



### SAFE HARBOR STATEMENT

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements include uncertainties with respect to : our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema ("ILUVIEN"), which depends on Alimera's ability to continue as a going concern and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the number of clinical trials and data required for the Durasert three-year uveitis marketing approval applications in the U.S. and EU; our ability to file and the timing of filing and acceptance of the Durasert three-year uveitis marketing approval applications in the U.S.; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; our ability to successfully commercialize Durasert three-year uveitis, if approved; potential offlabel sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; potential declines in Retisert® royalties;; efficacy and our future development of an implant to treat severe osteoarthritis; our ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; effects of the potential U.K. exit from the EU; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. You should read and interpret any forward-looking statements in light of these risks. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.



### **PSIVIDA AT A GLANCE...**

...a commercial stage company with multiple proprietary and partnered products based on a proven, de-risked drug delivery platform



## EXECUTING STRATEGIES TO BUILD VALUE BY DELIVERING LOW-RISK INNOVATION



Focused on preventing blindness through proprietary sustained release drug technologies



Confidential and Proprietary Information of pSivida Corp.

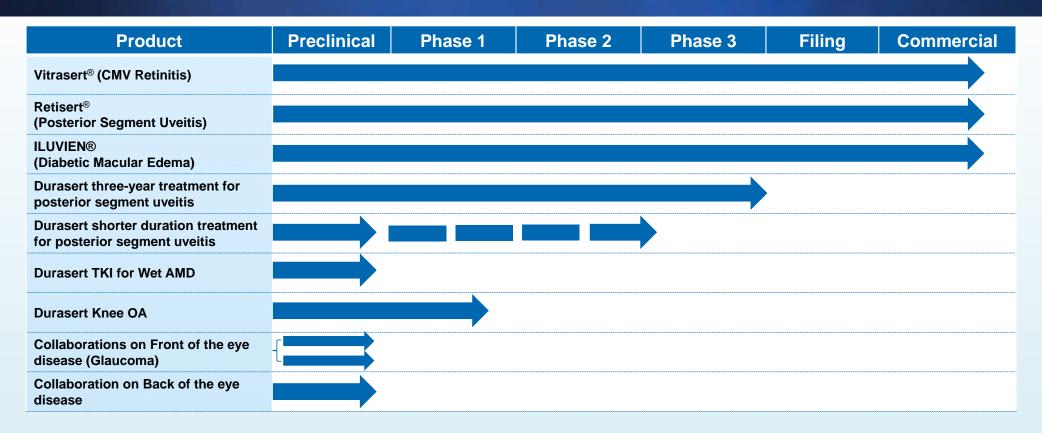


### **INVESTMENT CONSIDERATIONS**

- ▶ Durasert is based on proven technology: two commercial products and one product in regulatory approval submission phase
- ► Expect to submit next lead product candidate to the FDA in late December 2017/early January 2018
- ► Repeat FDA regulatory successes de-risks extensive product pipeline
- New collaboration agreement with Alimera expected to increase pSivida long-term returns
- ► Strong management team with clinical and commercial expertise



### **DURASERT TECHNOLOGY PRODUCT PIPELINE**



### DURASERT™: APPROVED TECHNOLOGY FOR OCULAR DELIVERY



#### **Long Duration**

▶ Up to 3 years from single injection minimizes ocular injections every 2-3 months; now focusing on 6-9 month regimen

