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): **October 22, 2018**

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 7.01 Regulation FD.

On October 22, 2018, Strongbridge Biopharma plc (the "Company") issued a press release entitled "Strongbridge Biopharma plc Presents Detailed Initial Results from Pivotal Phase 3 SONICS Study of RECORLEV™ (levoketoconazole) for the Treatment of Endogenous Cushing's Syndrome at the 18th Annual Congress of the European NeuroEndocrine Association". A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference into this Item 7.01.

The information contained in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing. The information set forth herein will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Table
99.1	Press Release issued by Strongbridge Biopharma plc, dated October 22, 2018.

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: October 22, 2018

Exhibit 99.1

Strongbridge Biopharma plc Presents Detailed Initial Results from Pivotal Phase 3 SONICS Study of RECORLEV™ (levoketoconazole) for the Treatment of Endogenous Cushing's Syndrome at the 18th Annual Congress of the European NeuroEndocrine Association

~ As Previously Reported, SONICS Met its Primary Endpoint With 30 Percent of the ITT Patient Population Reaching & Maintaining Mean Urinary Free Cortisol (mUFC) Normalization Following Six Months of Maintenance Therapy Without a Dose Increase ~

~ RECORLEV Monotherapy Normalized UFC Initially in 81 Percent of Patients Who Advanced into the Maintenance Phase ~

~ UFC Responder Analysis at End of Maintenance Phase Show Nearly Half of Patients Achieved a 50 Percent or More Decrease or Normalization in mUFC Regardless of Dose Increase ~

Dublin, Ireland and Trevose, Pa., October 22, 2018 — 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, announced today that positive results from its pivotal Phase 3, open-label, single-arm SONICS study, which evaluated the safety and efficacy of RECORLEV™ (levoketoconazole) in patients with endogenous Cushing's syndrome, were presented at the 18th Annual Congress of the European NeuroEndocrine Association (ENEA) held in Wrocław, Poland from October 17 — 20, 2018.

The SONICS study met its primary endpoint, with mean urinary free cortisol (mUFC) — a surrogate endpoint that predicts clinical outcomes — confirmed normal among 30 percent of the intent-to-treat (ITT) population, without a preceding dose increase following six months of maintenance therapy (one-sided P=0.0154). Top-line efficacy results were previously reported in August 2018.

Highlights of Newly Presented SONICS Data at ENEA:

- The SONICS study demonstrated that RECORLEV monotherapy normalized mUFC initially in 81 percent of patients with Cushing's syndrome who advanced into the maintenance phase.
- As part of a planned UFC responder analysis:
    - Normalization of mUFC, regardless of dose increase at the end of the maintenance phase, was achieved in 38 percent (95% CI, 28%-49%) of ITT patients.

    - Forty-two percent (95% CI, 32%-53%) of ITT patients achieved normalization when accounting for missing data after month 3 of maintenance phase by using the last observed mUFC.
    - Forty-eight percent (95% CI, 37%-58%) of ITT patients achieved a 50 percent or more mUFC decrease or normalization.
- For key secondary endpoints of cardiovascular risk biomarkers, RECORLEV demonstrated statistically significant and clinically meaningful improvements from baseline.
- Data from an exploratory analysis at the end of the maintenance phase indicated that RECORLEV effectively reduced mUFC regardless of the baseline mUFC level, with median reduction from baseline exceeding 80 percent in the highest tertile of baseline mUFC. This strong and broad effect of RECORLEV to reduce mUFC among those who advanced into the maintenance phase, coupled with other findings, suggests that a patient's baseline mUFC—which averaged approximately 5-fold higher than the upper limit of the reference range (i.e. 5X ULN) at baseline among the enrolled study population—was an important determinant of achievement of mUFC normalization.

These efficacy and safety analyses are based on 94 patients who were enrolled and treated in the study. The poster, entitled *Safety and Efficacy of Levoketoconazole in Cushing Syndrome: Initial Results From the Phase 3 SONICS Study*, can be accessed here.

