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 2, 2021**

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:

☐ 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
Ordinary shares, par value $0.01 per share	SBBP	The Nasdaq Global Select Market

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 Events

On March 2, 2021, the Company issued a press release announcing submission of a New Drug Application (NDA) for RECORLEV® (levoketoconazole) for the treatment of endogenous Cushing's syndrome to the U.S. Food and Drug Administration (FDA). A copy of the press release announcing these developments is attached as Exhibit 99.1 to this Current Report on Form 8-K 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 2, 2021.
104	Cover Page Interactive Data File (formatted as inline XBRL).

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/ Stephen Long
Name: Stephen Long
Title: Chief Legal Officer

Date: March 2, 2021

Exhibit 99.1

Strongbridge Biopharma plc Announces Submission of New Drug Application for RECORLEV® (levoketoconazole) for the Treatment of Endogenous Cushing's Syndrome to the U.S. Food & Drug Administration

~ RECORLEV® (levoketoconazole) New Drug Application is Supported by Previously-Reported Positive and Statistically Significant Results from the Phase 3 SONICS and LOGICS Studies ~

~ Nearly 40 Percent of Prescription-Treated Endogenous Cushing's Syndrome Patients in the U.S. Are Not Well-Controlled, Underscoring Need for New, Safe and Effective Pharmaceutical Options to Help Regulate Cortisol Levels ~

~ If Approved Following a Projected 10-Month Review Cycle, RECORLEV is Anticipated to Launch in First Quarter of 2022 ~

DUBLIN, Ireland and TREVOSE, Pa., March 2, 2021 — 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 that it submitted a New Drug Application (NDA) for RECORLEV® (levoketoconazole) for the treatment of endogenous Cushing's syndrome to the U.S. Food and Drug Administration (FDA). The submission is supported by previously reported positive and statistically significant results of the SONICS and LOGICS trials: two Phase 3 multinational studies designed to evaluate the safety and efficacy of RECORLEV when used to treat adults with endogenous Cushing's syndrome.

"The submission of the New Drug Application for RECORLEV® (levoketoconazole) represents not only a significant milestone for Strongbridge but also for the Cushing's syndrome community as a whole. As an organization focused on developing treatments for underserved rare disease patient populations, we are one step closer to helping address the needs of the estimated 8,000 Cushing's syndrome patients in the U.S. who are treated with prescription therapy, many of whom, as we learned in our market research, are not well-controlled with current therapies," said John H. Johnson, chief executive officer of Strongbridge Biopharma. "We look forward to working with the FDA through their review of our application, and we are actively preparing for the potential launch of RECORLEV in the first quarter of 2022, if approved."

RECORLEV, the pure 2S,4R enantiomer of the enantiomeric pair comprising ketoconazole, is a next-generation steroidogenesis inhibitor being investigated as a chronic therapy for adults with endogenous Cushing's syndrome. Two Phase 3 studies have demonstrated substantial evidence of efficacy and safety in a combined study population of 166 patients that was representative of the adult drug-treated U.S. population with Cushing's syndrome. The SONICS study met its primary and key secondary endpoints, demonstrating a statistically significant rate of mean urinary free cortisol normalization after six months of maintenance therapy without a dose increase (detailed results here). LOGICS, a double-blind, placebo-controlled randomized-withdrawal study, which also had statistically significant primary and key secondary endpoints, confirmed that the long-term cortisol-normalizing efficacy demonstrated in SONICS was due to use of levoketoconazole specifically (detailed results here). The long-term open-label extension study, OPTICS, is contributing safety information to the NDA.

“We want to thank the patients, their families, investigators, collaborators, and employees who have contributed to the RECORLEV clinical program leading to this important regulatory milestone,” said Fredric Cohen, M.D., chief medical officer of Strongbridge Biopharma.

RECORLEV has received orphan drug designation from the FDA and the European Medicines Agency for the treatment of endogenous Cushing's syndrome.

Strongbridge will host a conference call tomorrow, Wednesday, March 3, 2021 at 8:30 a.m. ET to discuss the Company’s fourth quarter and full-year 2020 financial results and recent corporate highlights, including the RECORLEV NDA submission.

