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): May 10, 2023

PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-37471**	**30-0784346**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

225 Franklin Street, 26th Floor **Boston, MA** **(Address of principal executive offices)**	**02110** **(Zip Code)**

Registrant's telephone number, including area code: 857-246-8998
N/A
(Former name or former address, if changed since last report.)

Check 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	**PIRS**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2023, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain financial results for the quarter ended March 31, 2023. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information set forth under this "Item 2.02. Results of Operations and Financial Condition," including Exhibit 99.1 furnished 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 7.01 Regulation FD Disclosure.

Furnished hereto as Exhibit 99.2 is the May 2023 Investor Presentation of the Company.

The information set forth under this "Item 7.01. Regulation FD Disclosure," including Exhibit 99.2 furnished hereto, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

99.1 Press Release, dated May 10, 2023.
99.2 Investor Presentation, dated May 2023.
104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

PIERIS PHARMACEUTICALS, INC.

Dated: May 10, 2023

/s/ Tom Bures
Tom Bures
Chief Financial Officer

Exhibit 99.1

May 10, 2023

PIERIS PHARMACEUTICALS REPORTS FIRST QUARTER 2023 FINANCIAL RESULTS AND BUSINESS UPDATES

COMPANY TO HOST AN INVESTOR CONFERENCE CALL TODAY,

WEDNESDAY, MAY 10, 2023, AT 8:00 AM EDT

- Enrollment for elarekibep (PRS-060/AZD1402) Phase 2a study for asthma continues to progress with topline clinical data anticipated by mid-2024; successful safety review completed for 10 mg dose cohort
- PRS-220, inhaled Anticalin protein for idiopathic pulmonary fibrosis (IPF), continues in Phase 1 study with topline results expected H2 2023
- PRS-400, inhaled Anticalin protein for muco-obstructive respiratory disease, advances toward anticipated development candidate nomination H2 2023
- New preclinical data to be presented at the American Thoracic Society (ATS) 2023 International Conference in May 2023 for both PRS-220 and PRS-400

BOSTON, MA, May 10, 2023 – Pieris Pharmaceuticals, Inc. (Nasdaq: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases, cancer, and other indications, reported financial results for the quarter ended March 31, 2023, and provided a business update.

“We continue to be excited by the potential of our inhaled biologics pipeline to reshape the treatment paradigm for patients living with uncontrolled asthma and other chronic respiratory diseases. Our top priority remains the study completion and clinical data read out from the elarekibep Phase 2a study in asthma, which is benefitting from increased operational resources from our partner, AstraZeneca,” said Stephen S. Yoder, President and CEO of Pieris. “Pieris continues to make measured investments in PRS-220 and PRS-400 while also expecting additional progress across partnered programs through our capital-efficient collaborations with Boston Pharmaceuticals, Genentech, Seagen and Servier.”

Respiratory Pipeline:

- **Elarekibep and AstraZeneca Collaboration:** Enrollment is ongoing in the multi-center, placebo-controlled Phase 2a study of dry powder inhaler-formulated elarekibep, an IL-4 receptor alpha (IL-4Rα) inhibitor being developed for the treatment of moderate-to-severe asthma. Topline results measuring placebo-adjusted FEV1 improvement at four weeks, the study’s primary efficacy endpoint, are expected by the middle of 2024. AstraZeneca previously communicated to the Company that completion of the Phase 2a study remains an important priority and that additional resources have been provided to achieve study completion. This includes a commitment to adding several new countries and a significant number of additional clinical sites, bringing the anticipated total number to more than 100 sites. As part of this commitment, AstraZeneca is on track to add three new geographies and related sites in the current quarter. Together with the previously announced protocol amendments, which are positively impacting study screening, we anticipate this will enable the achievement of the enrollment targets and timelines. In addition, the safety review of the 10 mg dose cohort in mild controlled asthmatics was successfully completed, which provides additional data supporting the elarekibep safety profile and enables doses greater than 3 mg to be evaluated in the future, if needed.

Previously reported elarekibep Phase 1 results demonstrated reduced fractional exhaled nitric oxide (FeNO) levels in mild asthma patients, and a favorable safety profile. Elarekibep is further validated by dupilumab, an FDA-approved inhibitor of IL-4Rα that has demonstrated reduced levels of FeNO and clinical efficacy in uncontrolled, moderate-to-severe asthma. Furthermore, dupilumab Phase 3 study results have shown efficacy in chronic obstructive pulmonary disease (COPD).

Pieris retains co-development and U.S. co-commercialization rights for elarekibep, which are exercisable following completion of the ongoing Phase 2a study.

- **PRS-220:** Pieris continues clinical development of PRS-220, a potential best-in-class inhaled Anticalin protein targeting connective tissue growth factor (CTGF) for the treatment of IPF, a disease with a large unmet medical need, and other fibrotic lung diseases. Preclinically, PRS-220 demonstrated superior on-target potency compared to pamrevlumab, an intravenously infused CTGF antagonist in late-stage clinical development. The Company believes inhaled administration will deliver high lung exposure, optimal pulmonary target engagement and superior clinical outcomes, while offering convenience of at-home administration.

  The Company is dosing healthy volunteers in a Phase 1 study with PRS-220 and expects to report results in the second half of this year. On May 21, 2023, preclinical data will be presented at the ATS 2023 International Conference, including data demonstrating that inhaled PRS-220 significantly reduced collagen deposition in a silica-induced lung fibrosis mouse model. Pieris continues to benefit from a meaningful grant from the Bavarian government, which supports early-stage development of this program.

