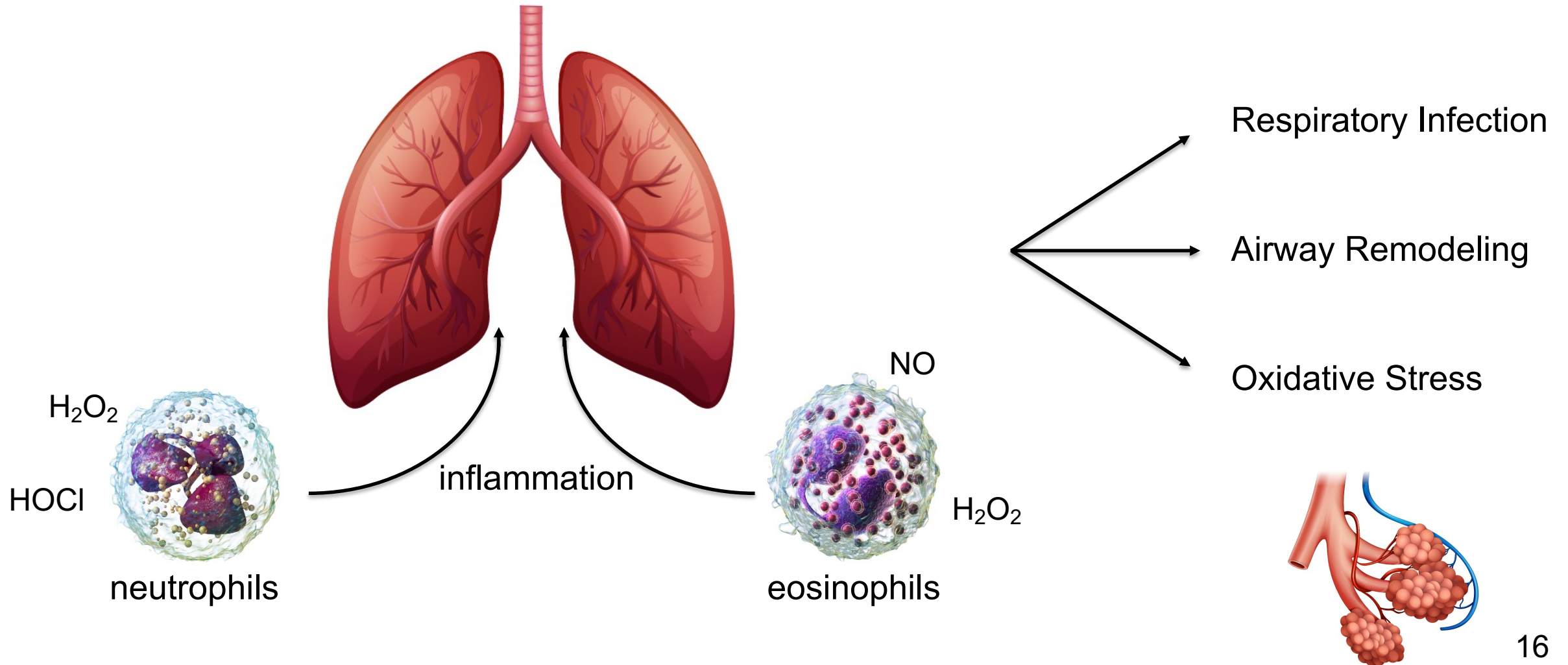
Predictive Algorithm

- Prevent exacerbations
- Medication reminders
- Decision support algorithms



# eH<sub>2</sub>O<sub>2</sub>: Airway Inflammation, Neutrophils, & Disease

*How can airway inflammation be tracked non-invasively?*







# H<sub>2</sub>O<sub>2</sub> FDA Strategy

- 1<sup>st</sup> Pre-Submission meeting to validate regulatory plan
  - Completed: FDA recommends 510(k) for BioSense AMD**
- 2<sup>nd</sup> Pre-Submission meeting to validate study design
- 100 patient study over 3 sites (3 Months)
- 500-1000 patients to establish baseline values for eH<sub>2</sub>O<sub>2</sub> (9 Months)
- File FDA 510(k) application (Product Code: MXA)



# Respiratory Assumptions & References

**\*Altered Treatment Decision Assumptions:** COPD & asthma are inflammatory airway diseases. There is limited data available on the effect of airway inflammation testing on COPD treatment decisions and more research is needed to understand the impact that it will have on overall treatment plans. Studies 11, 12, & 13 highlight the value of airway inflammation testing when selecting therapies for COPD patients. A key assumption in the TPP model is that airway inflammation testing will have a similar impact on COPD treatment decisions as it has in asthma management (31-33%). Further studies will be needed to validate this assumption.