### **Proprietary Sustained Polymer Technology**

▶ Tailored to be bio-erodible or non-erodible

### **Broadly Applicable**

Can deliver many types of small molecule drugs

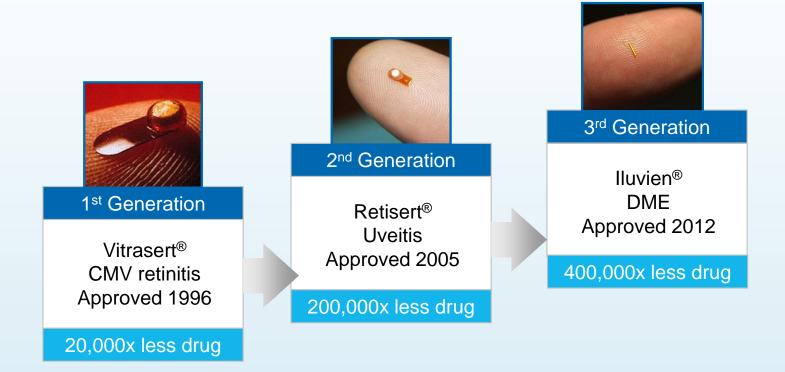
#### **Strong Patent Estate**

Issued patents covering Durasert technology and inserter extend until 2027





### **APPROVED DURASERT TECHNOLOGY PRODUCTS**





### **NEXT OPPORTUNITY: DURASERT FOR UVEITIS**

Preparing
filing package
for NDA filing
in late December
2017/early January 2018

Study 001 Phase III clinical trial: 129 patients

Filing Indication:
Treatment and
prevention of
posterior uveitis

Study 005 Phase III clinical trial: 150 patients

Study 006 Inserter clinical trial: 26 patients



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### **OUR EXPERIENCED MANAGEMENT TEAM** SIGNIFICANT CLINICAL AND COMMERCIAL EXPERIENCE





**Nancy Lurker** President and CEO





**Previous Companies** 



Plavix Ambien Exforge Reclast Pravachol DiovanHCT Detrol/DetrolLA Xolair Axert Focalin XR **Exelon Patch Famvir** Estrace Inspra

**Drugs Launched** 

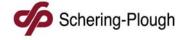






Vasotec Singulair Fosamax Nasonex Asmanex Jublia Detrol LA Ocuvite Prolensa Lotemax Gel Onexton





















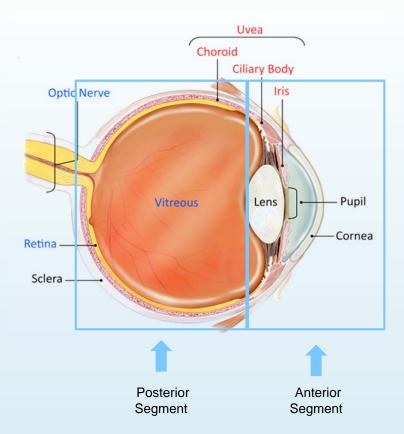


### UVEITIS IS THE THIRD LEADING CAUSE OF PREVENTABLE BLINDNESS IN THE DEVELOPED WORLD



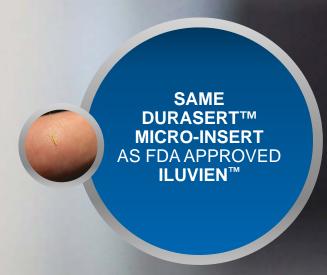
### **UVEITIS REPRESENTS A SIGNIFICANT UNMET MEDICAL NEED**

UVEITIS is inflammation of the uveal tract (iris, ciliary body, choroid) or adjacent structures



## DURASERT™ PHASE III TREATMENT FOR POSTERIOR SEGMENT UVEITIS

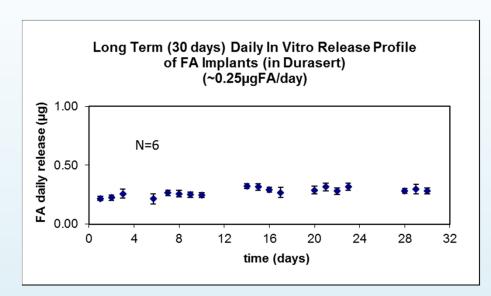


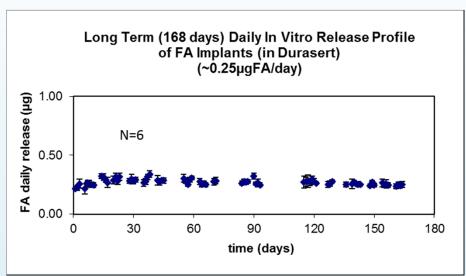


SAME DRUG AS
RETISERT® AND ILUVIEN®
DELIVERS
FLUOCINOLONE
ACETONIDE
(CORTICOSTEROID)

