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 11, 2019**

STRONGBRIDGE BIOPHARMA plc

(Exact name of registrant as specified in its charter)

Ireland	**001-37569**	**98-1275166**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

900 Northbrook Drive **Suite 200** **Trevose, PA**	**19053**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(610) 254-9200**

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 (*see* General Instruction A.2. below):

☐ 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))

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

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 8.01 Other Information

On March 11, 2019, Strongbridge Biopharma plc issued a press release announcing top-line results from the extended evaluation phase of its pivotal Phase 3 SONICS study of RECORLEV™ (levoketoconazole) for the potential treatment of endogenous Cushing's syndrome. A copy of the press release announcing the results is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Table
99.1	Press Release issued by Strongbridge Biopharma plc, dated March 11, 2019.

SIGNATURES

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.

STRONGBRIDGE BIOPHARMA PLC

By: /s/ A. Brian Davis
Name: A. Brian Davis
Title: Chief Financial Officer

Date: March 11, 2019

Exhibit 99.1

Strongbridge Biopharma plc Announces Top-Line Results from Extended Evaluation Phase of the Pivotal Phase 3 SONICS Study of RECORLEV™ (levoketoconazole) for the Potential Treatment of Endogenous Cushing's Syndrome

~ Extended Evaluation Phase Meets Objective of Showing Positive Long-Term Benefit-Risk Profile of RECORLEV™ (levoketoconazole) ~

~ Favorable Liver-Related Findings: No Patients Experienced an Increase in Either Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) of Greater than Three Times the Upper Limit of Normal During the Extended Evaluation Phase ~

~ Long-Term Efficacy Results of RECORLEV™ (levoketoconazole) Continue to Demonstrate Clinically Meaningful Improvements in Mean Urinary Free Cortisol (mUFC) and Key Cardiovascular Risk Markers ~

Dublin, Ireland and Trevose, Pa., March 11, 2019 — Strongbridge Biopharma plc, (Nasdaq: SBBP), a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs, today announced the top-line findings from the extended evaluation phase of the pivotal Phase 3 SONICS study of RECORLEV™ (levoketoconazole) for the potential treatment of endogenous Cushing's syndrome. The purpose of the six-month extended evaluation phase was to evaluate the long-term safety, tolerability and benefit-risk during chronic use of RECORLEV.

"We are encouraged by the top-line results from the SONICS extended evaluation phase. RECORLEV™ (levoketoconazole) treatment was associated with no new clinically relevant liver-related findings or other new safety signals, while demonstrating long-term efficacy to reduce mean urinary free cortisol, or mUFC, as well as key cardiovascular risk markers such as weight and LDL-cholesterol," said Fredric Cohen, M.D., chief medical officer of Strongbridge Biopharma. "A Type C meeting with FDA is progressing as planned in the first quarter of 2019 to seek guidance on the regulatory path forward to obtain marketing approval for RECORLEV for the treatment of endogenous Cushing's syndrome, and we anticipate providing an update in the second quarter of 2019."

RECORLEV was generally well-tolerated during the extended evaluation phase and no new drug-related safety signals were observed:

- 60 out of 61 study participants who completed the maintenance phase elected to participate in the extended evaluation phase
- Of the 60 patients that entered the extended evaluation phase, 46 patients completed it

- Data were collected twice, at three-month intervals, which is common practice for the long-term follow-up of chronic medical therapy for endogenous Cushing's syndrome
- Four patients (6.7%) discontinued due to adverse events
- No patients (0%) experienced an increase in either alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than three times (3x) the upper limit of normal and there were no (0%) reported adverse events of special interest (AESI) related to liver injury or dysfunction
- The most commonly reported (≥5%) treatment-emergent adverse events (TEAEs) in the extended evaluation phase were arthralgia (7%), QTc prolongation (7%), headache (7%), hypokalemia (7%), and nasopharyngitis (5%); QTc prolongation greater than 460 msec was not observed in the extended evaluation phase
- Nausea (2%) and headache (7%) were reported at lower rates as compared to the previously reported aggregate rates of 32% (nausea) and 28% (headache) from the dose titration and maintenance phases

Summary of RECORLEV extended evaluation phase efficacy results:

- In this exploratory evaluation, an observed-case analysis of completers was used to evaluate mUFC responders
- At the end of the extended evaluation phase, normalization of mUFC was observed in 41% of patients, and normalization of, or at least 50% improvement in, mUFC was observed in 68% of patients
- Clinically meaningful improvements in key cardiovascular risk markers (hemoglobin A1c, fasting glucose, total and LDL-cholesterol) were observed throughout the extended evaluation phase
- Weight loss and reduction in body mass index (BMI) continued throughout the extended evaluation phase

About the SONICS Study

SONICS is an open-label, Phase 3 study of RECORLEV as a treatment for endogenous Cushing's syndrome that enrolled 94 patients at centers in North America, Europe and the Middle East. Following a screening phase, SONICS has three treatment phases:

(1) Dose Titration Phase: Patients started RECORLEV at 150 mg twice daily (300 mg total daily dose) and titrated in 150 mg increments with the goal of achieving a therapeutic dose — a dose resulting in mean UFC normalization — at which point titration was stopped; (2) Maintenance Phase: The dose was fixed and should not have been changed other than for safety reasons or loss of efficacy. At the end of the six-month maintenance phase, the mean UFC response rate was measured; and (3) Extended Evaluation Phase: Patients continued on RECORLEV for another six months to evaluate long-term safety and tolerability and explore efficacy durability.

About Strongbridge Biopharma

Strongbridge Biopharma is a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs. Strongbridge's commercial portfolio within its rare endocrine franchise includes RECORLEV™ (levoketoconazole), a cortisol synthesis inhibitor currently being studied in Phase 3 clinical

studies for the treatment of endogenous Cushing's syndrome, and veldoreotide extended release, a pre-clinical next-generation somatostatin analog being investigated for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation. Both RECORLEV and veldoreotide have received orphan drug designation from the FDA and the European Medicines Agency. The Company's rare neuromuscular franchise includes KEVEYIS® (dichlorphenamide), the first and only FDA-approved treatment for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis. KEVEYIS has orphan drug exclusivity in the United States.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws. The words "anticipate," "estimate," "expect," "intend," "may," "plan," "potential," "project," "target," "will," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All statements, other than statements of historical facts, contained in this press release, are forward-looking statements, including statements related to the potential advantages of RECORLEV, the results of SONICS and other clinical trials, Strongbridge's strategy, plans, status and, outcomes of product development efforts, and objectives of management for future operations. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed in such statement, including risks and uncertainties associated with clinical development and the regulatory approval process, the reproducibility of any reported results showing the benefits of RECORLEV, the adoption of RECORLEV by physicians, if approved, as treatment for any disease and the emergence of unexpected adverse events following regulatory approval and use of the product by patients. Additional risks and uncertainties relating to Strongbridge and its business can be found under the heading "Risk Factors" in Strongbridge's Annual Report on Form 10-K for the year ended December 31, 2018 and subsequent filings with the SEC. These forward-looking statements are based on current expectations, estimates, forecasts and projections and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors. The forward-looking statements contained in this press release are made as of the date of this press release, and Strongbridge Biopharma does not assume any obligation to update any forward-looking statements except as required by applicable law.

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