



'a global bio-nanotech company'

**Mr Gavin Rezos**

**CEO/ Managing Director**

**NanoEquity Europe**

**July 2006**

[www.psivida.com](http://www.psivida.com)

PSDV  
**NASDAQ**  
LISTED



# pSivida at a Glance

- **Revenues from FDA Approved Products on the Market**
  - Retisert™ is the only FDA approved product for Uveitis
  - Vitrasert® approved in US, EU, Japan for CMV Retinitis
- **Broad and well-balanced R&D pipeline**
  - Medidur™ for DME – in Phase III pivotal trials
  - BrachySil™ for non-operable liver cancer – in Phase IIb pivotal trials
  - BrachySil™ for non-operable pancreatic cancer – in Phase IIa pivotal trials
  - Multiple early stage products based on BioSilicon™ drug delivery technology
- **Synergistic technologies**
  - Validated FDA approved implantable drug delivery devices
  - Versatile biomaterial – nanostructured porous silicon (BioSilicon™)
- **Strong Partners**
  - Multiple partnerships/ collaborations; Novartis, Bausch & Lomb, Alimera Sciences and Beijing Med-Pharm
  - Evaluation agreements with multiple Global Pharma/ Medical device companies
  - Large institutional shareholders
  - Strong intellectual property portfolio
- **Experienced Board & Management**
  - International experience
  - State-of-the-art facilities in Boston and the UK
- **Cash position of US\$13m as of 31 March, 2006 (US\$5m raised in Rights Issue in June 2006)**

Shares traded globally on ASX, NASDAQ and Frankfurt and included in the Merrill Lynch Nanotech Index and NASDAQ Healthcare Index



# Product Development

Product Candidate (Indication)	Preclinical	Phase I	Phase II	Phase III	Marketed
Vitrasert <sup>®</sup> (CMV)					
Retisert <sup>™</sup> (Uveitis)					
Medidur <sup>™</sup> (DME)					
BrachySil <sup>™</sup> (Liver Cancer)					
BrachySil <sup>™</sup> (Pancreatic Cancer)					
BioSilicon <sup>™</sup> (Reformulated Drugs)					
Medidur <sup>™</sup> (Other Eye Diseases)					
BrachySil <sup>™</sup> (Secondary Liver Cancer)					

# Licenses, Co-development & Collaborations

Partner	Details
Bausch & Lomb	<ul style="list-style-type: none"><li>• Broad License for first generation device for use in ophthalmic disease</li><li>• Manufacturing and marketing partner for Vitrasert<sup>®</sup> &amp; Retisert<sup>™</sup></li></ul>
Novartis	<ul style="list-style-type: none"><li>• Co-promotion of Retisert<sup>™</sup> in the United States with Bausch &amp; Lomb</li></ul>
Alimera Sciences	<ul style="list-style-type: none"><li>• Co-development agreement for Medidur<sup>™</sup> for DME device</li><li>• Alimera to market the product</li></ul>
Beijing Med-Pharm	<ul style="list-style-type: none"><li>• Geographic license to BrachySil<sup>™</sup> in China</li><li>• Partner to develop product in China</li><li>• Royalty of up to 30% of sales with development milestone payments</li></ul>
Global Pharmaceutical Companies	<ul style="list-style-type: none"><li>• Evaluating our technologies in multiple therapeutic fields</li></ul>
Global Medical Device Company	<ul style="list-style-type: none"><li>• Evaluate cardiovascular delivery of drugs using pSivida's drug delivery technologies</li></ul>



## Retisert™ (Uveitis)

- A surgically placed, non-erodible intravitreal implant that releases a constant amount of drug over a 30 month period
- Only FDA approved back of the eye treatment for Posterior Uveitis, a sight threatening inflammatory disease
- Three year follow-up data study showed three line improvement in vision
- Selling price for 30 months treatment, US\$18,250 – Medicare covered
- Posterior Uveitis - Autoimmune disease causing severe inflammation of the eye → blindness
- Estimated 180k patients in the US, 200k in the EU and 800k worldwide
- B&L and Novartis co-promote in the United States
- pSivida receives royalties based on net sales

# Retisert™ Revenues

- 175,000 – 200,000 people in US require treatment for Uveitis (3rd largest cause of blindness)
- **Each 3% US market penetration = US\$100,000,000 in sales\***
- 200,000 people in the EU require treatment for Uveitis and 800,000 people worldwide
- Next regions targeted for approval are Japan and Europe

## Significant Royalties Payable to pSivida

Retisert™ together with Vitrasert®, are the only approved sustained release delivery systems for the back of the eye.

