



CAPNIA

June 2016



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Investment Highlights

Commercial Stage

Products Currently on the Market

CoSense® ETCO Monitor

Serenz® Allergy Relief

Infant pulmonary resuscitation solutions

World-class Partners

Global Distributors

Active partnerships in place in the U.S., Asia, Europe, and Middle East

Planning to engage in further geographies in 2016

Clinical Stage Pipeline

Portfolio of Therapeutic and Diagnostic Candidates

Two Phase 2 trials ongoing in cluster headache and trigeminal neuralgia

Top-line data readouts expected in 2016

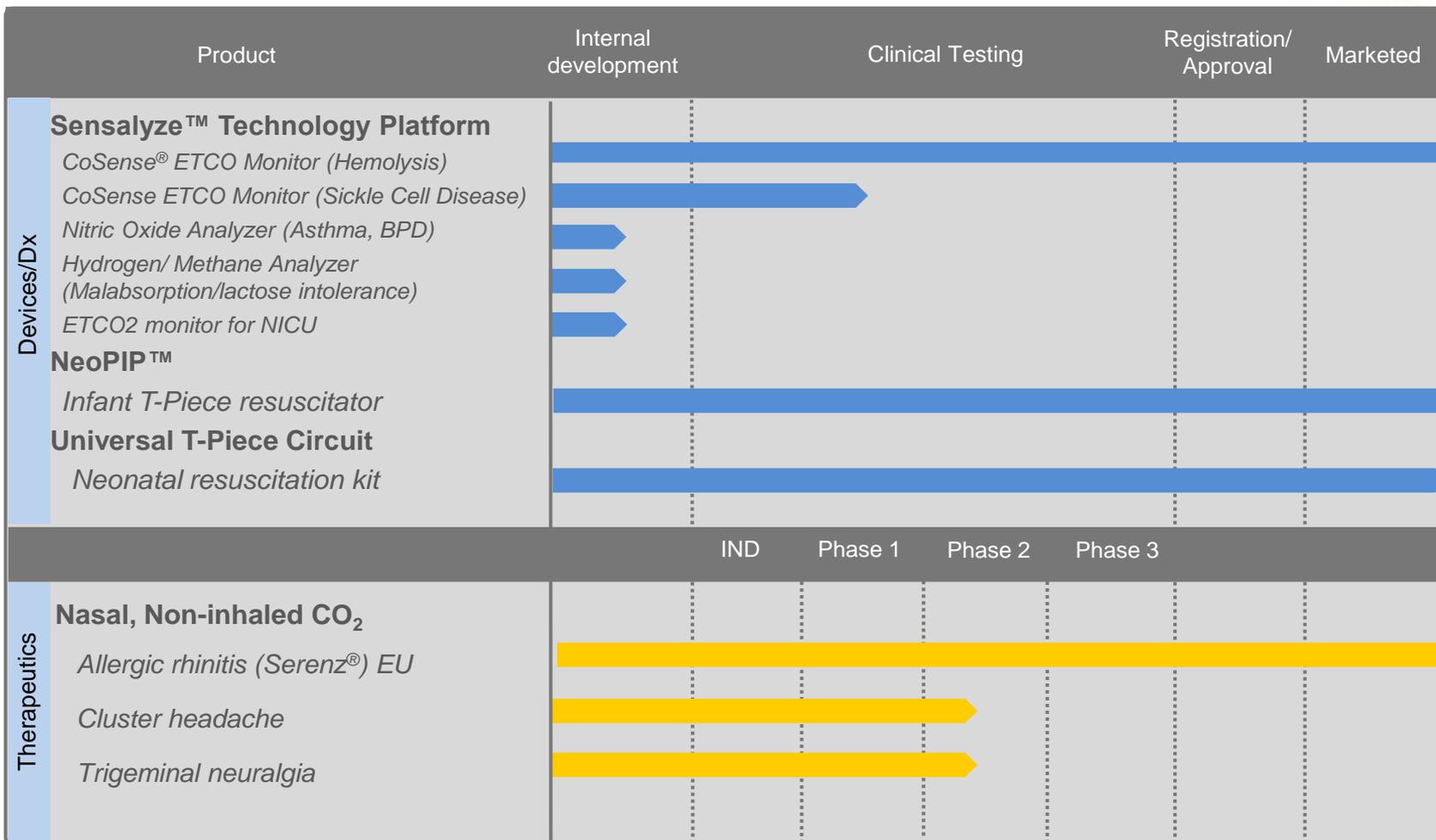
Platform Technology

Cutting edge device for detecting breath analytes

Patent portfolio (issued and pending) with expirations out to 2030s

Applicable across a broad range of therapeutic areas

Pipeline



COMMERCIAL PRODUCTS

SERENZ[®] ALLERGY RELIEF



NEW

Love Spring

Introducing a gentle and effective way to treat nasal allergy symptoms

Serenz[™] Allergy Relief

To relieve allergy symptoms such as nasal congestion, sneezing, nasal itching and runny nose.

- ✓ RAPID RELIEF
- ✓ USE ONLY WHEN NEEDED
- ✓ CLINICALLY PROVEN
- ✓ NASAL CLEANSE

Serenz[™] gently cleanses the nasal passages with carbon dioxide to relieve allergy symptoms of nasal congestion, itchy, runny noses and sneezing. In clinical studies, the most common side effects were temporary nasal discomfort and watery eyes while cleansing with Serenz[™].

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Pilot Launch in Europe



- ▶ Fast-acting, gentle cleansing of nasal mucosa for relief of nasal allergy symptoms
- ▶ Disposable device holds doses for ~1-2 weeks
- ▶ As of April 2016, available OTC at 150+ retail pharmacies in the UK
- ▶ Initial customer reports positive

WELDRICKS
PHARMACY


paydens

Allergic Rhinitis (Nasal Allergies)



- ▶ Characterized by episodic nasal congestion, itching, sneezing and runny nose
- ▶ One of the most common ailments in the western world
 - Affects millions globally and growing rapidly