- **PRS-400:** Pieris continues its preclinical advancement of PRS-400, an inhaled anti-Jagged-1 Anticalin therapeutic program with transformative potential in a wide range of respiratory diseases driven by mucus hypersecretion. PRS-400 was designed to allow patients to exit the vicious cycle of mucus hypersecretion, infection and airway obstruction, while avoiding inhibition of healthy, normal mucus production outside of the lungs. On May 22, 2023, preclinical data will be presented at the ATS 2023 International Conference demonstrating that PRS-400 reduced inflammation-driven goblet cell metaplasia and mucus hypersecretion in a therapeutic disease model. PRS-400 is advancing toward development candidate nomination in the second half of this year.

Immuno-Oncology Pipeline:

Pieris' immuno-oncology pipeline continues to progress in a cost-efficient manner with the benefit of its partners. The Company believes that multiple opportunities exist to generate value from this portfolio based on promising data generated to date.

- In April, clinical results from the Company's clinical study of cinrebafusp alfa (PRS-343) in 2L+ HER2-positive gastric cancer were presented at the American Association for Cancer Research annual meeting, including an unconfirmed 100% objective response rate and promising emerging durability profile in the five patients enrolled into the study prior to study discontinuation of enrollment for strategic reasons. Pieris is considering a range of transactions to facilitate program continuation, from an immuno-oncology focused spinout to a traditional partnering transaction.

- Boston Pharmaceuticals continues to advance BOS-342 (also known as PRS-342), a 4-1BB/GPC3 bispecific Mabcalin™ (antibody-Anticalin protein) compound, toward the clinic, with Phase 1 expected to begin in the coming months.
- Pieris and Servier continue to progress the escalation portion of the Phase 1/2 study of PRS-344/S095012, a 4-1BB/PD-L1 bispecific Mabcalin compound for the treatment of solid tumors, for which Pieris holds full U.S. rights.
- As previously announced, Seagen initiated a Phase 1 study for SGN-BB228 (also known as PRS-346), triggering a $5 million milestone payment to Pieris. SGN-BB228 is a first-in-class CD228/4-1BB bispecific antibody-Anticalin compound designed to provide a potent costimulatory bridge between tumor-specific T cells and CD228-expressing tumor cells. Pieris and Seagen continue to collaborate on two other undisclosed bispecific programs.

Fiscal Year End Financial Update:

Cash Position – Cash, cash equivalents, and investments totaled $48.4 million for the quarter ended March 31, 2023, compared to a cash and cash equivalents balance of $59.2 million for the year ended December 31, 2022. The decrease was due to funding operations in the first quarter of 2023. The Company believes operations are sufficiently funded for more than the next 12 months.

R&D Expense – R&D expenses were $13.4 million for the quarter ended March 31, 2023, compared to $14.1 million for the quarter ended March 31, 2022. The decrease was due primarily to lower clinical costs for cinrebafusp alfa and lower personnel costs, license fees and software costs. These lower costs were partially offset by higher overall program costs for PRS-220 and higher preclinical costs for discovery-stage programs, both partnered and proprietary.

G&A Expense – G&A expenses were $4.0 million for the quarter ended March 31, 2023, compared to $4.4 million for the quarter ended March 31, 2022. The period-over-period decrease was driven primarily by lower professional services, consulting and insurance costs.

Other Income – For the quarter ended March 31, 2023, $2.0 million of grant income was recorded with respect to PRS-220, compared to $2.1 million for the quarter ended March 31, 2022, indicating that costs incurred on PRS-220 were comparable for both periods. Interest income was $0.4 million for the quarter ended March 31, 2023, given the impact of rising interest rates compared to a de minimis amount of interest income in the quarter ended March 31, 2022

Net Loss – Net loss was $13.2 million or $(0.45) per share for the quarter ended March 31, 2023, compared to a net loss of $5.1 million or $(0.07) per share for the quarter ended March 31, 2022.

***Conference Call**:*

Pieris management will host a conference call beginning at 8:00 AM EDT on Wednesday, May 10, 2023, to discuss the first quarter 2023 financial results and provide a corporate update. Individuals can join the call by dialing 866-682-6100 (Toll Free US & Canada) or +1 862-298-0702 (International) at least five minutes prior to the start of the call. Alternatively, a listen-only audio webcast of the call can be accessed **here.**

A replay will be available on the Investors section of the Company's website, www.pieris.com.

***About Pieris Pharmaceuticals**:*

Pieris is a clinical-stage biotechnology company that combines leading protein engineering capabilities and deep understanding into molecular drivers of disease to develop inhaled medicines that drive local biology to produce superior clinical outcomes for patients. Our pipeline is focused on inhalable Anticalin proteins to treat respiratory diseases and locally-activated bispecifics for immuno-oncology. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by strong partnerships with leading pharmaceutical companies. For more information, visit www.pieris.com.

***Forward-looking Statements**:*

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, our expected cash runway; our product candidates clinical and therapeutic potential in their intended indications; the advancement of our proprietary and co-development programs into and through the clinic, including the achievement of enrollment targets and timelines, and the expected timing for reporting data, including through participation in conferences; the receipt of royalty and/or milestone payments provided for in our collaboration agreements; making IND filings or achieving other milestones related to our programs, including elarekibep, PRS-220, PRS-400, PRS-344/S095012, SGN-BB228 and BOS-342; the therapeutic potential and safety profile of our Anticalin platform; the potential addressable market for our product candidates; our continued progress in the area of co-stim bispecifics and inhaled therapeutics; and the advancement and funding of our developmental programs generally. Actual results could differ from those projected in any forward-looking statement due to numerous factors. Such factors include, among others, the amounts of anticipated funding actually received for our continued development programs and our actual reductions in spending as compared to anticipated cost reductions; our ability to raise the additional funding, including through partnership transactions, that we will need to continue to pursue; our business and product development plans; the inherent uncertainties associated with developing new products or technologies, including in collaboration with other parties, and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates, including our ability to recruit and enroll patients in our studies; the fact that data and results from preclinical and clinical studies may not necessarily be indicative of future results; competition in the industry in which we operate; delays or disruptions due to COVID-19 or geopolitical issues, including the conflict in Ukraine; and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the Securities and Exchange Commission (SEC) available at www.sec.gov, including, without limitation, the Company's most recent Annual Report on Form 10-K, the Company's Quarterly Reports on Form 10-Q, and subsequent filings with the SEC.