\*These are examples not projections. We are not able to predict what the market penetration will be.



## Medidur™ for DME

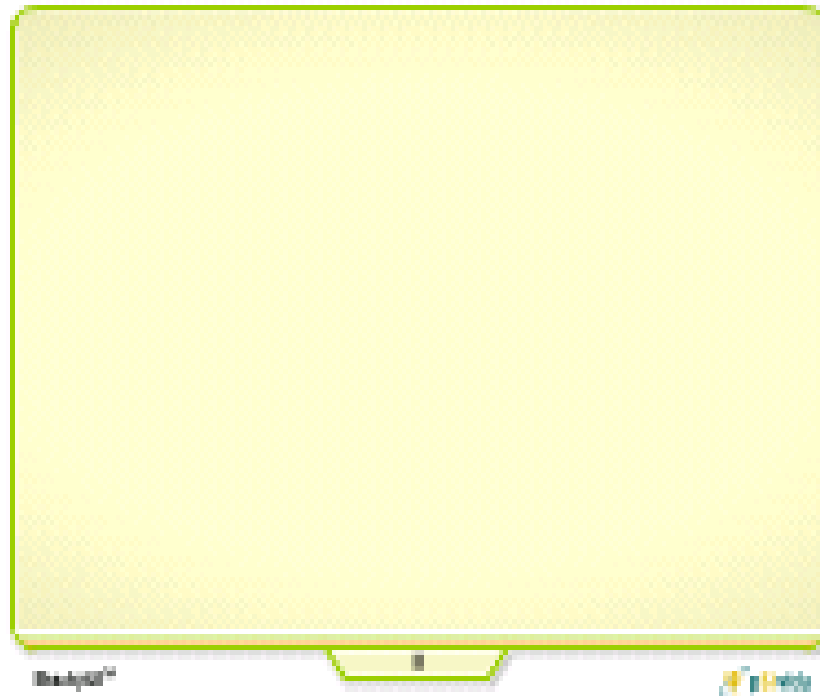
- Next generation injectable intravitreal implant designed to release a constant amount of drug over an 18 to 36 month period
- Office procedure rather than surgical
- Co-developed with Alimera Sciences, Inc. in phase III clinical study
- A leading cause of vision loss for Americans under age of 65
- At least 500,000 treatable cases in the US alone, but no FDA approved drug therapy
- Three year follow-up data study of Retisert™ in DME showed three line improvement in vision over standard of care

# Sustained Release FA in Diabetic Eye Disease

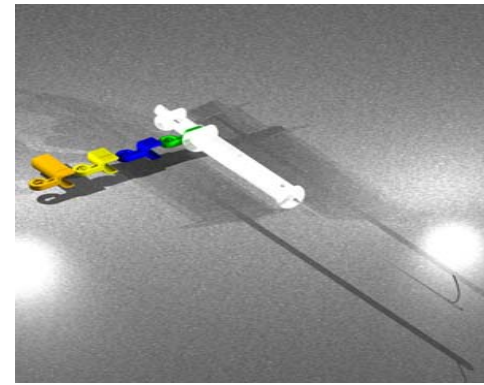
- Medidur™ and Retisert™ release the same drug, FA (fluocinolone acetonide)
- 2 year & partial 3 year clinical trials of Retisert™ in DME show that sustained release intraocular FA can:
  - Increase the % of patients whose vision improves by 3 lines
  - Decrease the % of patients whose Diabetic Retinopathy gets worse
- Medidur™, now in phase III clinical trials, can release FA at the same or lower rate as Retisert™