**\*Reduced Exacerbation Rate Assumptions:** Studies 9 & 13 show a significant difference in asthma exacerbation rates between patients using airway inflammation testing in a clinical setting vs. those using the current standard of care. These values range from a 40-58% difference in exacerbation rates, and we assume a 25% reduction in exacerbation rates given this data. There is limited data on the effects of airway inflammation testing on COPD exacerbations, but the literature supports our assumption that exacerbation and a rise in inflammation can be identified early using our technology. Further studies will be needed to validate this assumption. Study 14 shows an improvement in COPD exacerbation detection and readmission rates using only a telehealth remote monitoring system (questionnaires, blood oximetry, blood pressure).

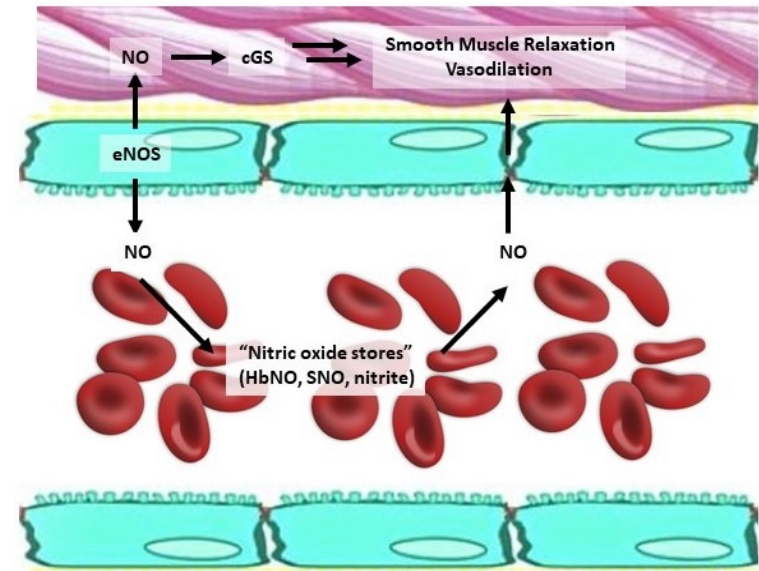
1. <https://www.ncbi.nlm.nih.gov/pubmed/26108382>
2. <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2016.22.7.848>
3. <https://www.aaaai.org/global/latest-research-summaries/New-Research-from-JACI-In-Practice/refractory-asthma>
4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3694800/>
5. <https://www.aafa.org/asthma-facts/>
6. <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb106.pdf>
7. <https://www.ncbi.nlm.nih.gov/pubmed/29408317>
8. <https://www.ncbi.nlm.nih.gov/pubmed/25060819>
9. <https://www.ncbi.nlm.nih.gov/pubmed/27825189>
10. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6357290/>
11. <https://www.ncbi.nlm.nih.gov/pubmed/20210889>
12. [https://journals.lww.com/md-journal/FullText/2018/11210/Treatment\\_of\\_chronic\\_obstructive\\_pulmonary\\_disease.1.aspx](https://journals.lww.com/md-journal/FullText/2018/11210/Treatment_of_chronic_obstructive_pulmonary_disease.1.aspx)
13. <https://www.ncbi.nlm.nih.gov/pubmed/23601567>
14. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5382257/>



# Nitric Oxide Signaling

## Targeting nitric oxide signaling

- NO is critically important to human health, and NO-signaling has been an impactful therapy target for >100 years
- Multiple classes of therapy: direct NO donors, PDE5 inhibitors, & soluble guanylyl cyclase stimulators
- Low NO is central factor in HF, hypertension, atherosclerosis, diabetes, erectile dysfunction, and other diseases



## Competition - no way to measure nitric oxide in clinic

- NO measurement requires expensive instrumentation & expertise
- Many methods are indirect & measure NO metabolites
- There is no way to measure NO in the clinic & indirect methods in the lab are prohibitively expensive

Table 1. Therapies targeting nitric oxide signaling.