## CONSISTENT DAILY MICRODOSING WITH DURASERT MINIMIZES IOP SPIKES







### DURASERT™ 3-YEAR CLINICAL PROGRAM WITH HIGHLY POSITIVE RESULTS



# FIRST PHASE III TRIAL: PREVENTION OF RECURRENCE

**PRIMARY ANALYSIS COMPLETED** 

Study 001 Phase III clinical trial: 129 patients

Primary end-point:
Prevention of recurrence

Result: p < 0.001

# SECOND PHASE III TRIAL: PREVENTION OF RECURRENCE

**PRIMARY ANALYSIS COMPLETED** 

Study 005 Phase III clinical trial: 153 patients

Primary end-point: Prevention of recurrence

Result: p < 0.001

### INSERTER TRIAL: EASE OF ADMINISTRATION

PRIMARY ANALYSIS COMPLETED

Study 006 Phase III clinical trial: 26 patients

Primary end-point: Ease of administration

Result:

Positive usability

## EFFICACY END-POINT: UVEITIS RECURRENCE RATES AT 6 AND 12 MONTHS (STUDY 001)



6 MONTHS
RECURRENCE

18.4%
Durasert™ eyes
vs
78.6%
sham

Durasert™ eyes 3.9X more likely to be recurrence free Primary end-point achieved p < 0.001

12 MONTHS RECURRENCE **27.6% Durasert™ eyes**vs
85.7%
sham

Durasert™ eyes
5.1X
more likely to be recurrence free

Evidence of durable response

p < 0.001

## EFFICACY END-POINT: UVEITIS RECURRENCE RATES AT 6 (STUDY 005)



6 MONTHS
RECURRENCE

21.8%
Durasert™ eyes
vs
53.8%
sham

Durasert™ eyes 2.5X more likely to be recurrence free Primary end-point achieved p < 0.001



### **SAFETY RESULTS OF STUDY-005 AND STUDY-001**

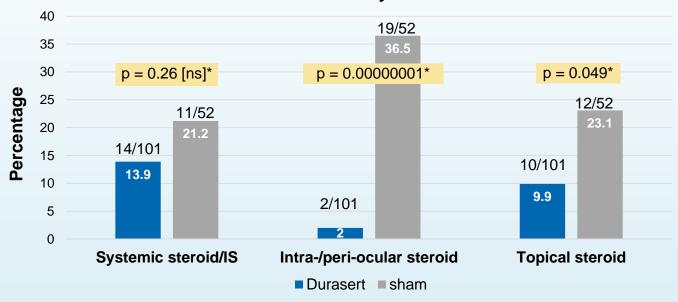
- ► Intraocular pressure (IOP) mean increase of +1.3mm HG (-005 study) and +1.7mmHG (-001 study) at six months, similar to known corticosteroid effects.
- ► Cataract surgery incidence at six months of 4.9% for Durasert vs 8.6% for Sham (-005 study) and 9.5% Durasert vs 4.8% sham (-001 study) similar to known effects of corticosteroids.



### **ADJUNCTIVE TREATMENTS [EXPLORATORY ENDPOINT]**

 Durasert group required fewer adjunctive treatments than sham group

### Subjects with at least one adjunctive treatment after Day 1



# DURASERT™ 3-YEAR PRODUCT FOR POSTERIOR SEGMENT UVEITIS HIGH UNMET NEED WITH PENT-UP DEMAND



- ▶ pSivida intends to commercialize Durasert for posterior segment uveitis in the US
- ► Uveitis has high unmet need for sustained delivery of efficacious drugs
  - Corticosteroids are first line treatment
- Relatively modest size market but limited number of uveitis specialists to call on
- ► Expected highly profitable product due to modest commercial costs and low COGS
- ▶ pSivida will continue to receive royalties on global sales of ILUVIEN for DME and EMEA sales for posterior segment uveitis







#### Corticosteroid injections are frequently required to address uveitis flares

### Corticosteroids approved for the IVT Rx include Retisert<sup>®</sup>, Ozurdex<sup>®</sup>, Triesence<sup>®</sup> and Trivaris<sup>®</sup>

