## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 9, 2015

#### PIERIS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Nevada (State of Incorporation)

333-190728 (Commission File Number) EIN 30-0784346 (IRS Employer Identification No.)

Lise-Meitner-Strasse 30 85354 Freising-Weihenstephan, Germany (Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: +49 81 6114 11400

Chec	heck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:						
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)						
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)						
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))						
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))						

#### Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 and incorporated by reference herein is an investor presentation of Pieris Pharmaceuticals, Inc.

The information set forth under this "Item 7.01. Regulation FD Disclosure," including the exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 Investor Presentation of Pieris Pharmaceuticals, Inc., dated March 9, 2015.

#### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 9, 2015 PIERIS PHARMACEUTICALS, INC.

By: /s/ Darlene Deptula-Hicks
Name: Darlene Deptula-Hicks
Title: Acting Chief Financial Officer

#### EXHIBIT INDEX

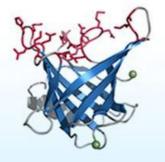
Exhibit No.

No. Description

99.1 Investor Presentation of Pieris Pharmaceuticals, Inc., dated March 9, 2015.







The Anticalin Company™

Pieris Pharmaceuticals, Inc. (OTC:PIRS)

The 27th Annual ROTH CONFERENCE

Stephen Yoder CEO

**March 2015** 

## **Forward Looking Statements**



Statements in this presentation that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. In some cases, you can identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or the negative of these terms or other comparable terminology. Factors that could cause actual results to differ materially from those currently anticipated include, without limitation, risks relating to the results of our research and development activities, including uncertainties relating to the discovery of potential drug candidates and the preclinical and clinical testing of our drug candidates; the early stage of our drug candidates presently under development; our ability to obtain and, if obtained, maintain regulatory approval of our current drug candidates and any of our other future drug candidates; our need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need; our ability to retain or hire key scientific or management personnel; our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; competition in our industry; regulatory developments in the U.S. and foreign countries; as well as those risks more fully discussed in the "Risk Factors" section of our Current Report on Form 8-K filed with the SEC on December 18, 2014 and the other reports we file with the SEC. In light of these risks, uncertainties and assumptions, the forward-looking statements regarding future events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements included in this presentation speak only as of the date hereof, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations.

# Pieris Pharmaceuticals, Inc. – The Corporation (OTC:PIRS)



- R&D company developing first-in-class biologics
- Built on cutting-edge Anticalin® technology
  - Highly differentiated next generation therapeutic proteins
  - Multispecifics, Inhaled Delivery, Tunable Kinetics
  - Superior drug-like properties
- Protected by strong IP
  - Strong patent position and no 3 <sup>rd</sup> party IP identified to date for FTO
- Strong pipeline validated by clinical data
  - Clinical activity, lack of immunogenicity in cancer patients
  - Proprietary pipeline in Immuno-Oncology, Immunology, Anemia and Respiratory
- Proven track record for successful collaborations with Pharma

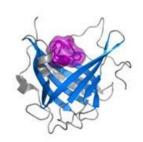














# Pieris Pharmaceuticals, Inc. – The Corporation (OTC:PIRS)



Balance Sheet

#### Solid Financial Position

- \$54M in total revenues
- \$82.6M total capital raised
- Went public in Dec 2014 through reverse merger
  - Raised \$13.6M
  - Straight common stock
- \$18M in cash as of Dec 2014 year end
- Major shareholders include Ally Bridge Group, Forbion Capital, Gilde, GLSV, Lombard Odier, Montrose Capital, Novo Nordisk, OrbiMed Advisors, Sphera Funds and Zydus Cadila

#### Highly experienced international leadership team

- CEO, CSO, Head of Discovery, Head of BD all formerly at MorphoSys
- Potential to repeat German Biotech MorphoSys success story:
   MorphoSys currently with >20 clinical programs, multiple
   high-value pharma partnerships, approx. \$2bn market cap