# BrachySil™

## Targeted Cancer Therapy



# BrachySil™



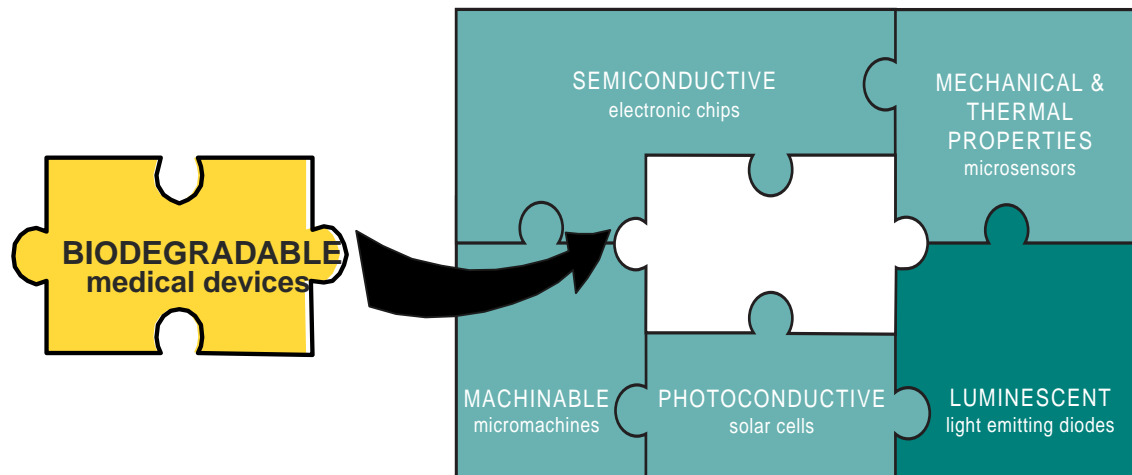
- Medical device
- 30 micron etched BioSilicon™ particles containing radio-labeled phosphorous ( $^{32}\text{P}$ )
- Easy-to-use, localized and targeted treatment for solid tumors
- Administered under local anesthetic via direct intratumoral injection using a fine gauge needle with ultrasound or CT guidance
- Patients discharged next day
- \$600 million market expected to grow to \$1billion over next few years
- Currently in Phase IIb pivotal clinical trials in primary liver cancer
- Pancreatic cancer – Phase IIa scheduled to commence in June

# Controlled Drug Delivery Hours, Weeks, Months



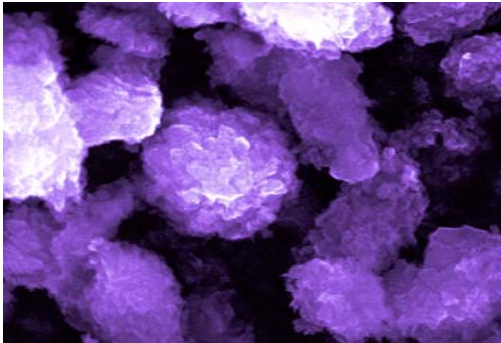
# BioSilicon™

- **Nanostructured porous silicon** – biocompatible and biodegradable with semi-conductor properties
- **Degrades into a natural byproduct** - silicic acid
- **Large surface area for high drug loading (80-95%)**
- **Machinable into a variety of different forms: micro/ nano particles, 3-D scaffolds, coated threads/ fabrics, etc.**
- **Abundant, low cost manufacture and proven scale-up**
- **Range of different dosage forms, routes of administration, and delivery rates: injectable depots, oral, implants, coatings, and patches**
- **Potential for 'smart' devices including electronic components**