Investor Relations Contact:

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Investors@pieris.com
Joe Patneaude
Kendall Investor Relations
Joe@kendallir.com

PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	$ 39,742	$ 38,635
Short term investments	8,637	20,534
Accounts receivable	1,055	5,810
Prepaid expenses and other current assets	11,071	8,445
Total current assets	60,505	73,424
Property and equipment, net	16,706	16,992
Operating lease right-of-use assets	3,796	3,705
Other non-current assets	1,251	1,369
Total Assets	$ 82,258	$ 95,490
Liabilities and stockholders' equity:		
Accounts payable	$ 5,833	$ 4,154
Accrued expenses	10,354	11,605
Deferred revenue, current portion	26,688	20,824
Total current liabilities	42,875	36,583
Deferred revenue, net of current portion	11,727	18,734
Operating lease liabilities	12,198	12,244
Total Liabilities	66,800	67,561
Total stockholders' equity	15,458	27,929
Total liabilities and stockholders' equity	$ 82,258	$ 95,490

PIERIS PHARMACEUTICALS, INC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share data)

	Three Months Ended March 31,	
	2023	**2022**
Revenues	$ 1,936	$ 10,988
Operating expenses		
Research and development	13,424	14,066
General and administrative	4,023	4,379
Total operating expenses	17,447	18,445
Loss from operations	(15,511	(7,457)
Interest income	357	(3)
Grant income	2,028	2,130
Other income (expense), net	(57	229
Net loss	$ (13,183	$ (5,101)
Basic and diluted net loss per share	$ (0.18	$ (0.07)
Basic and diluted weighted average shares outstanding	74,519	73,711