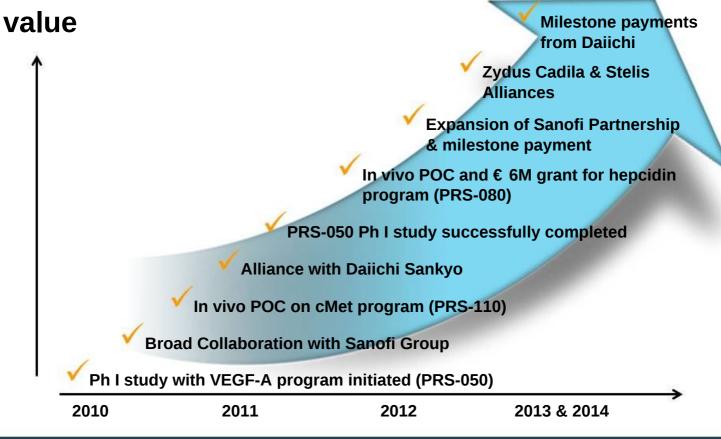
## **Experienced Management Team**



	Stephen Yoder	Ulrich Moebius	Christine Rothe	Shane Olwill	Eckhard Niemeier	Darlene Deptula
Title	CEO	cso	Head Discovery	Head Dev	Head BD	CFO
Education	JD BS/BA	PhD Post doc	PhD Post doc	PhD Post doc	MS	MBA
Prior Experience	morphosys	medigene	morphosys	fusion antibodies	McKinsey&Company	MICROLINE.  SURGICAL   ICAD  Never stop looking*

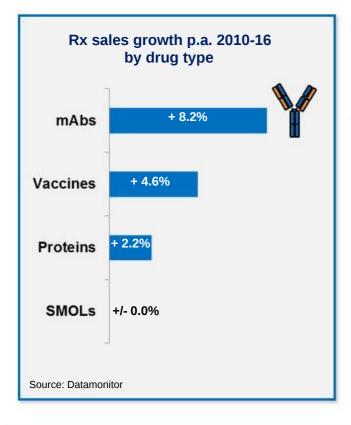
# Significant Achievements 2010 to 2014





## mAbs – Fast Growing Rx Segment Anticalins – Differentiated Fast-Followers





- Monoclonal Antibodies (mAbs) are highly successful drugs showing very high sales growth within prescription pharmaceuticals
- Anticalins share many of the beneficial properties of mAbs and are at the same time highly differentiated



- > Formatting flexibility for multispecific drugs
- ➤ Alternative delivery routes (e.g. inhaled) due to size and biophysical properties
- > Tunable kinetics to match biological need
- **Lower COGS** due to bacterial expression

NON-CONFIDENTIAL TO STATE OF THE PROPERTY OF T

# Human Lipocalins – Scaffold for Novel Anticalin Therapeutics



## Human lipocalin "template"



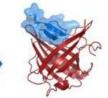
- Human, natural binding proteins
- Low molecular weight (~1/8 of mAb size)
- Extracellular
- Non-immunogenic
- Very stable "cuplike" structure

- Highly diverse libraries (>10<sup>11</sup>) of potential drug candidates
- Highly automated selection and screening technology (phage display)
- Deep protein engineering know-how to yield ideal drug candidates

#### High-affinity (pM) Anticalin bound to



Small target



Medium target



Large target

# Choice – Anticalins Meet the Industry Demand for Multispecifics



**Pure Anticalin formats** 



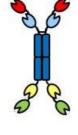


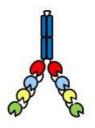


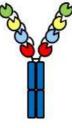


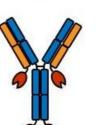


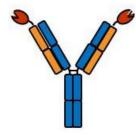














- Molecules designed for optimal target engagement and drug like properties
- Binding site geometry can be adjusted to biological need

## **Commercialization Strategy**

Multiple Shots on Goal: Partnered & Proprietary



#### Fully Proprietary

#### Pieris selects target, funds all costs

- Immuno-oncology, anemia, respiratory: strong networks
- High barriers to entry: e.g. IP, multispecifics, inhalation