 - One of the largest potential pharmaceutical markets

▶ SERENZ®

- Conducted studies of 975 patients in six randomized, controlled clinical trials
- Well-tolerated and statistically significant improvements in standard TNSS endpoints
- Patent protection to 2020 or beyond: 9 issued US patents

Overview

CoSense[®] ETCO MONITOR

The *CoSense* ETCO Monitor is indicated for the monitoring of carbon monoxide from endogenous sources (including hemolysis) and exogenous sources (including CO poisoning and smoke inhalation) in exhaled breath. The end-tidal carbon monoxide level can be used for the monitoring of carbon monoxide in medical conditions in which the rate of hemolysis may be relevant. It is also for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation.

Clinical Management of Jaundiced Infants: A Significant Unmet Need



140 million births worldwide

9 million births in US + Europe



 **60-80%**

develop JAUNDICE

Condition caused by elevated levels of bilirubin or hyperbilirubinemia

In some cases

Hyperbilirubinemia + JAUNDICE

are caused by a **hemolytic condition**
(red blood cells degrade rapidly)



Increased risk of neurological damage

Hemolysis: A Key Risk Factor for Neurological Damage

▶ CO and Bilirubin are produced **1:1** during hemolysis



▶ CO is elevated in the newborn with a hemolytic condition



▶ CO is eliminated through lungs (ETCO)



CoSense® ETCO Monitor

- Measures ETCO
- May improve treatment decisions

*“ETCOc levels can confirm the presence or absence of hemolysis, and measurement of ETCOc is the **only clinical test** that provides a direct measurement of the rate of bilirubin production...”¹*

The *CoSense* End Tidal Carbon Monoxide Monitor is not a diagnostic or treatment device for any specific disease or condition. Rather, it is a detection tool to be used for the monitoring of carbon monoxide from endogenous sources (including hemolysis) and exogenous sources (including CO poisoning and smoke inhalation) in exhaled breath.

¹ Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. Pediatrics 2004;114:297-316.

