

**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 24, 2021

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
Incorporation)

001-37471
(Commission
File Number)

30-0784346
(IRS Employer
Identification No.)

225 State Street, 9th Floor **02109**
Boston, MA
(Address of principal executive offices) (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 1.01: Entry into a Material Definitive Agreement.

On March 24, 2021, Pieris Pharmaceuticals, Inc. (“Pieris” or the “Company”) announced that Seagen Inc. (together with its affiliates, “Seagen”) had made a strategic equity investment in Pieris, and that the companies had entered into a combination study agreement (the “Combination Study Agreement”) to evaluate the safety and efficacy of combining Pieris’ cinrebafusp alfa (PRS-343), a 4-1BB/HER2 bispecific, with Seagen’s TUKYSA[®] (tucatinib), a small-molecule tyrosine kinase HER2 inhibitor, for the treatment of gastric cancer patients expressing lower HER2 levels (IHC2+/ISH- & IHC1+) as part of the upcoming phase 2 study to be conducted by Pieris. The companies have also entered into an Amended and Restated License and Collaboration Agreement (the “Amended Collaboration Agreement”), in which their existing immuno-oncology collaboration agreement has been amended relating to joint development and commercial rights for the second program in the alliance.

The combination of cinrebafusp alfa and TUKYSA could potentially address a high medical need in HER2 low-expressing gastric cancer patients who do not respond to traditional HER2-targeted therapies. Preclinical studies show that TUKYSA synergizes with cinrebafusp alfa to enhance its 4-1BB mediated immune cell stimulation. This effect was observed across a range of HER2 expressing cell lines (IHC3+, 2+ and 1+), including those where cinrebafusp alfa had limited single-agent activity.

Under the Amended Collaboration Agreement, Pieris’ option to co-develop and co-commercialize the second of three programs in the collaboration has been amended to provide it with a co-promotion option in the United States, with Seagen solely responsible for the development and overall commercialization of that program. Pieris will also be entitled to increased royalties from that program in the event that it chooses to exercise the option. In connection with the agreements described above, the Company and Seagen entered into a subscription agreement (the “Subscription Agreement” and together with the Combination Study Agreement and the Amended Collaboration Agreement, the “Agreements”) pursuant to which the Company agreed to issue to Seagen, and Seagen agreed to acquire from the Company, 3,706,174 shares of the Company’s common stock, \$0.001 par value per share, for a total purchase price of thirteen million U.S. Dollars (\$13,000,000), or \$3.51 per share, in a private placement transaction pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended.

A copy of the Combination Study Agreement, the Amended Collaboration Agreement and the Subscription Agreement will be filed as exhibits to the Company’s quarterly report on Form 10-Q for the quarter ending March 31, 2021.

Item 3.02: Unregistered Sales of Equity Securities.

The information called for by Item 1.01 of this Current Report on Form 8-K regarding the Subscription Agreement is incorporated by reference into this Item 3.02.

Item 8.01. Other Events.

On March 25, 2021, the Company issued a press release related to the Agreements. A copy of the press release announcing the Agreements is attached to this Current Report as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

99.1 [Press Release Dated March 25, 2021.](#)

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: March 25, 2021

/s/ Tom Bures

Tom Bures

Vice President, Finance

March 25, 2021



Pieris Announces Amendment of Existing Immuno-oncology Multi-target Collaboration with Seagen, a Clinical Trial and Supply Agreement to Evaluate Cinrebafusp Alfa (PRS-343) in Combination with TUKYSA® (tucatinib) in Gastric Cancer, and Strategic Equity Investment by Seagen

- *Seagen will supply Pieris with TUKYSA® to evaluate the drug in combination with cinrebafusp alfa (PRS-343) in gastric cancer*
- *Pieris' co-development option for one program from existing multi-target collaboration amended to US co-promotion option with increased royalties if exercised*
- *Seagen to purchase \$13 million equity stake in Pieris common stock*

BOSTON, MA / ACCESSWIRE / March 25, 2021 / 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, today announced that Seagen has made a strategic equity investment in Pieris as part of an ongoing collaboration between the companies. In addition, the companies have entered into a clinical trial collaboration agreement to evaluate the safety and efficacy of combining Pieris' cinrebafusp alfa (PRS-343), a 4-1BB/HER2 bispecific, with Seagen's TUKYSA® (tucatinib), a small-molecule tyrosine kinase HER2 inhibitor, for the treatment of gastric cancer patients expressing lower HER2 levels (IHC2+/ISH- & IHC1+) as part of the upcoming phase 2 study to be conducted by Pieris. The companies have also amended their existing immuno-oncology collaboration agreement around joint development and commercial rights for the second of up to three products in the alliance.