#### Co-Dev

#### **Shared investment, shared ownership**

- Alternative mechanism to advance several programs in a proprietary-like fashion
- Retain commercialization rights in major markets

# Fully Partnered

#### Partner selects target, funds all costs

- Industry validation
- Significant cash flow upfront and milestone payments

## Pipeline: Today & Planned Progression Through End of 2016



	Target(s)	1° Indication		Discovery	Preclinical	Phase 1	Phase 1b	Phase 2
PRS-050	VEGF-A	Oncology	-pieris-			*		
PRS-080	Hepcidin	Anemia	-pieris-	ĵ				
PRS-060	IL4Ra	Asthma	-pieris-	Į.				
PRS-300	multiple	Ю	-pieris-					
PRS-110	cMet	Oncology	Zydus dedicated/i/					
PRS-NN	n.d.	n.d.	Zydus					
PRS-NN	n.d.	Ophthalmology	Stelis	ļ				
PRS-NN	n.d.	Ophthalmology	Stelis					
Sanofi Group	n.d.	Sept 2010 Initiation	SANOFI					
Daiichi Sankyo	n.d.	April 2011 Initiation	O	ļ				
n.d. = not disclosed				Status To	oday	Pieris to fur	nd Partr	ner to fund

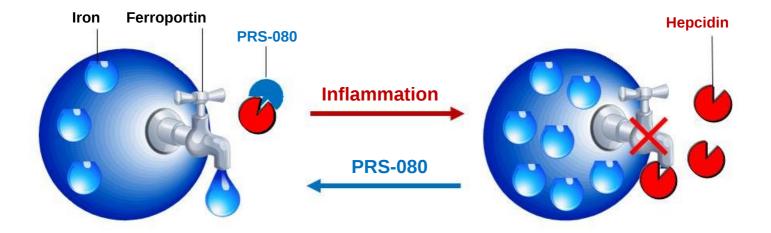
## Validating Collaborations



Partner	Overview	Financials	Comments
SANOFI	<ul> <li>Multispecifics drug discovery collaboration – 2010</li> </ul>	■ > 50M € potential for each program; royalties	<ul><li>2 milestone payments to date</li><li>Multispecifics project handover achieved 4Q14</li></ul>
Daiichi-Sankyo	<ul> <li>Two-program drug discovery collaboration – 2011</li> </ul>	■ > 100M € potential for each program; royalties	<ul> <li>5 milestone payments to date</li> <li>Several potential milestone payments 2015-17</li> </ul>
collaboration incl cMet		<ul><li>Funded through clinical POC</li><li>Pieris retains major markets</li></ul>	Retained strategic oversight
Stelis Biopharma	■ Co-development in ophthalmology – 2013		
Anticalin program in ophthalmology – 2009		■ \$10M upfront	<ul><li>Program handed off to Allergan</li></ul>

## PRS-080: Intended to Reverse Hepcidin-Mediated Functional Iron Deficiency

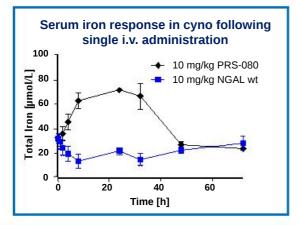


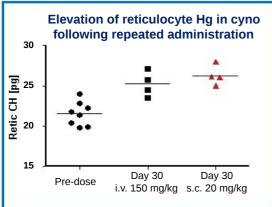


- PRS-080 reverses hepcidin-mediated anemia by mobilizing iron trapped in the body's iron storage cells
- Addresses patients unresponsive to ESA and iron therapies
- PK profile of PRS-080 designed to match hepcidin biology

# PRS-080: Effective in vivo – Currently in Phase 1







#### ✓ Demonstrated efficacy and safety in cynos

- Single-dose serum iron response
- Increased reticulocyte hemoglobin after multiple doses
- No adverse events in GLP tox

#### ✓ Funded through Ph I by ongoing € 6M EU grant

#### ✓ First-in-man study initiated December 2014

- Single-dose escalation in HVs (n=48)
- Endpoints:
  - Safety, MTD, PK, immunogenicity
  - Target engagement
  - PD effects: serum iron, ferritin, transferrin saturation, reticulocyte count, hemoglobin
- Final cohort of subjects planned mid 2015
- Reporting of results expected 2H 2015