"In addition to the SONICS study achieving statistical significance of its primary and secondary endpoints, the exploratory responder analyses indicate that levoketonazole provided clinical benefit across the spectrum of baseline comorbidities in Cushing's syndrome, including hypercholesterolemia and diabetes," said Maria Fleseriu, M.D., FACE, professor of Medicine and Neurological Surgery and director of the Oregon Health Sciences University Northwest Pituitary Center who presented the data. "Importantly, many markers of cardiovascular risk, an important cause of morbidity and mortality in Cushing's syndrome, also improved significantly, thus offering a potential therapeutic advance. Relative mUFC reductions from baseline were substantial and were not related to baseline UFC. Furthermore, liver enzyme abnormalities greater than three times the upper limit of normal, which occurred in 11 percent of patients, were all noted in the first 60 days, thus suggesting a timeline interval for monitoring and were fully reversible upon drug discontinuation without clinical sequelae."

As previously reported, safety and tolerability data collected through the six-month maintenance phase showed that RECORLEV was generally well-tolerated. No unexpected safety signals were observed. The most common adverse events were nausea, headache, peripheral edema, hypertension, fatigue, diarrhea, alanine aminotransferase (ALT) increase and gamma-glutamyl transferase (GGT) increase.

"The findings presented at ENEA continue to advance our overall understanding of the clinical profile of RECORLEV and its potential role in the treatment of Cushing's syndrome, a rare and potentially lethal endocrine disease," said Fredric Cohen, M.D., chief medical officer of Strongbridge Biopharma. "We continue to be encouraged by the positive efficacy results

of SONICS and the overall benefit-to-risk profile of RECORLEV and look forward to sharing additional planned analyses from the study in the near future."

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 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 UFC response rate was measured; and (3) Extended Evaluation Phase: Patients continue for another six months. In order to be considered a UFC responder for the primary efficacy analysis, a patient must have met either three of four criteria, as applicable: (1) have completed the six-month maintenance phase; (2) have normal (at or below the ULN) mean 24-hour UFC on the basis of at least two (and up to four) adequate 24-hour urine samples; (3) must not have increased the dose of RECORLEV used during the entire maintenance phase and; (4) for patients with a recent history of pituitary radiation, must have exhibited a rebound increase in mean UFC above the ULN following a two-week minimum withdrawal of RECORLEV at the end of maintenance phase.

About Endogenous Cushing's Syndrome

Endogenous Cushing's syndrome (CS) is a rare but serious and potentially lethal endocrine disease caused by chronic elevated cortisol exposure. Most people with CS have a variety of signs and symptoms — many of which, when they occur by themselves, are common and do not necessarily point to an underlying disease; this makes recognition of CS difficult. Common presenting symptoms include weight gain or obesity, fatigue, muscle weakness, headaches, mood or sleep disturbances, facial rounding or redness, excess body hair growth in women or baldness in men, thinned skin with stretch marks, easy bruising and other skin changes including acne, mood or sleep disturbances and irregular periods or loss of libido. Patients are often found by their doctors to have new-onset or worsening of high blood pressure, abnormal levels of blood lipids, such as cholesterol, polycystic ovaries and abnormal blood glucose or diabetes. People with uncontrolled disease are seriously ill and have a 2- to 4-fold higher mortality rate than age- and gender-matched controls, mainly due to metabolic and cardiovascular complications. Treatment options for CS include surgery, radiation therapy, and medical treatment. CS most commonly affects adults ages 20-50 and is more prevalent in females, accounting for about 70 percent of all cases.

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 MACRILEN™ (macimorelin), the first and only FDA-approved oral drug indicated for the diagnosis of adult growth hormone deficiency, 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. MACRILEN has orphan drug exclusivity in the United States, and 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 release of additional planned analyses of the SONICS study, Strongbridge's strategy, plans, status and results of SONICS and other clinical trials, 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, 2017 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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