Current Standard of Care: Adverse Outcomes and Higher Costs

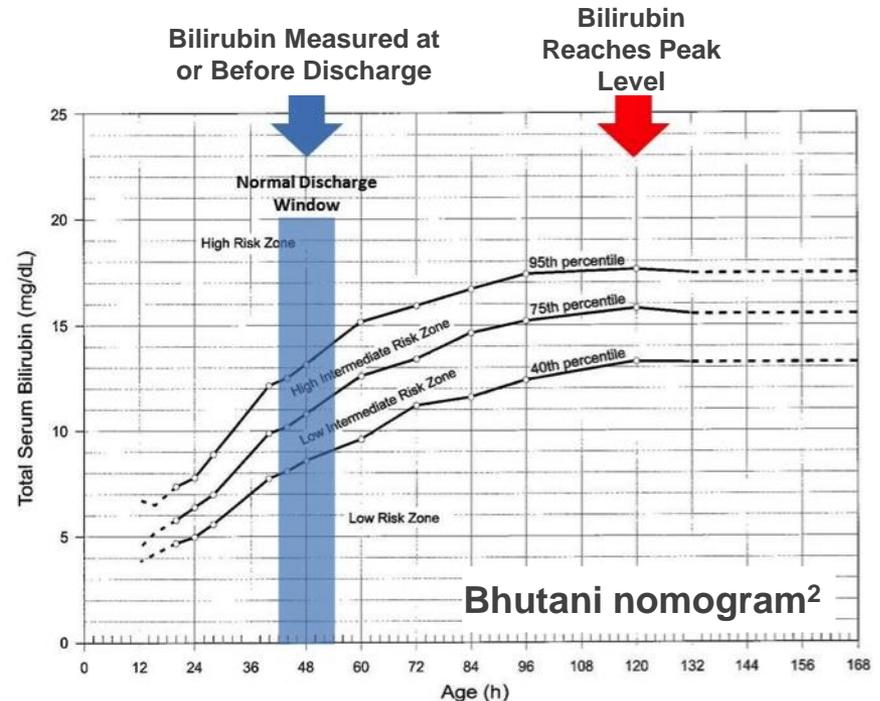
CHALLENGES

- Bilirubin typically peaks after discharge
- Current diagnosis of hemolysis is invasive and inadequate



CONSEQUENCES

- Hemolysis is under-diagnosed
- Treatment is delayed
- Adverse neurological outcomes
- Jaundice is #1 cause of infant readmits to hospital¹



AAP guidelines recommend ETCO for identification of hemolysis but no tool exists

¹ Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project Fact Book 4: Care of Children and Adolescents in U.S. Hospitals. <http://archive.ahrq.gov/data/hcup/factbk4/factbk4.htm> . April 27, 2014.

² Bhutani VK, Johnson L, Sivieri EM. Predictive ability of a predischarge hour-specific serum bilirubin for subsequent significant hyperbilirubinemia in healthy term and near-term newborns. Pediatrics.1999;103: 6– 14

Capnia Solution: *CoSense*[®] ETCO Monitor



- ▶ Portable, breath test device that measures ETCO₂, which can be used to detect the rate of hemolysis
- ▶ Provides physician information to
 - Assess risk of serious disability and supports early action if needed
 - Identify lower risk newborns needing less intervention, less hospital time
- ▶ FDA 510(k) clearance, CE certification
 - Reusable device + Precision Sampling Set (single use)
- ▶ Quick bedside results, no lab delays