- Retisert (FA) is the only <u>true sustained release</u> product for uveitis but requires surgery to implant
- Ozurdex sustained clinical efficacy is known to be only approx. 3 months 2016 global revenue at \$263M for uveitis/DME/RVO

Market research consistently demonstrates preference for both 6-9 month and three year delivery over multiple shorter ocular indications

#### **Completed Formulation Development**

- Preliminary animal safety complete and indicates well tolerated
- In vitro release testing shows release is linear and rates of release on target
- GLP safety/PK to be initiated September 2017









- ► Product was perceived as a very positive addition to current treatment options given ability to provide continuous, long-term control of chronic condition
- ▶ Level of interest in using the product on a scale of 1-10 (low to high) ranged from an "8" to a "10"
- Strong interest driven by Phase 3 study results showing significant efficacy and safety over full 12 month follow-up
- ► Physicians indicated that Durasert will likely source patients from Ozurdex because of longer duration and Retisert because of ease of administration (injection versus surgical implantation) and safety profile





### **NEW COLLABORATION AGREEMENT WITH ALIMERA**

#### **Global Diabetic Macular Edema**

- Approved for DME in US, 17 EU countries
- PSDV received over \$55M up front payments received from 2008-2014
- ➤ ALIM generated DME revenue of \$16.9 million in 1H 2017, \$33.4 million in FY 2016

### **Posterior Segment Uveitis**

- EU Type II Variation to be filed in 1Q 2018 for Uveitis
- ALIM has key relationships in EU with target market
  - Regulatory and product knowledge
- ▶ PSDV maintains US rights and plans to commercialize through direct sales force; intend to file with the FDA in December 2017 or early January 2018

Lasts for 3 Years

ILUVIEN™ Licensed Product

late



### BENEFITS OF COLLABORATION AGREEMENT TO PSIVIDA

#### **OLD COLLABORATION AGREEMENT**

### **Royalties on DME Net Profit Share:**

- 20% of any product profit plus net losses for commercialization, effectively enabling the company to receive 16% of the profit
- ► Alimera cash basis profitability unpredictable
- Cumulative revenue received between '15-'17 equals \$0.78 million
- Complicated accounting monitoring required

#### **NEW COLLABORATION AGREEMENT**

- Royalties on Global DME+ EMA Uveitis Net Sales:
  - 2% on global sales, 6% no later than 1/1/2019
  - 8% after \$75M in global ILUVIEN revenues; partial royalty offsets on accumulated ILUVIEN commercial losses
- Greater transparency
- Predictable revenue
- Substantially improve the potential total value of the Global Alimera agreement beyond a stand alone EU uveitis partner alone





### INVESTIGATOR-SPONSORED IND PHASE 1 EFFICACY AND SAFETY STUDY IN SEVERE KNEE OSTEOARTHRITIS

**STUDY ONGOING** 

Site: Hospital for Special Surgery

Study Design: Open label

Sample Size: 6 patients

Primary Endpoint: Efficacy and Safety

Secondary Endpoints: Pain Assessment

**Status:** Final patient implanted in April 2017



### DURASERT™ WITH TKI FOR WET AMD

- ► Tyrosine kinase inhibitors (TKIs) are antiangiogenic small molecules known to inhibit VEGF, a factor involved in wet AMD
- ► Sustained delivery of a TKI could result in reduced frequency of intravitreal injections versus current therapies
- ► TKI candidate demonstrated effectiveness in a non-clinical model of wet AMD with Durasert™
- ▶ Ongoing TKI candidate evaluation underway additional formulation study to optimize candidate selection

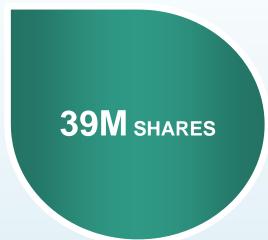






CASH: \$16.9M At June 30, 2017







### **SUMMARY HIGHLIGHTS**

- ▶ Durasert is based on proven technology: two commercial products and one product in regulatory approval submission phase
- ► Submitting next lead product candidate to the FDA in late December 2017/early January 2018
- ► Repeat FDA regulatory successes de-risks extensive product pipeline
- ► New collaboration agreement with Alimera increases pSivida returns
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### DELIVERING INNOVATION TO THE EYE

