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): April 24, 2021

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 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 April 24, 2021, Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH (together, “Pieris” or the “Company”) and BP Asset XII, Inc. (“Boston Pharmaceuticals”), a subsidiary of Boston Pharma Holdings, LLC, entered into an Exclusive Product License Agreement (the "Agreement"), to develop PRS-342, a 4-1BB/GPC3 preclinical immuno-oncology Anticalin®-antibody bispecific fusion protein. Under the terms of the Agreement, Boston Pharmaceuticals has exclusively licensed worldwide rights to PRS-342. Pieris will receive an upfront payment of $10 million and is further entitled to receive up to $352.5 million in development, regulatory, and sales-based milestone payments, tiered royalties up to low double-digits on sales of PRS-342, and a percentage of consideration received by Boston Pharmaceuticals in the event of a sublicense of a program licensed under the Agreement or a change of control of Boston Pharmaceuticals. Pieris will also contribute an undisclosed amount toward manufacturing activities.

The term of the Agreement ends upon the expiration of all of Boston Pharmaceuticals’ payment obligations under such Agreement. The Agreement may be terminated by Boston Pharmaceuticals in its entirety for convenience beginning 9 months after its effective date upon 60 days’ notice or, for any program under the Agreement which has received marketing approval, upon 120 days’ notice. If any program is terminated by Boston Pharmaceuticals, Pieris will have full rights to continue such program. The Agreement may also be terminated by Boston Pharmaceuticals or Pieris for an uncured material breach by the other party upon 180 days’ notice (60 days in the case of non-payment of undisputed amounts due and payable), subject to extension for an additional 180 days in certain cases and subject, in all cases, to dispute resolution procedures. The Agreement may also be terminated due to the other party’s insolvency. Pieris may also terminate the Agreement if Boston Pharmaceuticals challenges the validity of any patents licensed under the Agreement, subject to certain exceptions.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, which Pieris intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2021. A copy of the press release announcing the Agreement 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 April 26, 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: April 26, 2021

/s/ Tom Bures
Tom Bures
Vice President, Finance

PRESS RELEASE

Pieris Pharmaceuticals and Boston Pharmaceuticals Enter into an Exclusive Worldwide Product License for PRS-342, a 4-1BB/GPC3 Immuno-Oncology Bispecific

- **Pieris will receive $10 million upfront and be entitled to receive additional milestone payments and tiered royalties**
- **Boston Pharmaceuticals will be primarily responsible for development of the program, with both parties collaborating during the investigational new drug (IND)-enabling stage**

BOSTON and CAMBRIDGE, Mass., April 26, 2021 - ***Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS)*** and Boston Pharmaceuticals today announced that the companies have entered into an exclusive product license agreement to develop PRS-342, a 4-1BB/GPC3 preclinical immuno-oncology Anticalin®-antibody bispecific fusion protein. Under the terms of the agreement, Boston Pharmaceuticals has exclusively licensed worldwide rights to PRS-342. Pieris will receive an upfront payment of $10 million and is further entitled to receive up to approximately $353 million in development, regulatory, and sales-based milestone payments, and tiered royalties on sales of PRS-342. Pieris will also contribute an undisclosed amount toward manufacturing activities.

“Based on the encouraging preclinical data from PRS-342, as well as data demonstrative of the 4-1BB mechanism of action we have seen from Pieris’ other immuno-oncology programs, we are excited to have the opportunity on a global scale to progress this program into clinical development in areas of significant unmet need,” said Robert Armstrong, Chief Executive Officer of Boston Pharmaceuticals. “We look forward to working with Pieris, benefiting from both their strong early-stage development expertise and their deep understanding of immuno-oncology bispecifics.”

“Our recent presentations at AACR for our HER2- and PD-L1-targeting 4-1BB bispecifics demonstrate the potency of our costimulatory approach, especially our bispecific antibodies’ ability to achieve clinical benefit, including in patients who have failed checkpoint therapy. It is therefore rewarding to see another one of our 4-1BB-based Anticalin bispecifics for immuno-oncology moving towards the clinic,” said Stephen S. Yoder, President and Chief Executive Officer of Pieris. “Boston Pharmaceuticals has a strong leadership team and proven track record of developing a broad range of assets, including in oncology, and we look forward to the advancement of this next-generation bispecific and to directly supporting some crucial next steps towards clinical initiation.”

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.

About Boston Pharmaceuticals:

Boston Pharmaceuticals is a clinical stage biopharmaceutical company that leverages an experienced drug development team to advance a portfolio of high value candidates that address important unmet medical needs. The Company partners with innovative biotechnology and pharmaceutical companies to acquire drug development candidates. We adhere to a rigorous decision-making process, follow the data, and advance only those programs that meet our stringent development hurdles. We look to establish value creating partnerships with the world’s leading biotechnology and pharmaceutical companies that help advance programs to commercial stage. We are continuously seeking new opportunities to leverage

our model to create a path to value for our patients and partners. Boston Pharmaceuticals is a portfolio company of Waypoint Capital, an investment firm based in Europe and focused on healthcare, medical technologies, and asset management. For more information, please visit www.bostonpharmaceuticals.com or follow us on Twitter @BosPharma and LinkedIn.

***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 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; 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, 2020 and the Company's Quarterly Reports on Form 10-Q.

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