Easy to
use



Point-of-care
testing



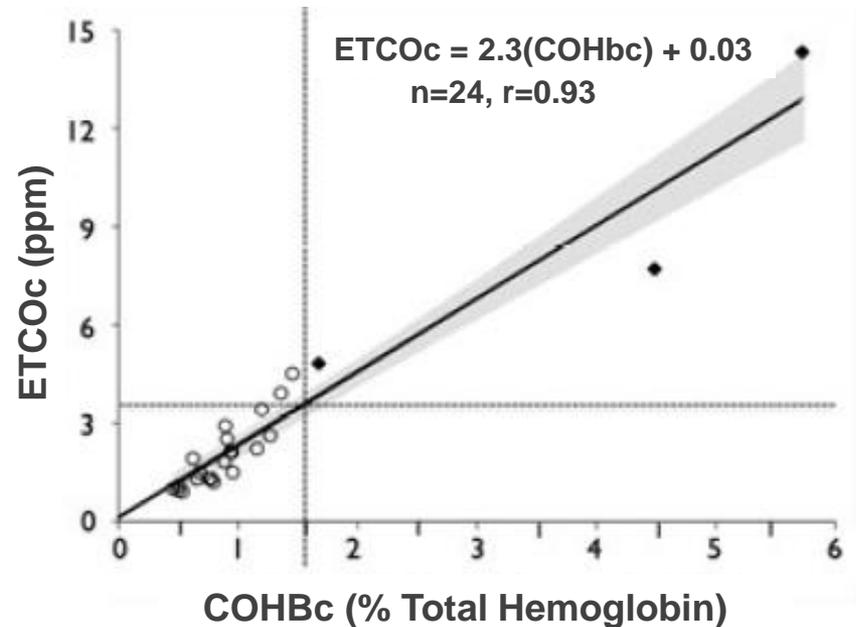
Rapid
results



No
calibration

CoSense[®] Effectively Measures ETCO

- ▶ CoSense[®] ETCO values from 73 newborns (102 separate measurements) at Stanford University
- ▶ Carboxyhemoglobin (COHb) levels in blood are used for experimental measurements of hemolysis
- ▶ Linear correlation between CoSense[®] ETCO and COHb indicates accurate detection of hemolysis
- ▶ $r = 0.93$



Commercial Strategy

▶ US

- ▶ New nationwide distribution agreement with Bemis, Inc.
 - 50 states; 44 neonatology-focused sales reps
 - Extensive network of sub-distributors
- ▶ Capnia employees as regional managers
- ▶ Executing direct sales of NeoForce products
- ▶ Evaluating new product opportunities with similar call points

▶ Outside US

- ▶ Ongoing discussions in several geographies
- ▶ Active Partnerships
 - Asia
 - Europe
 - Middle East
- ▶ Regulatory submissions in process where needed

NEOFORCE COMMERCIAL PRODUCT LINE

NeoForce Business

Highlights

- ▶ Expands Capnia's revenue-generating product line
- ▶ Significant potential for growth with Capnia resources
- ▶ Adds several existing hospital relationships/contracts; NICU services
- ▶ Multiple new product development opportunities
- ▶ NeoForce CEO joined Capnia as VP and General Manager, Neonatology
 - 25+ years of neonatology experience



NeoPiP™ Infant T-Piece Resuscitator



Consumables (e.g., temperature probes, resuscitator circuits)