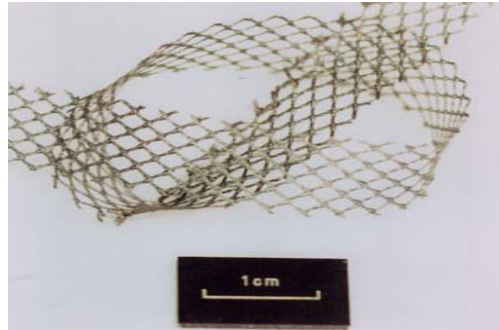


# Diverse Forms of BioSilicon™

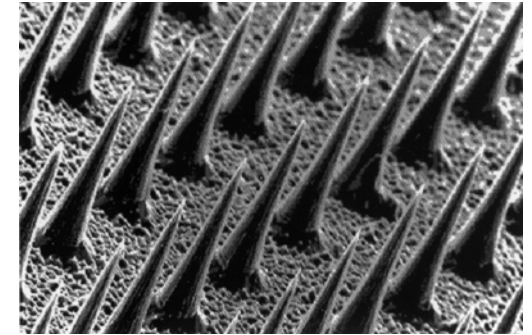
Microparticles



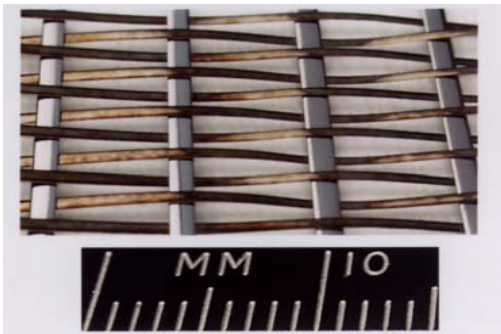
BioSilicon™ coated Fabric



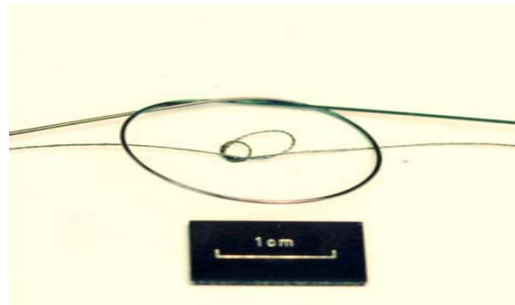
Microbarb array



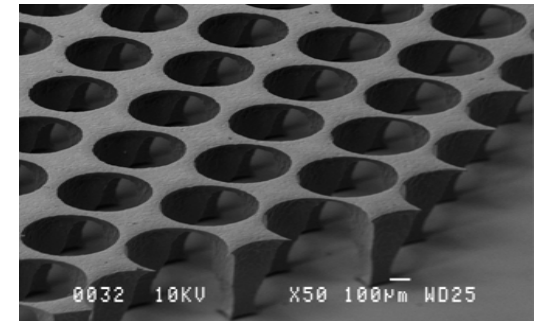
Woven pure BioSilicon™



BioSilicon™ coated Thread



Micromachined 3D scaffolds



# Chronotherapy

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Many human illnesses and their symptoms show a regular (rhythmic) pattern:

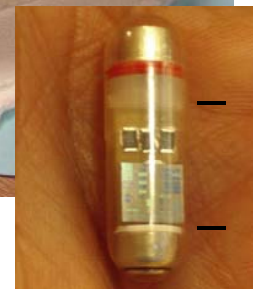
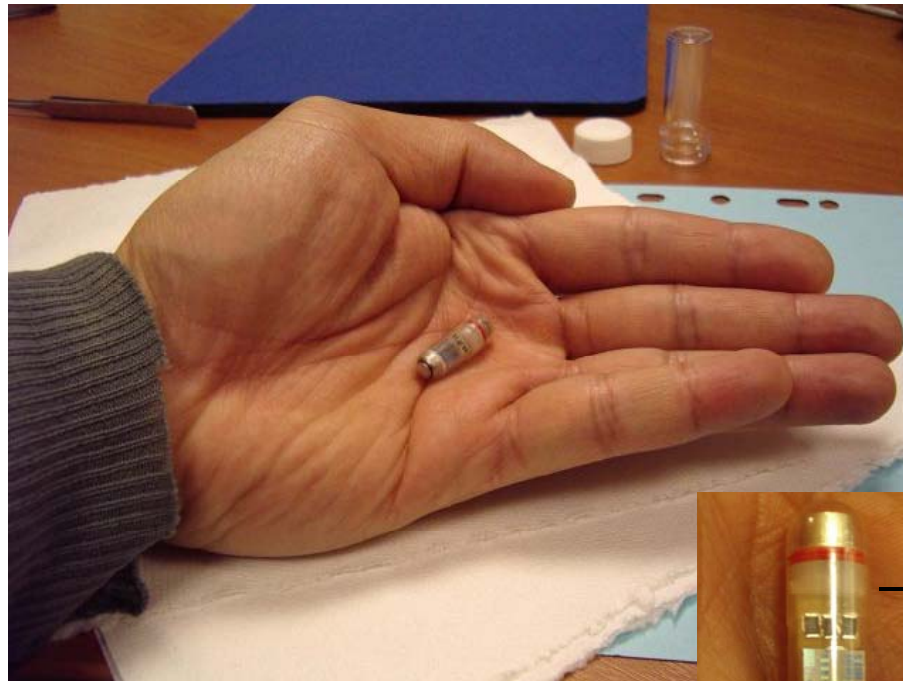
- hypertension (*early morning*)
- arthritic pain (*mid afternoon*)
- heart attack (*early morning + late afternoon*)
- asthma attack (*night*)