Exhibit 99.2

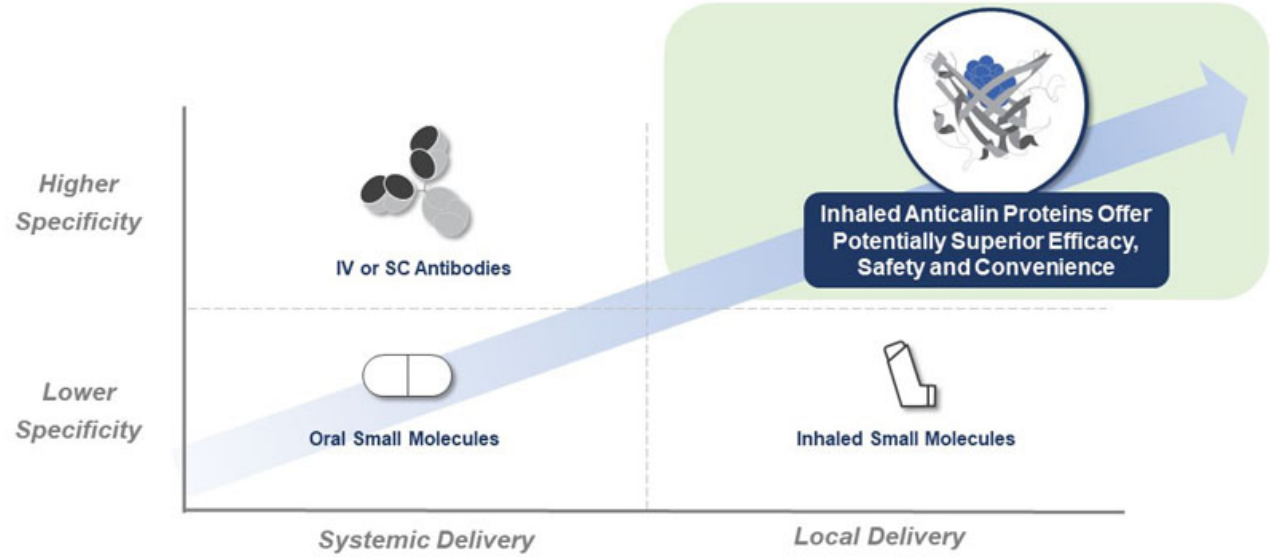
PIERIS PHARMACEUTICALS

CORPORATE PRESENTATION
May 2023

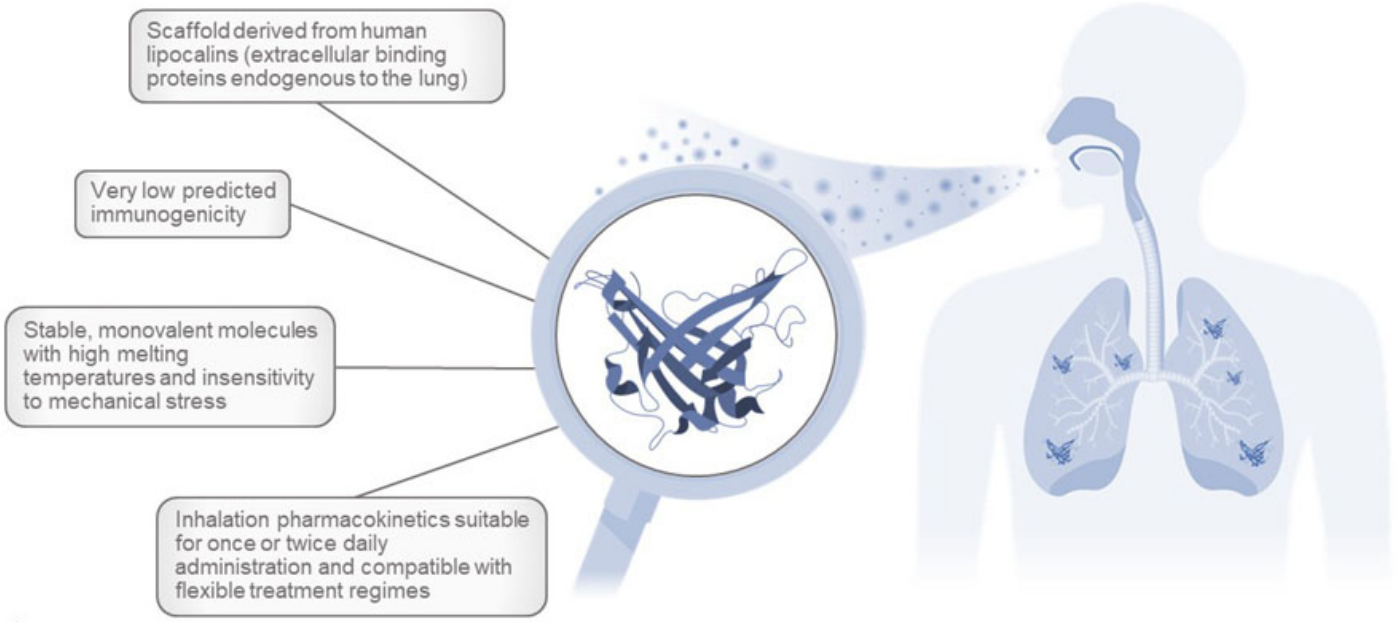
Forward-Looking Statements

This presentation contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this presentation that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, our expected cash runway, our product candidates' clinical and therapeutic potential in their intended indications; the receipt of royalty and/or milestone payments provided for in our collaboration agreements; references to novel technologies and methods and our business and product development plans, including the Company's cash resources, the advancement of our proprietary and co-development programs into and through the clinic and the expected timing for reporting data, making IND filings or achieving other milestones related to our programs, including elarekibep, PRS-220, PRS-400, PRS-344/S095012, PRS346/SGN-BB228 and PRS-342/BOS-342; our continued progress in the areas of co-stim bispecifics and inhaled therapeutics; the therapeutic potential and safety profile of our Anticalin platform; the unmet need and potential addressable market for our product candidates, the potential advantages of our product candidates over those of existing therapeutics and/or those of our competitors, and the advancement of and funding for our developmental programs generally. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need, including through partnering transactions, to continue to pursue our business and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company, including in collaboration with other parties; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates, including our ability to recruit and enroll patients in our studies; the fact that data and results from preclinical and clinical studies may not necessarily be indicative of future results; our ability to address the requests of the U.S. Food and Drug Administration; competition in the industry in which we operate; delays or disruptions due to COVID-19 or geo-political issues, including the conflict in Ukraine; and market conditions. These forward-looking statements are made as of the date of this presentation, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the Securities and Exchange Commission (SEC) available at www.sec.gov, including without limitation the Company's most recent Annual Report on Form 10-K, the Company's subsequent Quarterly Reports on Form 10-Q and the Company's other filings from time to time with the SEC.

Inhaled Administration of Biologics Would Address Many Limitations of Currently Approved Respiratory Therapeutics



Anticalin Proteins are Well Suited for Inhaled Administration



Pieris' Inhaled Protein Respiratory Pipeline Includes Partnered and Fully Proprietary Programs

Program	Target	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
Elarekibep* (PRS-060/AZD1402)	IL4Rα	Asthma	Phase 2a fully sponsored by AZ; co-dev option				AstraZeneca
PRS-220	CTGF	IPF#	>50% grant-funded‡				
PRS-400	Jagged-1	COPD-CB◊					
AstraZeneca	n.d.	n.d.					AstraZeneca
Genentech	n.d.	n.d.					Genentech A Member of the Roche Group

* *Pieris has separate co-development and U.S. co-commercialization options on elarekibep*

\# *Idiopathic pulmonary fibrosis ("IPF") and other forms of fibrotic lung diseases*

‡ *~$17 million grant from the Bavarian government to evaluate PRS-220 in PASC-PF expected to cover more than half of early-stage and phase 1 development costs of PRS-220*

◊ *COPD-CB - chronic obstructive pulmonary disease with chronic bronchitis*

Pieris is Developing Three Differentiated Inhaled Biologics to Address Significant Unmet Need in Respiratory Diseases