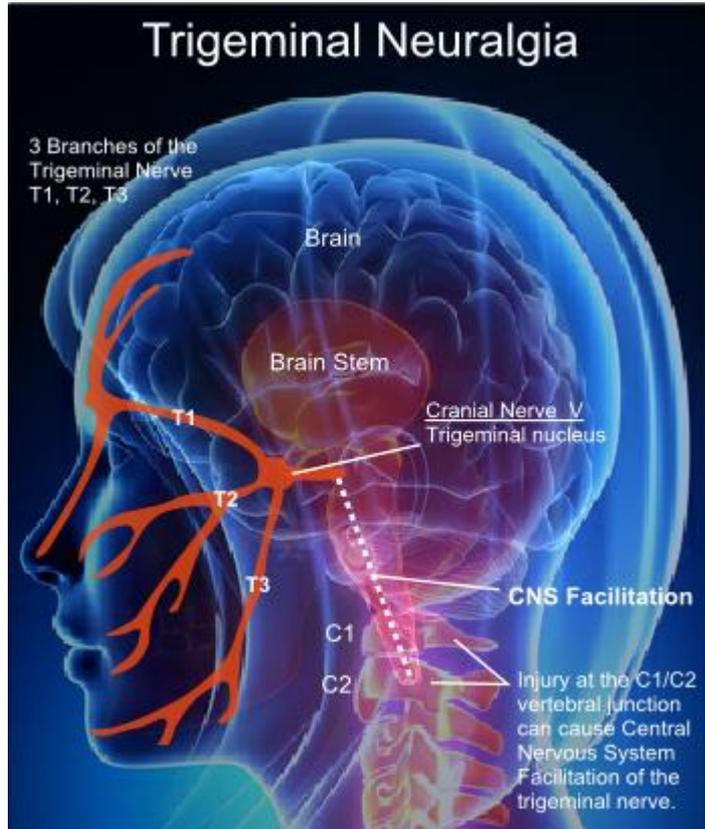
Nasal, Non-inhaled Carbon Dioxide

THERAPEUTIC DEVELOPMENT PROGRAMS

Nasal CO₂ Mechanism of Action

- ▶ In vitro
 - Suppresses secretion of neuropeptides such as CGRP from cultured trigeminal neurons
- ▶ In vivo
 - Normalizes pain sensitivity in hyperalgesic rat model
 - Decreases SNAP25 expression
 - Decreases gap junction activity
- ▶ Local: gentle cleansing of nasal mucosa
- ▶ Human studies
 - Central effect: pain relief in migraine patients
 - Local effect: relief from symptoms of allergic rhinitis

Trigeminal Neuralgia

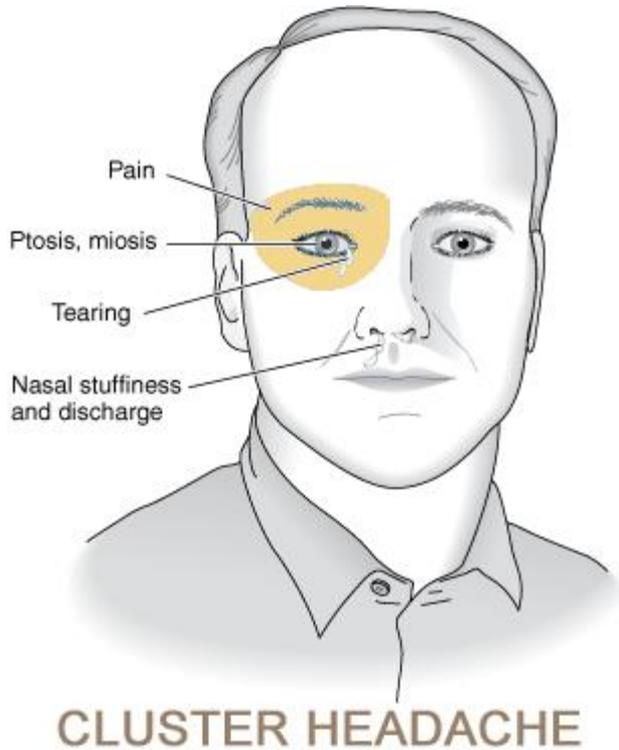


- ▶ Debilitating unilateral facial pain, one of the worst known to man
- ▶ Current treatments: Chronic drug therapy, surgery
- ▶ Acute treatments typically ineffective
- ▶ MOA
 - Target trigeminal system via nerve endings in nasal mucosa to provide immediate relief

Trigeminal Neuralgia

- ▶ Received Orphan Drug Designation from FDA in December 2015
- ▶ IND submitted to the FDA
- ▶ Pilot clinical trial initiated, with major academic centers participating
 - Designed to enroll up to 50 patients with symptomatic Trigeminal Neuralgia
 - First patient in enrolled in February 2016

Cluster Headache



- ▶ Severe, recurring bouts of unilateral headache associated with symptoms in the eye, nose, etc.
- ▶ Intensely painful
- ▶ Bouts can last from 15 minutes to three hours, and occur several times per day
- ▶ No effective treatments are currently available

Cluster Headache

- ▶ Investigator-sponsored clinical trial commenced
- ▶ Pilot, single-center; conducted under a collaboration agreement between Capnia and Clinvest®
- ▶ Designed to enroll 25 patients with episodic cluster headaches
- ▶ Primary efficacy endpoint is the greatest change from pre-treatment headache pain intensity to post treatment
- ▶ Capnia expects to report top-line data from this trial in 2016