**It is recognised that treatment can be made more effective if the drug intake into the body is timed to match the severity of the symptom.**

# The 'Ticking Capsule'

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Chronotherapeutic devices employ some electrical means of controlling pulsatile drug release coupled with electronic timing.

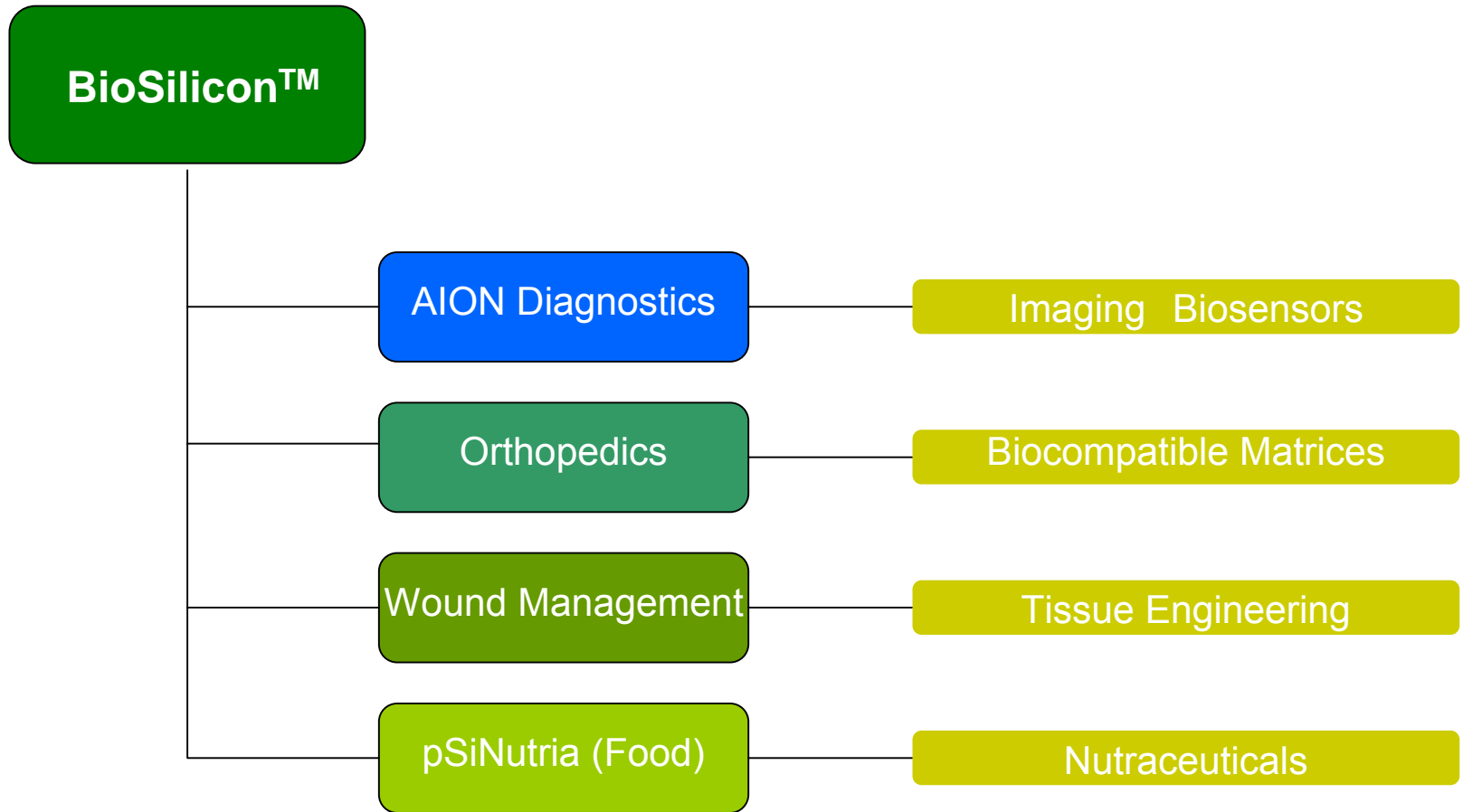


Porous Si -based  
drug delivery module

Electronic control  
module (e.g.  $\mu$ -controller)

Battery

# Maintain focus: Spin out Non-Core



# Intellectual Property

## **Holder or exclusive licensee of:**

- 70 patent families
  - 75 granted patents
  - Over 280 applications
- 
- Patents granted in core markets; US, Europe, Japan, China, Korea and Australia.

# Experienced Board

## pSivida Limited

Mr. Gavin Rezos  
**CEO/ Managing Director**  
*(ex HSBC Investment Banking Director)*

Dr. Roger Brimblecombe  
**Non executive Chairman**  
*(ex Smith Kline Chairman of Research)*

Dr. Paul Ashton  
**Director of Strategy**  
*(ex CEO of Control Delivery Systems)*

Mr. Stephen Lake  
**Non executive Director**  
*(Investment Director, QinetiQ)*

Dr. David Mazzo  
**Non executive Director**  
*(CEO, Chugai Pharma US)*

Mr. Michael Rogers  
**Non executive Director**  
*(CFO, Indevus Pharmaceuticals Inc)*

Ms. Heather Zampatti  