Class	Drug	Disease <sup>a</sup>
Nitric oxide donors	Nitroglycerin	Approved: angina pectoris
	Isosorbide mononitrate (Imdur)	Approved: angina pectoris
	Isosorbide dinitrate/hydralazine (BiDil)	Approved: Heart failure
	Nitroprusside	Approved: hypertensive crisis Approved: reduce bleeding during surgery Approved: acute heart failure
	Inhaled NO	Approved: infant PAH
PDE5 inhibitors	Sildenafil	Approved: erectile dysfunction Approved: PAH
	Vardenafil	Approved: erectile dysfunction
	Tadalafil	Approved: erectile dysfunction Approved: PAH Approved: benign prostatic hyperplasia Phase 4: diabetic cardiomyopathy
sGC stimulators	Riociguat	Approved: PAH Approved: CTEPH Phase 2: heart failure
	Vericiguat	Phase 3: HFREF Phase 2b: HFpEF
	Nelociguat	Phase 2: erectile dysfunction
	Praliciguat	Phase 2: diabetes/hypertension Phase 2: HFpEF
	Olinciguat	Phase 2: achalasia Phase 2: sickle cell disease

<sup>a</sup>PAH: pulmonary arterial hypertension; CTEPH: chronic thromboembolic pulmonary hypertension; HFREF: heart failure with reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction;

Table 2. Comparison of nitric oxide measurement methods.

	VeNO	EPR	Electrochemistry	Fluorometry	Griess Assay	Ozone CL
<b>Advantages</b>	Direct, potentially continuous and quantitative	Direct Considered most specific	Direct Real-time Portable	Direct Fluorescence response	Cheap Commercial kits available	Established use in blood
<b>Disadvantages</b>	Sensitivity and use in blood need to be investigated	Specialized equipment Technical Expertise Spin traps	Difficult calibration Variability Biofouling	Uncertain specificity Semiquantitative Blood interferes with fluorescence	Indirect Measures nitrite Dietary interferences Limited to plasma	Indirect Specialized equipment
<b>Cost</b>	\$2,000 (device + \$25 cartridges)	\$183,365 <sup>a</sup>	\$6,591 <sup>b</sup>	\$2,970 <sup>c,d</sup>	\$1,110 <sup>d,e</sup>	\$51,724 <sup>f</sup>



# Expansion on Dr. Lippert

**Dr. Alex Lippert - Chief Science Officer** - Alex is a globally recognized expert in chemiluminescence bioimaging with 20 years of experience in synthetic chemistry and the development of optical techniques for imaging biological analytes in living cells, animals, and clinical samples.

He has filed five patents, published more than 50 papers, and has been awarded nearly \$3M in funding from the National Institutes of Health, National Science Foundation, and several private research foundations. Alex's scientific knowledge and mindset has been a strong driving force for BioLum's product development.

Dr. Lippert Publications:

[View List of Dr. Lipperts Publications on Reactive Oxygen and Nitrogen Species](#)



# Strategic Partnership Opportunities

## 1. Precision Medicine R&D Partnership

- a. Accelerate development by measuring and validating efficacy of novel therapeutic compounds
- b. Maximize potential of therapeutic assets

## 2. Co-development and Commercialization Partnership

- a. Custom assay services
- b. Expand lines of future products that include RPM device + digital for cardiovascular and respiratory patient conditions
- c. Assay component sourcing and/or clinical development of assays/products, sales platform and distribution channels

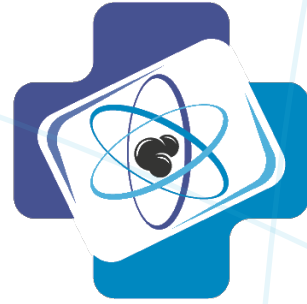
## 3. Strategic Corporate Venture Investment, In-licensing, Acquisition

- a. Explore novel biomarker assays with BioLum's scalable chemiluminescent solution
- b. Expand commercial reach with research and clinical sales in key therapy areas/segments
- c. Explore and identify complementary/companion diagnostics (CDx)

## 4. Clinical Study Collaboration - Enhance therapy development and clinical trials

- a. Stratify patients with additional clinical endpoints (nitric oxide bioavailability and *neutrophilic* airway inflammation)
- b. Improve patient selection and Likelihood of Approval (LOA)
- c. Monitor response to treatment

*Commercialize biomarker assays to improve therapies and the lives of those living with chronic diseases alongside global strategic partners.*



**BioLum**  
S C I E N C E S

*Innovating Chronic Disease Treatment and Management*

**CEO Jack Reynolds**  
**[jpreynolds@biolumsciences.com](mailto:jpreynolds@biolumsciences.com)**  
**(720) 985-3131**  
**[www.biolumsciences.com](http://www.biolumsciences.com)**