# PRS-080 in Chronic Kidney Disease Market Opportunity



# Hemodialysis Patients (Total 1.9M Worldwide) No anemia 18% Hemodialysis Patients with Anemia (Total 1.6M Worldwide) FID 76% FID 24%

# Target Functional Iron-Deficient (FID) population:

U.S. 80,000 EU 61,000 JP 57,000 ROW 186,000

# **Estimated yearly treatment costs:**

~ \$5,000 - \$10,000

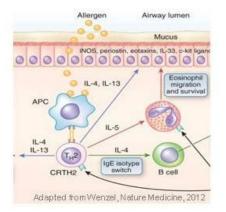
Treating FID anemic HD patients with PRS-080 has large commercial potential

Sources:

USRDS 2014 Annual Data Report (2012 numbers): Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the U.S ESRD Patients in 2011 – A Global Perspective, Fresenius Medical Care; Artisan Healthcare Consulting market research study

# PRS-060 – First-in-Class Inhaled Biologic Targeting IL4Ra





#### Strong target validation & biomarker availability

- ✓ IL4Ra a key mediator in Th₂ pathway disorders including asthma
- ✓ IL4Ra mediates IL4 and IL13 signaling
- ✓ Patient selection with ↑Th₂ pathway is now straight-forward
- ✓ IL4/13 mAbs (e.g. dupilumab) with strong efficacy in Phase 2b
- √ Validated biomarkers (e.g. FeNo) allow for early clin. read-out

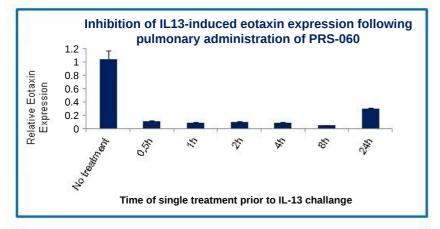
#### **Clear differentiation from systemic mAbs**

- ✓ Broader therapeutic index: Low systemic exposure may lead to better side effect profile long-term (e.g. role of Th2 in metabolic balance)
- ✓ More convenient: Inhalation preferred over s.c. injections
- ✓ More flexible: Daily dosing may allow combination with SoC
- ✓ Micro-dosing & Lower COGS: May allow reaching broader patient populations

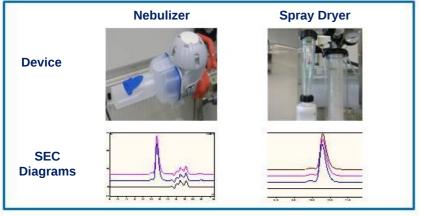


# Pulmonary Delivery of PRS-060 Effective in vivo & Feasible Formulation





Early onset of inhibition and durability of effect up to 24h post pulmonary administration



Nebulization and spray drying feasibility demonstrated

- **✓** Appropriate particle size
- **√** No aggregation
- **√** Full functional activity
- ✓ High Yield

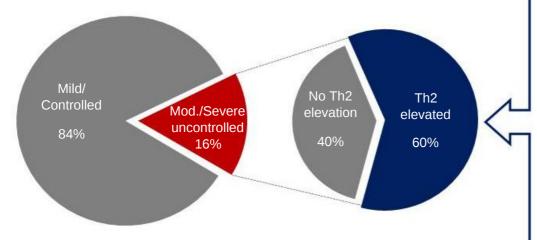
## PRS-060 in Asthma Market Opportunity



## Asthma Patients

## Moderate/Severe uncontrolled Patients

(Total 195M in Major Markets<sup>1</sup>) (Total 32M in Major Markets)



# Target Th2 elevated Asthma population:

19M in Major Markets

## Estimated yearly treatment costs:

~ \$10,000 - \$15,000

Treating Th2elevated uncontrolled Asthma patients with PRS-060 is a blockbuster opportunity