About Cushing’s Syndrome
Endogenous Cushing’s syndrome is a rare, serious and potentially lethal endocrine disease caused by chronic elevated cortisol exposure - often the result of a benign tumor of the pituitary gland. This benign tumor tells the body to overproduce high levels of cortisol for a sustained period of time, and this often results in undesirable physical changes. The disease is most common among adults between the ages of 30 to 50, and it affects women three times more often than men. Women with Cushing's syndrome may experience a variety of health issues including menstrual problems, difficulty becoming pregnant, excess male hormones (androgens), primarily testosterone which can cause hirsutism (growth of coarse body hair in a male pattern), oily skin, and acne. Additionally, the internal manifestations of the disease are potentially life threatening. These include metabolic changes such as high blood sugar, or diabetes, high blood pressure, high cholesterol, fragility of various tissues including blood vessels, skin, muscle and bone, and psychologic disturbances such as depression, anxiety and insomnia. Untreated, the five-year survival rate is only approximately 50 percent.

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 mUFC 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 mUFC 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 the LOGICS Study
The Phase 3, multinational, double-blind, placebo-controlled, randomized-withdrawal study, LOGICS, randomized Cushing’s syndrome patients with baseline mean urinary free cortisol (mUFC) at least 1.5 times the upper limit of normal (ULN) following completion of a single-arm, open-label treatment phase of approximately 14 to 19 weeks, with RECORLEV individually titrated according to mUFC response.

A total of 79 patients were dosed during the open-label titration-maintenance phase, 7 of whom had previously received RECORLEV during the SONICS study, and 72 who had not previously received RECORLEV. At study baseline, the median mUFC was 3.5 times the ULN, indicative of significant hypercortisolemia.

A total of 44 patients (39 who had completed the titration-maintenance phase and five who directly enrolled from the SONICS study), were randomized to either continue RECORLEV (n=22) or to have treatment withdrawn by receiving a matching placebo regimen (n=22) for up to 8 weeks, followed by restoration to the prior regimen using blinded drug. Of the 44 patients randomized, 11 patients (25 percent) had previously received RECORLEV during the SONICS study. Patients who required rescue treatment with open-label RECORLEV during the randomized-withdrawal phase were considered to have lost mUFC response at the visit corresponding to their first dose of rescue medication. Patients who did not qualify for randomization were removed from open-label treatment prior to randomization and excused from the study.

About RECORLEV
RECORLEV® (levoketoconazole) is an investigational cortisol synthesis inhibitor in development for the treatment of patients with endogenous Cushing's syndrome, a rare but serious and potentially lethal endocrine disease caused by chronic elevated cortisol exposure. RECORLEV is the pure 2S,4R enantiomer of ketoconazole, a steroidogenesis inhibitor. RECORLEV has demonstrated in two successful Phase 3 studies to significantly suppress serum cortisol and has the potential to be a next-generation cortisol inhibitor.

The Phase 3 program for RECORLEV includes SONICS and LOGICS: two multinational studies designed to evaluate the safety and efficacy of RECORLEV when used to treat endogenous Cushing's syndrome. The SONICS study met its primary and secondary endpoints, demonstrating a statistically significant normalization rate of urinary free cortisol at six months. The LOGICS study, which met its primary endpoint, is a double-blind, placebo-controlled randomized-withdrawal study of RECORLEV that is designed to supplement the long-term efficacy and safety information supplied by SONICS. The ongoing long-term open label OPTICS study will gather further useful information related to the long-term use of RECORLEV.

RECORLEV has received orphan drug designation from the FDA and the European Medicines Agency for the treatment of endogenous Cushing's syndrome.

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 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 data from the LOGICS and SONICS studies, the potential advantages of RECORLEV, the anticipated timing for potential approval of a marketing authorization for RECORLEV and for the potential launch of RECORLEV, Strongbridge's strategy, plans, 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, 2019 and its subsequent Quarterly Reports on Form 10-Q, as well as its other 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.

Contacts:

Corporate and Media Relations
Elixir Health Public Relations
Lindsay Rocco
+1 862-596-1304
lrocco@elixirhealthpr.com

Investor Relations
Solebury Trout
Mike Biega
+1 617-221-9660
mbiega@soleburytrout.com