UNDERLYING SENSALYZE™ TECHNOLOGY PLATFORM

Sensalyze™ Technology Platform

▶ BREATH ANALYSIS BACKGROUND

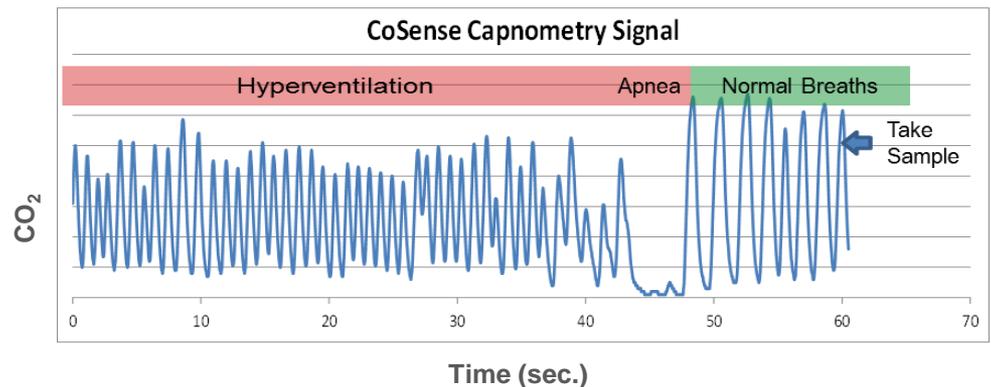
- Thousands of unique substances have been identified in the breath, including nitrogen, oxygen, carbon dioxide, nitric oxide, carbon monoxide and other gasses
- Similar to a fingerprint, every individual has a “breathprint” that can provide useful information about his/her state of health
- There are more than 30 FDA-cleared breath analyzers for various indications: alcohol intake, respiration during anesthesia, asthma diagnosis, H Pylori infection, CO₂ status

▶ THE PROBLEM

Current sampling technologies require breath control

- Breath holding or forced exhalation
- Impossible for babies... often inconvenient for adults

Infant Breathing Pattern: *Fast, Irregular, Hard to Capture*



Sensalyze™ Technology Platform

▶ THE CAPNIA SOLUTION

Sophisticated, IP-protected technology for detecting analytes in breath

- Effective with very young, very old and others who cannot benefit from limited breath testing technologies that are currently available
- Combination of sampling hardware and software
- High sensitivity even in small breath volumes and rapid, irregular breath rates
- Patent portfolio (issued and pending) with expirations out to 2030s
- Applicable across a broad range of therapeutic areas



Sickle Cell Initiative

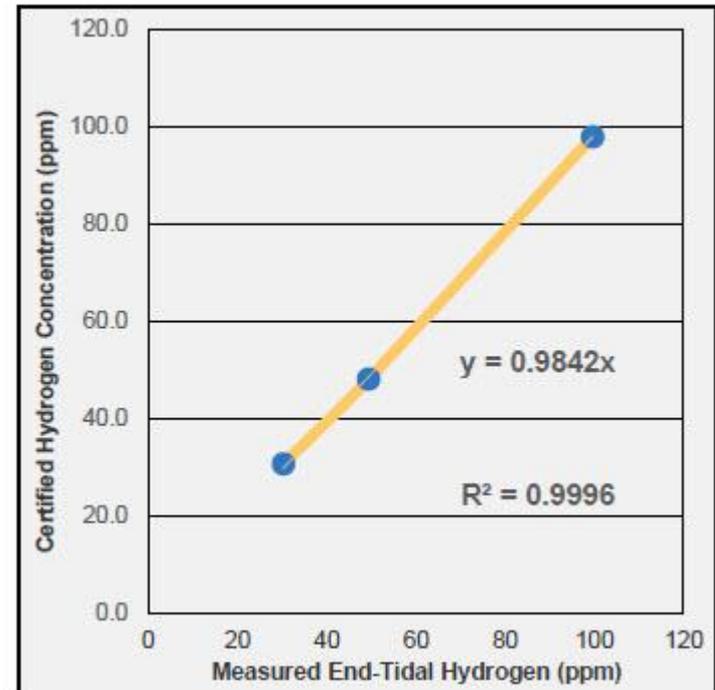
- ▶ Exploring potential of using *CoSense*[®] Monitor to screen for SCD
- ▶ Phase I SBIR grant received from NIH
 - Work completed to ensure operation in challenging environmental conditions
- ▶ Significant potential for use as
 - non-invasive screening device
 - aid in development of new therapeutics
 - assist in dose determination
- ▶ Ongoing conversations with governmental and other agencies