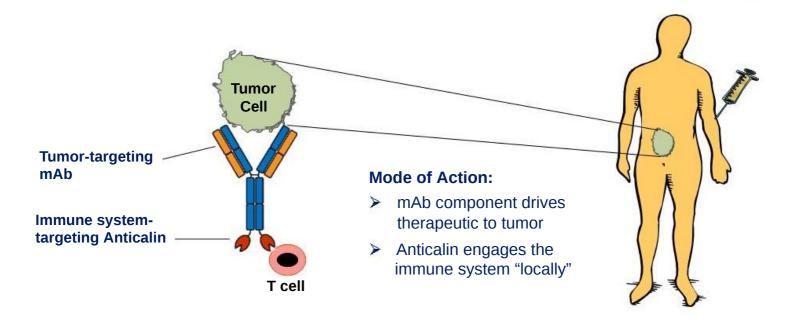
Source:

Artisan Healthcare Consulting market research study

<sup>&</sup>lt;sup>1</sup> Major Markets: U.S., EU, Japan, Brazil, Russia, India, China

# PRS-300 Series – Addressing Two High Unmet Needs in Oncology



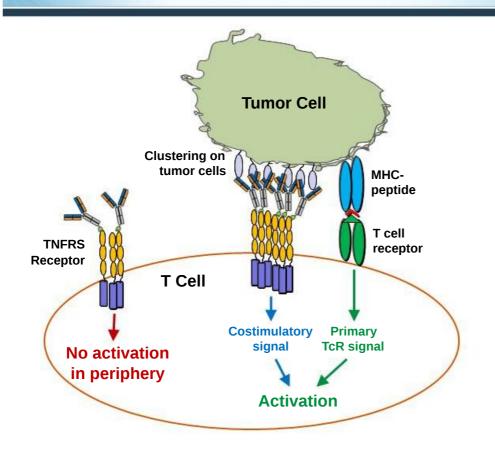


Potential benefits of tumor-localized engagement of immune system:

- > Increased efficacy in patients unresponsive to targeted therapies
- > Enhanced tolerability with reduced on-target "off-tumor" effects

# PRS-300 Series Costimulatory T cell Engagement





Costimulatory T cell
engagement in the
tumor microenvironment to
maintain
T cell receptormediated tumor
antigen specificity

# PRS-300 Series Differentiates from Current IO Approaches

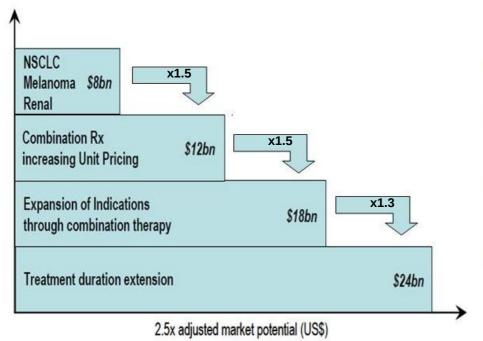


Approach	Tumor- targeted activation	TcR- mediated specificity	Toxicity	Delivery
Agonistic mAbs	No	Yes	Low to significant	Injection
BiTE	Yes	No	Observed	Slow infusion
CAR-T	Yes	No	Observed	Individualized adoptive therapy
PRS-300	Yes	Yes	Expected low	Injection

# Differentiated Immuno-Oncology Drugs Have Blockbuster Potential



#### Checkpoint agents have a market potential in excess of \$20bn by 2021



- Consensus forecasts in initial indications
- Price of therapy per patient set to increase due to migration to checkpoint combination therapy
- Combination strategies with chemo/ radio/mAbs/vaccines/cryo likely to expand potential indications
- Duration of immunotherapy likely to expand given anticipated improvements in progressionfree and overall survival

Source: Citi Research

# Anticalin Intellectual Property – Safe & Sound



### **Exclusivity**

- Drug class protected through 2020s
- Controlled patent filings and prior art enable broad follow-on protection
- Unique IP for each program