**Non executive Director**  
*(Head of Wealth Management, Australia Bell Potter)*

# Management Team

## pSivida Limited

Mr. Gavin Rezos  
**CEO/ Managing Director, Aust.**  
(ex HSBC Investment Banking Director)

Dr. Paul Ashton  
**Director of Strategy, US**  
(ex CEO of Control Delivery Systems)

Mr. Michael Soja  
**Vice President of Finance, CFO and Treasurer, US** (ex CDS)

Ms. Lori Freedman  
**Vice President of Corporate Affairs, General Counsel and Secretary, US** (ex CDS)

Prof. Leigh Canham  
**Chief Scientific Officer, UK**  
(ex Principal Scientist, QinetiQ)

Dr. Roger Aston  
**Consultant, Aust**  
(ex Director Peptech & Cambridge Antibody)

Dr. Mark Parry-Billings  
**Director R&D, pSiMedica UK**  
(ex Schering Healthcare)

Dr. Jill Ogden  
**Commercial Director, pSiMedica UK**  
(ex Elan)

Mr. Stephen Connor  
**Development Director, pSiMedica, UK** (ex Novartis)

Dr. Beng Choo  
**BrachySil™ Clinical Development Mgr, pSiOncology, Sing.** (ex Pharmacia)

Mr. Aaron Finlay  
**CFO & Company Secretary, Aust.**  
(ex INVESCO)

Mr. Brian Leedman  
**Investor Relations, Aust.**  
(ex Ernst & Young)

# Financial Snapshot

Stock Exchange Listings	
2001	ASX (PSD)
2003	Frankfurt (PSI)
2005	NASDAQ (PSDV)

As of March 31, 2006	pSivida Limited
Market Capitalization	US\$206m
Shares Outstanding	387m
Cash	US\$13m +*\$5m

