

# INSPIRE PHARMACEUTICALS

MARCH 2009



## OUR BUSINESS

Inspire is a biopharmaceutical company focused on researching, developing and commercializing prescription pharmaceutical products for ophthalmic and pulmonary diseases. We intend to build and commercialize a sustainable pipeline of innovative new products based on our technical and scientific expertise.

## OUR INVESTMENT HIGHLIGHTS

- Integrated biopharmaceutical company with R&D and commercial capabilities in two therapeutic areas: ophthalmology and pulmonology
- Robust pipeline with multiple Phase 3 product candidates
- Growing revenue stream from the promotion of *AzaSite*<sup>®</sup>, co-promotion of *Elestat*<sup>®</sup> and royalties on *Restasis*<sup>®</sup>

## FINANCIAL SUMMARY

Revenues	Full year 2008	\$70.5 million
Net Loss	Full year 2008	(\$51.6) million
Cash and Investments	As of 12/31/08	\$73.0 million
Common Stock Outstanding	As of 12/31/08	56.7 million shares
Employees	As of 12/31/08	250



## RECENT NEWS

Inspire Reports Fourth Quarter and Full Year 2008 Financial Results

Inspire Elects Alan F. Holmer to Board of Directors

Inspire Initiates Phase 3 *Prolacria*<sup>™</sup> Dry Eye Trial Under Special Protocol Assessment Agreement

Inspire Announces New Data from Denufosol Phase 3 Program at North American Cystic Fibrosis Conference

Inspire Initiates Phase 1 Trial of INS117548 for Glaucoma

## OUR COMMERCIAL PRODUCTS

Inspire employs a U.S. sales force for the promotion of *AzaSite*<sup>®</sup> for bacterial conjunctivitis and *Elestat*<sup>®</sup> for allergic conjunctivitis. Inspire licensed *AzaSite* from InSite Vision Incorporated. *Elestat* is co-promoted under an agreement with Allergan, Inc.

### *AzaSite*<sup>®</sup>

*AzaSite*<sup>®</sup> (azithromycin ophthalmic solution) 1% delivers high and sustained concentrations in ocular tissue<sup>1,2</sup> while delivering broad spectrum coverage against the most common ocular pathogens<sup>3</sup>. Additionally, the active ingredient in *AzaSite* is azithromycin, which has anti-inflammatory activity.\*<sup>4,5,6</sup>



### *Elestat*<sup>®</sup>

*Elestat*<sup>®</sup> (epinastine HCl ophthalmic solution) 0.05% provides fast-acting, long-lasting relief of ocular itching and is soothing to the eyes. *Elestat* is a mast cell stabilizer, a potent antihistamine and the only product with labeling that cites activity at both the H<sub>1</sub> and H<sub>2</sub> receptors.



\* The anti-inflammatory activity of topically administered *AzaSite*<sup>®</sup> has not been clinically established.

<sup>1</sup> Torkildsen G, O'Brien TP. *Clinical Therapeutics*, 2008; 30 (11):1-10.

<sup>2</sup> Data on file, Inspire Pharmaceuticals, Inc., Study Report 041-103.

<sup>3</sup> Data on file, Inspire Pharmaceuticals, Inc., NDA Clinical Summary.

<sup>4</sup> Jacot JL, Jacot TA, Sheppard JD Jr, Lattanzio FA Jr, Williams PB, Brubaker K. Evaluation of MMP 2/9 modulation by azithromycin and DuraSite on human corneal epithelial cells and bovine corneal endothelial cells *in vitro*. Poster presented at: 2008 Association for Research in Vision and Ophthalmology Annual Meeting; April 27-May 1, 2008; Fort Lauderdale, FL.

<sup>5</sup> Ianaro A, Ialenti A, Maffia P, et al. Anti-inflammatory activity of macrolide antibiotics. *J Pharmacol Exp Ther*. 2000; 292(1): 156-163.

<sup>6</sup> Shinkai M, Rubin BK. Macrolides and airway inflammation in children. *Paediatr Respir Rev*. 2005; 6(3): 227-235.

*Elestat*<sup>®</sup> is a registered trademark owned by Allergan, Inc. *AzaSite*<sup>®</sup> is a registered trademark owned by InSite Vision Incorporated.