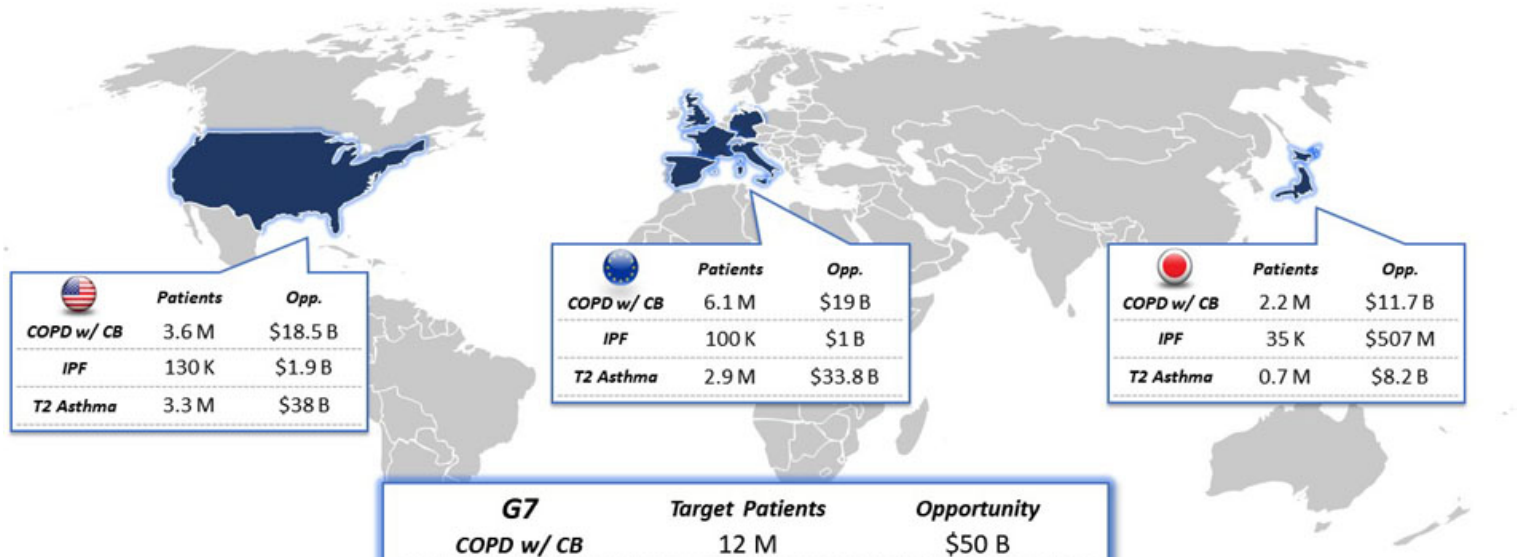
Vision

Pieris aspires to be a world-leading inhaled biologics company, developing transformative respiratory therapies that have the potential to materially improve patient quality of life (QoL) over existing therapies by combining the specificity of biologics with the benefit of local administration.

Our current portfolio is well positioned to achieve this vision

	Elarekibep (PRS-060)	*PRS-220*	*PRS-400*
	More convenient administration than available therapeutics, potentially improving patient QoL	***Inhalable, best-in-class anti-CTGF with disease-modifying potential***	***Novel mode of action that is challenging to target systemically***
MOA	Inhaled IL-4Rα antagonist	Inhaled CTGF antagonist	Inhaled Jagged-1 antagonist
Lead Indication	Moderate-to-severe T2 asthma	Idiopathic pulmonary fibrosis (IPF)	COPD with Chronic Bronchitis
Phase of Development	Phase 2a	Phase 1	Preclinical

Pieris' Respiratory Portfolio Targets Large Opportunity Indications in Both Primary and Specialty Markets



	Patients	Opp.
COPD w/ CB	3.6 M	$18.5 B
IPF	130 K	$1.9 B
T2 Asthma	3.3 M	$38 B

	Patients	Opp.
COPD w/ CB	6.1 M	$19 B
IPF	100 K	$1 B
T2 Asthma	2.9 M	$33.8 B

	Patients	Opp.
COPD w/ CB	2.2 M	$11.7 B
IPF	35 K	$507 M
T2 Asthma	0.7 M	$8.2 B

G7	Target Patients	Opportunity
COPD w/ CB	12 M	$50 B
IPF	265 K	$3.5 B
T2 Asthma	6.9 M	$80 B

Commercial opportunity represents total patients and average biologic price. No market share assumptions are factored into opportunity calculations

Elarekibep (PRS-060/AZD1402): Inhaled IL-4Rα Antagonist

Indications	Moderate-to-severe asthma
Development	Phase 2a ongoing
Commercial Rights	Co-development and U.S. co-commercialization options with gross margin share or royalties

Pieris' Vision for Elarekibep Future Potential

Brand Vision:

*To become the **first inhaled biologic** treating moderate-to-severe T2 asthma prior to injectable biologics, with future aspirations to expand into other diseases addressable via inhalation, including COPD*

Core Statement:

*Elarekibep is an inhaled IL-4Rα antagonist designed to **improve FEV1 and reduce the annual rate of exacerbations,** creating **broader access to biologics** for moderate-to-severe T2 asthma patients.*

For:	*Moderate-to-severe T2 asthma patients inadequately controlled on ICS ± LABA (standard of care) and before progression to injectable biologics*
Elarekibep Offers:	*Opportunity to become the first inhaled maintenance biologic therapy that improves lung function and reduces exacerbations*
Because:	*The inhibition of IL4-Rα disrupts IL-4 & IL-13 signaling, effectively demonstrating local target engagement and biomarker activity, supporting the inhaled approach in preclinical research and Phase 1 trials*