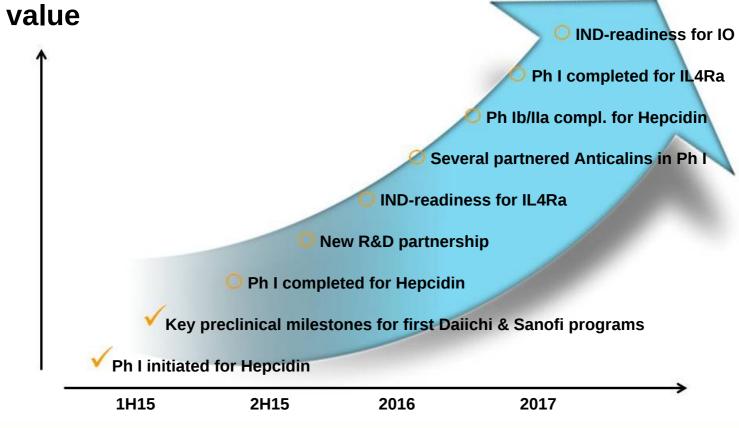
#### **Freedom to Operate**

 No third party IP identified to date for FTO on platform or therapeutic programs

Program (Target)	CoM Patent Term
cMet	2030
Hepcidin	2031
IL4Ra	2031
300 Series (IO)	2035+

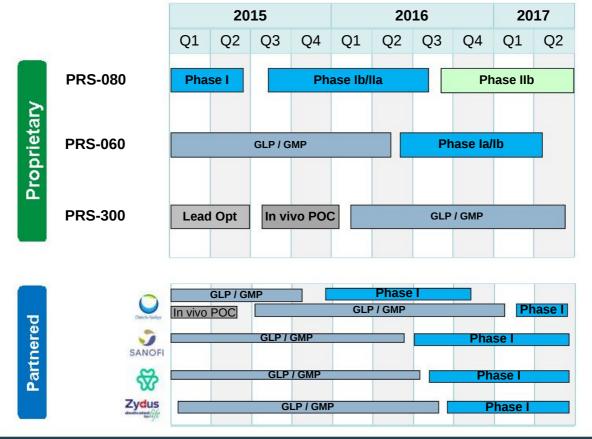
## Corporate Objectives 2015-2017





# 30-Month Projected Pipeline Progression





## Corporate & Financial Summary



- Company founded in 2001
- OTCBB: PIRS, December 2014, raised \$13.6M
  - Total capital raised \$82.6M
- Major shareholders include Ally Bridge Group, Forbion Capital, Gilde, GLSV, Lombard Odier, Montrose Capital, Novo Nordisk, OrbiMed Advisors, Sphera Funds and Zydus Cadila
- Revenues \$54M (\$40M licensing and \$14M grant revenue)
- At September 30, 2014 (9 months)

Net Loss \$5.7M
Cash & Cash Equivalents \$.9 M
Debt \$5.1M

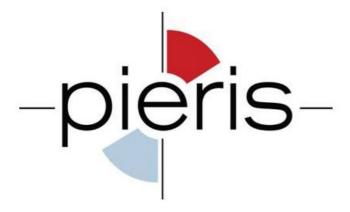
- Shares Outstanding Fully Diluted: 33,021,882
  - Includes 3.2M option pool & 542,360 warrants
- Validation through strategic partnerships and collaborations
  - Sanofi, Daiichi Sankyo, Zydus, Stelis, Allergan

## **Investment Highlights**



- ✓ Human PoC achieved with Anticalin platform
  - Novel therapeutic proteins
  - Superior drug-like properties
- ✓ Validation through strategic partnerships and collaborations
  - Sanofi, Daiichi Sankyo, Zydus, Stelis, Allergan
- ✓ Several differentiated proprietary and partnered drug candidates advancing towards or through clinical development
- ✓ Potential for rich news flow in 2015
  - Milestone payments; clinical data; new partnerships
- ✓ Proven management team and highly regarded Board of Directors





Pieris Pharmaceuticals, Inc. Lise Meitner Strasse 30 85354 Freising Germany

Tel.: +49 (0) 8161 1411 400 Fax: +49 (0) 8161 1411 444

info@pieris.com www.pieris.com