Background: Inflammatory Response Research, Inc. ("IRR") is a drug development company focused on pharmaceutical products for the treatment of inflammatory disorders and conditions. Our initial product is a combination of levocetirizine (Xyzal®) and montelukast (Singulair®) at specific dosing for treatment of the common cold as an Rx or ‘Behind the Counter’ dose pack. In parallel development is a ‘First response’ injectable for use in traumatic brain / blast injury.

Financials: The Company, formed in 2011, has successfully raised $2.25 million in seed capital and is seeking to license/partner.
Combination Product: Levocetirizine + Montelukast / Significantly more Effective than each Alone

**Concept:** repurposing of the most effective antihistamine (levocetirizine) + leading leukotriene antagonist (montelukast) in the world for multiple new indications. Leukotrienes are inflammatory mediators similar to histamine; however, 100-1000x more potent in the lung on a molar basis.

**Synergy:** Synergy between the two molecules was discovered in 2008/2009 during the throes of the H1N1 pandemic. Clinical data to date supported by independent laboratory research suggests the combination of levocetirizine and montelukast shortens the traditional 7-10 day course of the common cold and influenza by up to 50%.

**Safety:** Both compounds have excellent safety profiles / Pregnancy Category B.

**Intellectual Property:** 27 Issued Patents / 35 Patents Pending Worldwide
Our initial use patent for influenza and the common cold has issued in the United States, Canada, Mexico, Austria, and Japan. On **05/14/2018** we received notice of allowance in Europe (37 jurisdictions).

Patents for traumatic brain / lung injury have been issued in the United States, Japan, and Europe.

**Marked Clinical Unmet Needs:**

**Common Cold**
Presently there is no FDA approved product that actually decreases the duration of the common cold (Rx or OTC). Scientifically, levocetirizine and montelukast downregulate ICAM-1, the portal of entry of human rhinovirus into the cell. A significant clinical response can be seen in as little as two days.

**Traumatic Brain Injury**
Traumatic brain injury is currently the #1 US military medical unmet need with no new safe and effective product in over 30 years. Half of the injuries in the Middle East are roadside bombs inflicting both lung and brain injuries. Levocetirizine + montelukast can be formulated as an injectable ‘First Response’ medication. Recently expressed at the 8th Annual Traumatic Brain Injury Conference in Washington, DC, **05/16-17/2018**, was interest by the DOD to review our project for funding.


**Pathway to Success:**

With an established global patent portfolio, IRR is poised for development / licensing. We anticipate the University of Iowa Pharmaceuticals, the nation’s oldest and most experienced university affiliated, FDA approved facility, to formulate the product. A common cold ‘Challenge’ study in Australia has been designed to achieve simultaneous US/Australia approval by 2021. Limited animal data is necessary to comply with FDA requirements.

US market research predicts 170 million cold eligible patients by 2020.

Thank you,

B. Chandler May, MD, JD, MS, FCLM / CEO, Inflammatory Response Research, Inc.
bcmay@irrinc.net / 805-403-2320 cell