The combination of cinrebafusp alfa and TUKYSA could potentially address a high medical need in HER2 low-expressing gastric cancer patients who do not respond to traditional HER2-targeted therapies. Preclinical studies show that TUKYSA synergizes with cinrebafusp alfa to enhance its 4-1BB-mediated immune cell stimulation. This effect was observed across a range of HER2 expressing cell lines (IHC3+, 2+, and 1+), including those where

cinrebafusp alfa had limited single-agent activity.

Under the amended and restated agreement, Pieris' option to co-develop and co-commercialize the second of three programs in the collaboration has been amended to provide it with a co-promotion option in the United States, with Seagen solely responsible for the development and overall commercialization of that program. Under the co-promotion option, Pieris will also be entitled to increased royalties from that program in the event that it chooses to exercise the option. In connection with the amendment, on March 24, 2021, in a private placement transaction, Seagen made an equity investment of \$13 million in Pieris through the purchase of 3,706,174 newly issued shares of Pieris common stock at a price of \$3.51 per share.

"Seagen continues to be a supportive partner, and we look forward to combining efforts in studying the effects of cinrebafusp alfa with TUKYSA in gastric cancer patients expressing lower HER2-levels, following the generation of compelling preclinical data," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "We plan to initiate this combination study as part of our phase 2 protocol for cinrebafusp alfa, for which we will be sharing additional details at an upcoming corporate update."

"Preclinical data exploring the combination of cinrebafusp alfa and TUKYSA are encouraging and support evaluating the combination in the planned phase 2 clinical trial," said Marjorie Green, M.D., Senior Vice President, Late-Stage Development of Seagen. "We are pleased to supply drug for Pieris to explore the potential combination of these agents to address an important unmet medical need."

About Cinrebafusp Alfa

Cinrebafusp alfa (PRS-343) is a 4-1BB/HER2 fusion protein comprising a 4-1BB-targeting Anticalin protein and a HER2-targeting antibody. The drug candidate is currently in development for the treatment of HER2-positive solid tumors. Based on encouraging phase 1 study results, which demonstrated clinical benefit as single agent and biomarker data indicative of a 4-1BB-driven mechanism of action, the Company is actively working towards initiating a phase 2 study of cinrebafusp alfa in combination with ramucirumab and paclitaxel for the treatment of HER2-positive gastric cancer and, under the phase 2 protocol, in combination with tucatinib.

About Pieris Pharmaceuticals:

Pieris is a clinical-stage biotechnology company that discovers and develops Anticalin protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and immuno-oncology multi-specifics tailored for the tumor microenvironment. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies, including AstraZeneca, Seagen, and Servier. Anticalin[®] is a registered trademark of Pieris. 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 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, whether the

combination of cinrebafusp alfa and TUKYSA could address a high medical need in HER2 low-expressing gastric cancer patients who do not respond to traditional HER2-targeted therapies; whether the effects of the combination of cinrebafusp alfa and TUKYSA seen in preclinical studies will be observed in clinical trials; whether data from patients enrolled to date will be sufficient to inform the recommended phase 2 dose for the Company's planned proof of concept study of cinrebafusp alfa in gastric cancer; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its programs, references to novel technologies and methods and our business and product development plans, including 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 PRS-060/AZD1402, cinrebafusp alfa, PRS-344, and PRS-352 and the expected timing of the initiation of the next stage of cinrebafusp alfa's development in gastric cancer. 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 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; 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; our ability to address the requests of the FDA; competition in the industry in which we operate; delays or disruptions due to COVID-19; 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 SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and the Company's Quarterly Reports on Form 10-Q.

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View source version on accesswire.com:

<https://www.accesswire.com/637320/Pieris-Announces-Amendment-of-Existing-Immunology-Multi-target-Collaboration-with-Seagen-a-Clinical-Trial-and-Supply-Agreement-to-Evaluate-Cinrebafusp-Alfa-PRS-343-in-Combination-with-TUKYSAR-tucatinib-in-Gastric-Cancer-and-Strategic-Equity>