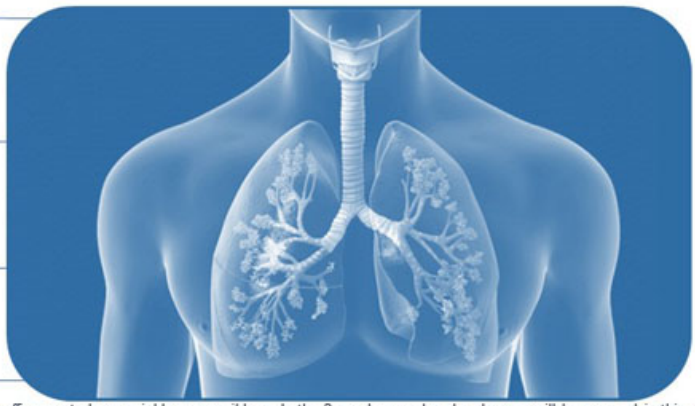
Elarekibep Phase 2a Study

Part 1 (Safety)	**Participant Population:** Moderate asthmatics controlled on ICS/LABA **Primary Endpoint:** Safety and tolerability compared to placebo from baseline until follow-up (approximately 56 days) **Doses:** 1 mg, 3 mg, 10 mg (all dosed completed; favorable safety profile demonstrated at all doses)
Part 2 (Efficacy)	**Participant Population:** Asthmatics uncontrolled on moderate or high dose ICS/LABA with blood EO count of ≥ 150 cells/µL and FeNO ≥ 25 ppb at screening **Primary Endpoint:** Improvement of FEV1 at four weeks relative to placebo **Dose*:** 3 mg (enrolling)

All doses passed safety review; efficacy readout expected mid-2024

Dry powder formulation, administered b.i.d. over four weeks on top of standard-of-care therapy (medium or high dose ICS with LABA)

Study is sponsored, conducted, and funded by AstraZeneca



*to enroll the efficacy study as quickly as possible, only the 3 mg dose and a placebo arm will be pursued in this study

DPI Formulation of Elarekibep Passed Safety Review (Part 1) at Each of Three Tested Doses

Safety Protocol: Moderate asthmatics controlled on standard-of-care therapy (medium dose ICS with LABA) were dosed twice daily over four weeks randomized across three dose levels and placebo

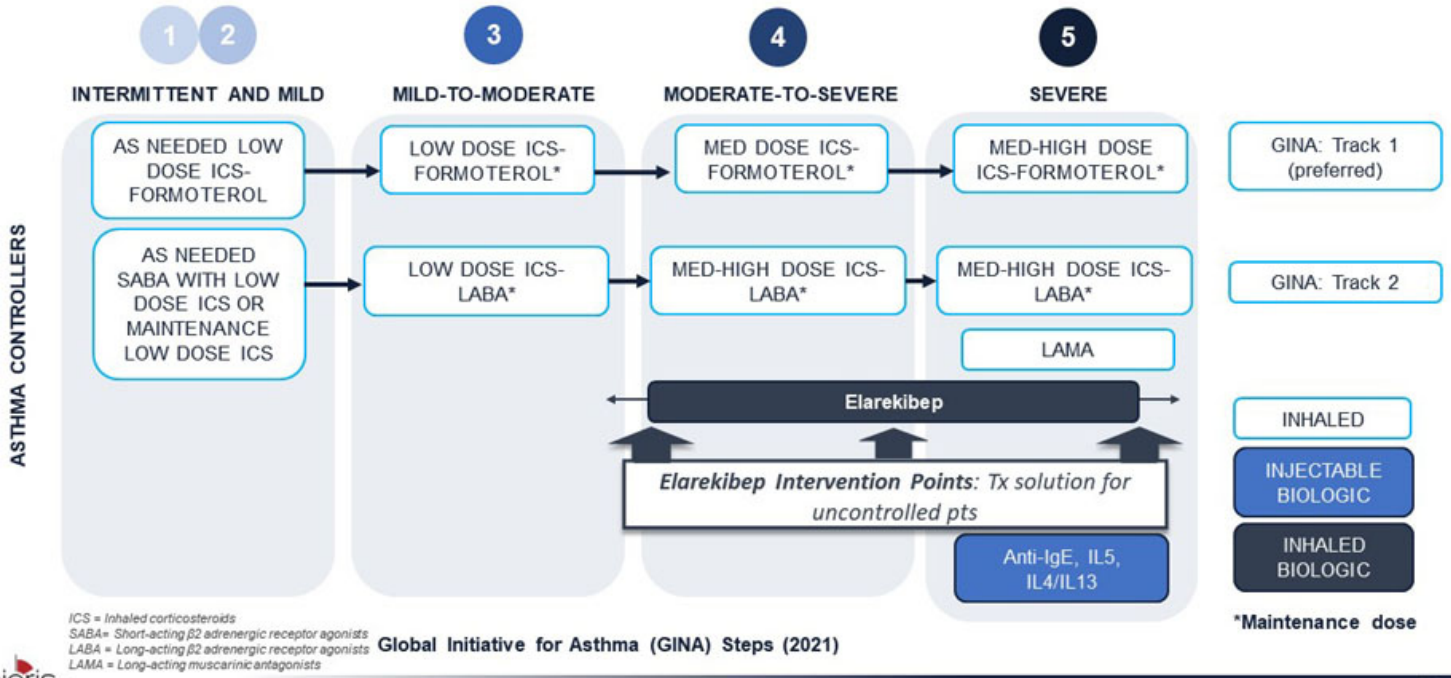
- Part 1a: 31 patients (1mg; 3mg; pbo)
- Part 1b: 18 patients (10mg; pbo)

Basis for safety review

- ☑ Incidence of adverse events
- ☑ Changes in laboratory markers (immune biomarkers, clinical chemistry, and hematology)
- ☑ Forced expiratory volume in 1 second (FEV1)
- ☑ Pharmacokinetics

Enables doses up to 10 mg dpi to be evaluated in future clinical studies

Potential Large Market Opportunity in Moderate-to-Severe Asthma not Addressed by ICS/LABA before Injectable Biologics