*\*US\$5m raised in Rights Issue in June 2006*

# Institutional Shareholders

<b>Larger and Institutional</b>		
<b>QinetiQ</b>	<b>UK</b>	<b>9.20%</b>
<b>Essex Woodlands Funds</b>	<b>US</b>	<b>5.68%</b>
<b>Bausch &amp; Lomb Incorporated</b>	<b>US</b>	<b>5.47%</b>
<b>T. Rowe Price Funds</b>	<b>US</b>	<b>3.41%</b>
<b>Morgan Stanley Funds</b>	<b>US</b>	<b>2.77%</b>
<b>Brookside Capital Partners LP (Bain Capital)</b>	<b>US</b>	<b>2.27%</b>
<b>Essex Private Placement Funds</b>	<b>US</b>	<b>1.70%</b>
<b>SMALLCAP World Fund, Inc (Capital Research)</b>	<b>US</b>	<b>1.70%</b>
<b>Invesco</b>	<b>UK</b>	<b>1.55%</b>
<b>Union Investment</b>	<b>Germany</b>	<b>1.50%</b>
<b>Anvil Investment Associates LP</b>	<b>US</b>	<b>1.42%</b>

## Value Drivers in 2006 –

- **Progress of pivotal registration trial on BrachySil™ in primary liver cancer**
- **Initiation of phase IIa pancreatic cancer trial for BrachySil™**
- **Continuation of Medidur™ phase III clinical trials**
- **Increasing Retisert™ revenues through Novartis**
- **Potential Licensing Deals on Drug Delivery Technologies**
- **Potential additional Co Development Deals on BrachySil™**
- **Potential Co Development Deals on Reformulated Generics using BioSilicon™**

# Investment Highlights

- **Two FDA approved products on market**
- **Strong product pipeline with late stage product candidates addressing large and unmet medical needs**
- **Validated drug delivery platform technologies continuing to feed product development pipeline focusing on ophthalmology and oncology**
- **Multiple existing and potential licensing/ partnering opportunities**
- **Seasoned management team with skill-sets to execute on stated growth strategy**



This document contains forward-looking statements that involve risks and uncertainties. The statements are indicated by the use of words such as "believes", "expects", "anticipates" and similar words and phrases. Although we believe that the expectations reflected in such forward-looking statements are reasonable at this time, we can give no assurance that such expectations will prove to be correct. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Actual results could differ materially from those anticipated in these forward-looking statements due to many important factors including: failure to complete negotiations for new centers for the BrachySil™ phase IIb clinical trial for inoperable primary liver cancer; the failure of our discussions with the FDA for BrachySil™ to continue or to lead to FDA approval; the failure of the BrachySil™ phase IIb clinical trial for inoperable primary liver cancer to determine the optimal dose, provide key safety data or support future pivotal efficacy trials or product registration or approval; failure to commence Phase IIa BrachySil™ trials for the treatment of pancreatic cancer; the failure of the results of the Retisert™ for DME trial to be a good indicator of the results of pSivida's ongoing Phase III Medidur™ for DME trial; failure of the Medidur™ trials in DME to show a very similar improvement in visual acuity and diabetic retinopathy severity score as Retisert™ for DME; inability to recruit patients for the Phase III Medidur™ for DME trial; our failure to develop applications for BioSilicon™ due to regulatory, scientific or other issues, our inability to successfully integrate pSivida Inc's operations and employees; the failure of the pSivida Inc's products to achieve expected revenues and the combined entity's inability to develop existing or proposed products; the failure of the Bausch & Lomb/Novartis co-promotion arrangement to provide faster royalty growth; failure of the slower progression or reduction of diabetic retinopathy resulting from the Retisert™ implant to have significant implications for Retisert™ and Medidur™; failure of our evaluation agreements to result in license agreements; failure of Medidur™ to release the same drug as Retisert™ at the same rate; failure of the Medidur™ trials in DME to show a very similar stabilization or improvement diabetic retinopathy as Retisert™ for DME; failure to achieve cost savings; failure to execute on US growth strategy; failure of the findings of the pancreatic cancer phase IIa trial to provide a platform for further multicentre efficacy and safety trials; failure of there to be optimisation and standardisation between the two pancreatic cancer study centres; failure of the BrachySil™ primary liver program that is in Phase IIb clinical trials to provide a valuable platform for the development and commercialisation of BrachySil™ for pancreatic cancer and other indications. Other reasons are contained in cautionary statements in the Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission, including, without limitation, under Item 3.D, "Risk Factors" therein. We do not undertake to update any oral or written forward-looking statements that may be made by or on behalf of pSivida.

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