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**INSPIRE**

PULMONARY		PHASE 1	PHASE 2	PHASE 3	NDA FILED
Denufosal tetrasodium	<i>Cystic Fibrosis</i>			○	
OPHTHALMIC					
<i>Prolacria™</i> (diquafosol tetrasodium)	<i>Dry Eye Disease</i>			○	YES
INS115644	<i>Glaucoma</i>	○			
INS117548	<i>Glaucoma</i>	○			

## PULMONARY

### Denufosal tetrasodium for cystic fibrosis (CF) Phase 3

- According to the CF Foundation, the median life expectancy for patients is 37 years. There are approximately 30,000 diagnosed CF patients in the U.S., included in an estimated 75,000 total in the eight major international prescription pharmaceutical markets.
- Denufosal is designed to enhance the lung's innate mucosal hydration and mucociliary clearance through stimulation of the P2Y<sub>2</sub> receptor.
- Inspire has fast-track and orphan drug status for denufosal in the U.S. and orphan drug status in Europe.
- In November 2006, Inspire initiated a required two-year inhalation carcinogenicity study in one species. The carcinogenicity final study report is expected in the second half of 2009.
- In June 2008, Inspire announced top-line results from TIGER-1, its first Phase 3 trial with denufosal for CF. The trial demonstrated statistical significance for its primary endpoint of change in FEV<sub>1</sub> from baseline compared to placebo (45 ml treatment group difference, p=0.047).
- In February 2008, Inspire initiated TIGER-2, the second pivotal Phase 3 trial with denufosal. TIGER-2 is a 48-week randomized, double-blind comparison of 60 mg of denufosal to placebo in approximately 450 subjects with mild CF lung disease (FEV<sub>1</sub> ≥ 75% and ≤ 110%). Inspire is targeting completion of TIGER-2 enrollment in 2009.

## OPHTHALMIC

### *Prolacria™* (diquafosol tetrasodium) for dry eye Phase 3; Approvable

- Inspire estimates, based on an extrapolation from U.S. data, that dry eye disease affects over thirty million people in the eight major international pharmaceutical markets, of which over nine million are in North America.
- *Prolacria* is being developed by Inspire as an eye drop that stimulates release of the three natural tear components involved in tear secretion - mucin, lipids and fluid - through stimulation of the P2Y<sub>2</sub> receptor.
- To date, Inspire has completed four Phase 3 clinical trials of *Prolacria*. In 2003, Inspire filed a New Drug Application (NDA) with the FDA for *Prolacria* for the treatment of dry eye disease. Inspire has received two approvable letters from the FDA (December 2003 and December 2005).
- In January 2009, Inspire initiated a Phase 3 clinical trial for *Prolacria* under a Special Protocol Assessment (SPA) agreement with the FDA. The Phase 3, randomized, placebo-controlled, environmental clinical trial will evaluate the efficacy and safety of *Prolacria* in approximately 450 subjects with dry eye who have a fluorescein staining score of three in the central region of the cornea at baseline, using the National Eye Institute (NEI) scale. The agreed upon primary efficacy endpoint is the proportion of subjects receiving *Prolacria* that achieve clearing of fluorescein staining of the central region of the cornea in the study eye (a score of zero on the NEI scale) at the six-week trial endpoint, compared to those receiving placebo.

### INS115644 for glaucoma Phase 1

- The annual U.S. market for prescription glaucoma products is approximately \$1.9 billion, based on IMS date for the 12 months ended December 31, 2007.
- In November 2004, Inspire licensed several patents for use in developing and commercializing new treatments for glaucoma from the Wisconsin Alumni Research Foundation (WARF).
- Inspire evaluated new and existing compounds that are active in disrupting the acto-cytoskeleton of the trabecular meshwork as potential treatments for glaucoma. The scientific hypothesis is that the mechanism of action may result in reduction of intraocular pressure by affecting the primary outflow pathway for aqueous humor.
- Inspire is conducting a Phase 1 proof-of-concept dose-ranging clinical trial of INS115644, a Latrunculin B compound, to evaluate the safety, tolerability and changes in intraocular pressure in approximately 40 subjects with early stage glaucoma or ocular hypertension. Results from this trial are expected in 2009.

### INS117548 for glaucoma Phase 1

- Inspire is conducting a Phase 1 placebo-controlled, dose-escalating trial designed to evaluate the safety, tolerability and intraocular pressure-lowering effects of INS117548, a Rho kinase inhibitor, in approximately 60 subjects with early stage glaucoma or ocular hypertension. Results from this trial are expected in 2009.

*This document contains forward-looking statements that present our expectations and plans regarding future performance, and these statements are subject to significant risks and uncertainties that could affect our future performance, including those relating to product development. Actual results could differ materially from those described herein. Information on various facts that could affect our results is detailed in our reports filed with the Securities and Exchange Commission.*