ICS = Inhaled corticosteroids
SABA= Short-acting β2 adrenergic receptor agonists
LABA = Long-acting β2 adrenergic receptor agonists
LAMA = Long-acting muscarinic antagonists

Global Initiative for Asthma (GINA) Steps (2021)

Co-Development Options for Elarekibep

PIRS Opt-in Decision Point

Phase 2a Primary Endpoint:
Improvement of FEV1 at 4 weeks relative to placebo

Co-Dev Option Requirements:
30-day opt-in period triggered upon both completion of Phase 2a trial and notice by AZ (must include product development plan & budget)

Three Possible Options

- **No opt-in & no cost sharing**
- Single digit up to mid-teen royalties for royalty term
- Same development milestones as 25% option; up to $1.9B in sales milestones

- **25% cost share with cost cap**
- Single digit up to high-teen royalties for product lifetime
- Development milestones approximating 50% of development costs
- Potential $3.5B+ in sales milestones

- **50% cost share without cost cap**
- Gross margin share percentage in mid-twenties for the product lifetime
- Development milestones approximating two-thirds of 25% option

PRS-220: Inhaled CTGF Antagonist

Indications	IPF* and other forms of fibrotic lung diseases
Development Stage	Phase 1 in healthy volunteers
Commercial Rights	Fully proprietary

*IPF - Idiopathic Pulmonary Fibrosis

Pieris' Vision for PRS-220 Future Potential

Brand Vision:

*To become the **first inhaled biologic** and disease-modifying therapy approved for the treatment of IPF and other progressive fibrosing interstitial lunch diseases (PF-ILDs)*

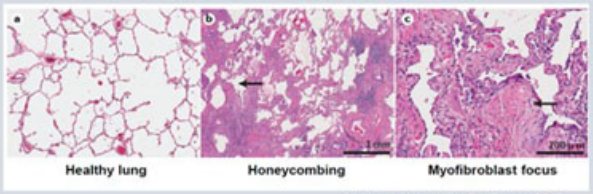
Core Statement:

*PRS-220 is designed to be a well-tolerated CTGF inhibitor that **halts disease progression, significantly reduces morbidity for IPF patients**, and **improves survival** compared to other antifibrotic therapies, while having the flexibility to be used as a monotherapy or in **combination with current SoC antifibrotic therapies***

For:	*All IPF patients, regardless of treatment history (+/- SoC), and eventually other patients with PF-ILDs*
PRS-220 Offers:	*The potential as an inhaled anti-fibrotic therapy that stabilizes disease with a favorable safety profile*
Because:	*CTGF is a key driver of fibrosis, and systemically delivered antibody demonstrated significant attenuation of FVC decline and fibrotic lung remodeling of IPF patients in Ph2 clinical trials. Inhaled delivery offers the potential for better exposure at the site of disease, translating to better efficacy over systemic therapies*

IPF: High Unmet Medical Need and Significant Commercial Opportunity

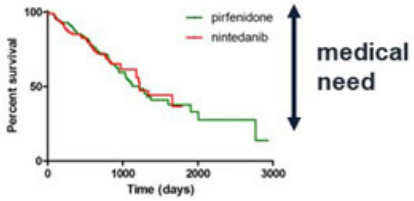
A chronic lung disease:
ultimately fatal lung disease of unknown cause characterized by progressive scarring of the interstitial lung tissue



Martinez, Nature Rev Dis Primer, 2017

3 to 5 years — **median survival from the time of diagnosis**
Hopkins, European Respiratory Journal, 2016

2 — **approved therapies nintedanib & pirfenidone providing modest benefit with significant side effects**



medical need

Adapted from Cameli, Frontiers in Molecular Biosciences, 2020

>$3B — **current market in sales**

Significant need for well-tolerated and effective therapies

PRS-220: Rationale for Best-in-Class Potential

Potential key points of differentiation of inhaled PRS-220 compared to systemically delivered CTGF antagonists:

More Efficient Target Saturation	• Avoidance of systemic CTGF sink (in blood) • Significantly higher affinity with superior binding profile
Superior Lung Biodistribution	• Local delivery to the site of the disease in the lung via inhalation • Increased concentration
Increased Convenience	• Inhalation at home compared to regular visits to infusion centers for intravenous administrations • Administration on top of standard of care

PRS-400: An Inhaled Jagged-1 Antagonist

Indications	COPD, CF, PCD, CRS, Bronchiectasis and Asthma*
Development Stage	Preclinical
Commercial Rights	Fully proprietary

*COPD - Chronic Obstructive Pulmonary Disease; CF - Cystic Fibrosis; PCD - Primary Ciliary Dyskinesia; CRS - Chronic Rhinosinusitis

Pieris' Vision for PRS-400 Future Potential

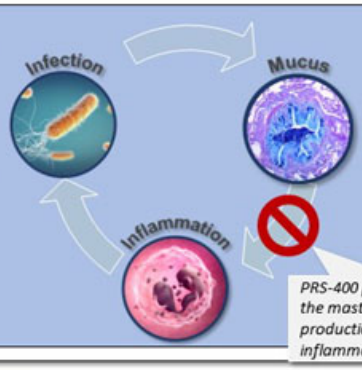
Brand Vision:

*PRS-400 is designed to be the **first inhaled biologic** maintenance therapy approved for moderate-to-severe COPD with chronic bronchitis and other muco-obstructive diseases, providing localized therapy that **rapidly improves patient QoL** and allows patients to **exit the vicious cycle of mucus hypersecretion, infection, & airway obstruction***

Core Statement:

*PRS-400 is a Jagged-1/Notch blocker designed to improve lung function and reduce exacerbation rates via a disease-modifying reversal of the muco-obstructive airway phenotype, providing tangible patient benefit. **This pathway may only be addressable via inhaled administration, given the desire to avoid systemic impact on mucus homeostasis**.*

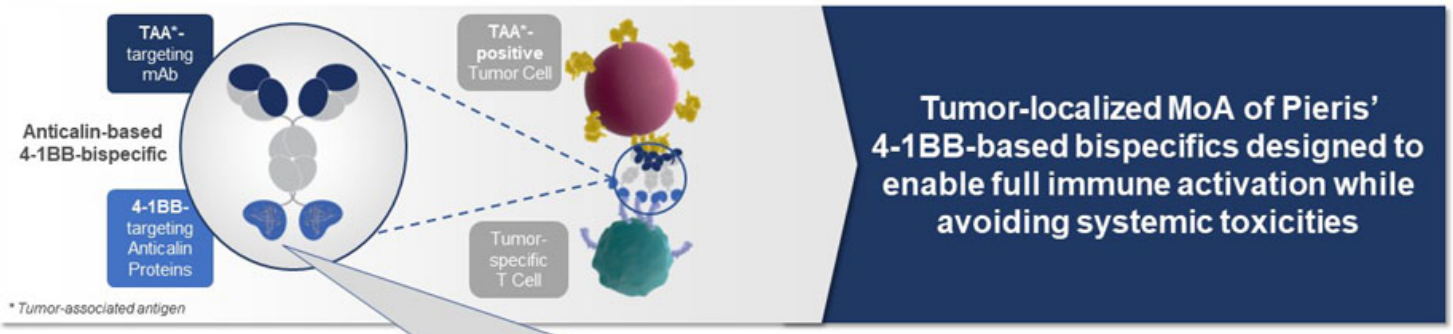
For:	*Moderate-to-severe COPD patients with chronic bronchitis and other muco-obstructive diseases such as CF, PCD, and NCFB*
PRS-400 Offers:	*A convenient therapy with potential to dramatically improve QoL for patients by improving lung function and reducing exacerbations*
Because:	*Jagged-1/Notch inhibition reverses mucus-producing cells in favor of ciliated cells, limiting hypersecretion and airway obstruction, key drivers of respiratory symptomatology and patient discomfort*



PRS-400 preclinically disrupts the master regulator of mucus production, halting the cycle of inflammation and infection


Immuno-oncology

Anticalin Proteins are Also Well Suited to Build Mabcalin™ Bispecific Immune Agonists to Treat Cancer



Tumor-localized MoA of Pieris' 4-1BB-based bispecifics designed to enable full immune activation while avoiding systemic toxicities

- Monomeric, monovalent Anticalin proteins can be genetically fused to full-length mAbs → Mabcalin (antibody-Anticalin) proteins
- Several 4-1BB-engaging Mabcalin proteins have been manufactured under GMP for clinical development

Pieris' IO Bispecifics Pipeline is Driven by Partnerships and Offers Future Milestone and Royalty Upside

Program	Target	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
cinrebafusp alfa*	4-1BB/HER2	HER2+ GC					
PRS-344/ S095012	4-1BB/PD-L1	n.d.	~50% co-dev cost share				SERVIER moved by you
PRS-346/ SGN-BB228	4-1BB/CD228	n.d.					Seagen
PRS-342/ BOS-342	4-1BB/GPC3	n.d.					BOSTON pharmaceuticals
SGN programs‡	n.d.	n.d.					Seagen

* *Announced stopping enrollment in 3Q22 due to strategic reasons, including focus on respiratory portfolio; spin-out and partnering discussions ongoing*

‡ *Two additional active bispecific programs in collaboration with Seagen, with Pieris retaining a U.S. co-promotion option in one of the programs in the collaboration*

Successful track record of partnering 4-1BB assets for value

Pieris' Partnerships Have Validated Both Respiratory and IO Franchises and are a Source of Non-Dilutive Capital

	Active Programs	Cash to Date*	Cash Potential*
AstraZeneca	Two (all with co-dev)	$70.5M	>$4.3B plus royalties
Genentech A Member of the Roche Group	One (two additional starts available)	$20M	~$1.1B plus royalties
SERVIER moved by you	One co-dev program	~$41M	~$20M plus royalties
Seagen	Three (one with U.S. copromotion option)	$40M	~$1.2B plus royalties
BOSTON pharmaceuticals	One	$10M	~$350M

**As of May 10, 2023 (date of first quarter earnings and business update press release)*

Multiple Inflections are Forecasted Over the Next 12-15 Months

- Elarekibep:
  - Phase 2a topline efficacy data (4-week placebo-adjusted FEV1)
  - Elarekibep: Pieris co-development opt-in decision
- PRS-220
  - Phase 1 topline data
  - Preclinical PoC demonstrating superior potential of inhaled vs. systemic administration of a CTGF antagonist in IPF
- PRS-400
  - Drug candidate nomination
  - Preclinical PoC in therapeutic preclinical model of disease
- IO
  - Clinical progress & milestone opportunities across partnered pipeline
  - Further partnering and other strategic opportunities, given strength of clinical data (cinrebafusp alfa)

Financial Overview (as of 3/31/23)

$48.4M	$0.00	74.5M
Cash, Cash Equivalents & Investments	Debt	CSO

>$175M non-dilutive capital from partnerships since 2017

~$17M[1] grant announced in 2021

[1] *Calculated based on the June 25, 2021, noon buying rate of €1.00 to U.S. $1.1938*

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