Neonatal/Pediatric Hydrogen Monitor

- ▶ Hydrogen breath tests routinely used to diagnose GI disorders, but limited to older patients
 - Lactose/fructose/sucrose intolerance
 - Irritable bowel syndrome
 - Small intestinal bacterial overgrowth
- ▶ Current tests use controlled forced exhalation through a mask or mouthpiece-not feasible for neonates

Sensalyze Hydrogen breath test feasibility data presented at PAS 2016

ETH₂ Linearity (Accuracy vs Hydrogen Level)



GR Gourley, et al. Poster Presentation 1511.499. PAS 2016

Capnia Leadership Team



MANAGEMENT

Anish Bhatnagar, M.D., *President & CEO*

- Senior Capnia executive since 2006
- Product approval experience at Coulter (Bexxar), Capnia (Serenz, *CoSense*), management at Titan

David O'Toole, *SVP & Chief Financial Officer*

- Former CFO for Codexis (CDXS), Response Genetics (RGDX), Abraxis (ABBI)
- Partner at Deloitte focused on biotech and life science industry

Otho Boone, *VP & General Manager of Neonatology*

- 25 years of neonatology medical device sales, operations and product development experience
- Founded NeoForce, which was acquired by Capnia in September 2015

Anthony Wondka, *SVP of R&D*

- Former VP R&D, VP Technology and Clinical Affairs for Breathe Technologies
- Several approvals of devices in the respiratory space in the US and globally

Kristen Yen, *VP of Clinical and Regulatory Affairs*

- Head of Clinical Operations at Capnia since 2006
- Program management of multiple U.S. and global clinical studies

Ann Rich, *VP of Marketing*

- Former Senior Marketing Director at ArthroCare, Apnicure and Johnson & Johnson
- Managed marketing and global development of numerous products

Key Financial Information

- ▶ Revenue being generated from three product lines
 - CoSense[®] ETCO Monitor w/consumable Precision Sampling Sets
 - Serenz[®] Allergy Relief
 - Infant Solutions (neonatal resuscitation products)
- ▶ Common stock outstanding¹: 15.4 million
- ▶ Fully-diluted share count¹: 27.2 million
- ▶ Market cap¹: \$ 20 million
- ▶ Cash balance¹: \$6.5 million
- ▶ \$10 million at-the-market equity arrangement with Aspire Capital
- ▶ No Debt

2016 Priorities

- ▶ Execute on commercial strategy for CoSense
- ▶ Prepare for Serenz full commercial launch in Europe
- ▶ Support recently announced distribution partnerships
- ▶ Report top-line results from Phase 2 trials in cluster headache and trigeminal neuralgia by year end

Recent Achievements

Commercial Products	Product Pipeline	Corporate/Financial
<ul style="list-style-type: none">✓ Launched CoSense® globally✓ Acquired NeoForce assets✓ Secured distribution partnerships in key territories✓ Serenz CE Mark re-activated✓ Commenced Serenz® pilot launch in Europe	<ul style="list-style-type: none">✓ Awarded NIH grant to develop device to screen for sickle cell disease✓ Initiated Phase 2 clinical trials in cluster headache and trigeminal neuralgia✓ Received orphan designation for nasal CO₂ in TN	<ul style="list-style-type: none">✓ Added to Russell Microcap Index✓ Remaining Series B warrants expired✓ Secured \$20M in funding through a private placement and at-the-market stock purchase agreements✓ Appointed Ann Rich, VP of Marketing

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*Targeting unmet needs.
Creating solutions.
Improving healthcare.*

