

# Corporate Report

a report by

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Lux Biosciences Inc. is dedicated to the identification, optimization, development, and commercialization of pharmaceutical products for the treatment of ophthalmic diseases.

Lux Biosciences Inc., founded in 2005, is a privately held biotechnology company characterized by:

- A focus on compounds with clinical proof of concept in non-ophthalmic indications that Lux Biosciences is developing for ophthalmic diseases, creating proprietary products addressing conditions of high medical need. Building on clinical data from related indications, Lux Biosciences is able to expedite the development of these compounds.
- A strong-staged product portfolio, including two product candidates targeting immune-mediated ophthalmic diseases entering pivotal clinical studies in early 2007, the first of which — if successful — could achieve commercialization in 2009.
- A next-generation calcineurin inhibitor with what is believed to be a superior therapeutic window that Lux Biosciences is initially developing for uveitis and for which it has received US orphan drug designation. This compound also presents further product opportunities, including the treatment of dry-eye syndrome and age-related macular degeneration (AMD).
- A silicone matrix implant that releases therapeutic doses of cyclosporine A (CsA) locally to the eye over one year for the prevention of corneal allograft rejection with potentially improved efficacy, safety, and compliance. Lux Biosciences has received orphan drug designation in both the US and Europe for this product.
- A proprietary, product-enabling bio-erodable polymer technology that facilitates targeted and controlled delivery of Lux Biosciences molecules locally to the eye.
- A seasoned management team with a history of achievement in drug development and commercialization and deep insight, scientific expertise, and collaborative networks in the fields of immunology and ophthalmology.
- Strong capitalization through a \$49 million Series A completed in summer 2006 with marquee investors SV Life Sciences, HBM Partners, Novo A/S, and Prospect Venture Partners.

Lux Biosciences is headquartered in Jersey City, New Jersey. Lux Biosciences has also established a European subsidiary, Lux Biosciences GmbH in Frankfurt, Germany, to support its focus on North America and Europe.

## Market Opportunity

Ophthalmology, and specifically uveitis, cornea transplantation, dry-eye syndrome, and AMD, represent major, under addressed market opportunities for new therapeutics targeting immunomodulatory and anti-inflammatory mechanisms of disease. Uveitis affects some 350,000 US patients, and approximately 35,000 US corneal transplants are performed each year, with prevalence in the range of 200,000. The dry-eye and AMD markets comprise millions of patients holding transformational revenue potential. Lux Biosciences expects to both gain approval for new products within its market segments and build a commercial presence to fully capitalize on these opportunities, which are highly focused markets based on physician referral networks.

## Product Pipeline

### LX211

LX211 is a next-generation calcineurin inhibitor, a class of molecules that is the mainstay of immunosuppressive regimens for organ transplantation and a variety of auto-immune diseases. Lux Biosciences has obtained an exclusive worldwide license from Isotechnika Inc the compound's discoverer, for its use in ophthalmic indications. Lux Biosciences is initially developing LX211 for the treatment of uveitis, specifically the more severe forms of the disease. Lux Biosciences initiated the Luminare (Lux Uveitis Multicenter Investigation of a New Approach to Treatment) pivotal program in uveitis during Q1 2007 with an oral formulation of LX211 that may offer significant safety advantages over existing therapies (only steroids are currently approved in most countries). Lux Biosciences believes that this calcineurin inhibitor may also be useful in several additional ophthalmic diseases, thus representing a pipeline of products addressing high medical needs in ophthalmic fields. The company is currently developing other uses of the compound in dry-eye syndrome and AMD.

### LX201

LX201 is a silicone matrix ocular implant that steadily releases therapeutic doses of CsA locally to the eye over the course of at least one year. Cyclosporine is used widely as systemic therapy for the prevention of rejection following solid organ transplantation. LX201 is implanted under the eyelid into the subconjunctiva (the area beneath the transparent membrane covering the white of the eye) in a minimally invasive procedure. Local delivery of CsA through LX201 potentially

offers significant benefits in the treatment of corneal transplantation related to:

- increased safety resulting from the lack of systemic toxicity;
- increased efficacy resulting from higher therapeutic levels at or near the transplanted cornea; and
- increased patient compliance due to good tolerability and the lack of missed dosing enabled by implantation.

Lux Biosciences initiated the Lucida (LUx Corneal Transplant Implant Development and Advancement of Therapy) pivotal clinical program of LX201 for the prevention of corneal transplant rejection in Q1 2007. No other drug is currently approved for this condition

### Polyarylate and Polycarbonate Technologies

Polyarylates are polymers derived from the natural amino acid tyrosine — an 'aryl' amino acid — and naturally occurring diacids, such as glutaric or adipic acid. Polycarbonates are polymers derived from the natural amino acid tyrosine, which are linked utilizing carbonate functional groups. Co-polymers such as block polymers with polyethylene glycol (PEG) chains in the polymer

backbone expand their versatility. Lux Biosciences has licensed the polyarylate and the second-generation polycarbonate technologies for exclusive, worldwide ophthalmic use from Rutgers, The State University of New Jersey.

The Rutgers combinatorial library of polyarylates consists of 114 polymers, and the combinatorial library of second-generation polycarbonates consists of some 10,000 polymers with a wide range of physical features, such as glass transition temperature, which is critical for molding of the polymer into specific shapes. The polymer matrix allows for hydrogen bonding and other stabilizing interactions with the embedded drug molecule and is thus also well suited for natural drug products such as peptides. The polymer is bio-erodable and resorbable, enabling the embedded drug molecule to elute slowly and provide therapeutic drug levels at a near-constant rate over the course of months or a year. A polyarylate polymer, developed by a Rutgers' partner company, has been successfully used as coating of a mesh for hernia repair, and was cleared recently by the US Food and Drug Administration (FDA). Another of Rutgers' partner companies is currently testing in humans a radio-opaque and bio-resorbable vascular stent made of a polycarbonate polymer. A large patent estate covers the technologies. ■

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