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): **January 9, 2020**

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))

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Trading Symbol	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 2.02 Results of Operations and Financial Condition.

On January 9, 2020, Strongbridge Biopharma plc (the "Company") issued a press release announcing preliminary fourth quarter and full-year 2019 financial results and providing an update on corporate priorities. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information contained in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 is being furnished to the Commission and shall not be deemed "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended (the "Securities Act"), 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 7.01 Regulation FD.

The response to Item 2.02 is incorporated herein by reference to this Item 7.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Table
99.1	Press Release issued by Strongbridge Biopharma plc, dated January 9, 2020.

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/ Robert Lutz
Name: Robert Lutz
Title: Chief Financial Officer

Date: January 9, 2020

Strongbridge Biopharma plc Announces Preliminary Fourth Quarter and Full-Year 2019 Financial Results and Provides Update on Corporate Priorities

~ Expects to Report KEVEYIS®(dichlorphenamide) Fourth Quarter 2019 Revenue of Approximately $5.6 Million and Full-Year 2019 Revenue of Approximately $21.7 Million, a 29 Percent Increase over 2018 Revenue of $16.8 Million ~

~ Provides Full-Year 2020 KEVEYIS®(dichlorphenamide) Revenue Guidance of Approximately $26 to $27 Million and Anticipates Continued Positive and Growing Contribution Margin ~

~ Phase 3 LOGICS Study of RECORLEV™ (levoketoconazole) has Achieved More than 70 Percent Target Enrollment To-Date; Company Continues to Anticipate Reporting Top-Line Results in Second or Third Quarter 2020 ~

~ Extends Cash Runway Guidance; Cash Sufficient to Fund Operations Through Third Quarter 2021, at Least One-Year Following Anticipated Receipt of LOGICS Top-line Results ~

Dublin, Ireland and Trevose, Pa., January 9, 2020 – 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 preliminary and unaudited financial results for the fourth quarter and full-year 2019 and provided an update on key corporate priorities for 2020.

“Based on our preliminary fourth quarter and full-year 2019 results, coupled with recent actions taken to strengthen the Company's overall financial position, we have extended our cash runway through the third quarter of 2021, which is at least one year beyond our anticipated timeframe for reporting top-line LOGICS results,” said John H. Johnson, executive chairman of Strongbridge Biopharma. “We remain confident in our long-term growth prospects and believe that 2020 will provide several opportunities to deliver shareholder value. As we enter this next phase of growth, our priorities remain focused on completing the Phase 3 LOGICS trial, submitting a quality new drug application for RECORLEV™ (levoketoconazole), pursuing life cycle opportunities for KEVEYIS® (dichlorphenamide), continuing to grow the primary periodic paralysis market, and identifying a new chief executive officer.”

Preliminary and Unaudited Fourth Quarter and Full-Year 2019 Financial Results and 2020 KEVEYIS Revenue Guidance

- The Company anticipates that it will achieve KEVEYIS net product sales of approximately $5.6 million for the fourth quarter ended December 31, 2019 and approximately $21.7 million for

the full-year ended December 31, 2019, exceeding its previous $18 to $20 million guidance range, and representing a 29 percent increase over 2018 revenue of $16.8 million.

- The Company projects that the full-year 2020 revenue guidance for KEVEYIS will be approximately $26 to $27 million; based upon current assumptions, the Company anticipates a continued positive and growing contribution margin.
- Strongbridge expects to report approximately $78 million of cash and cash equivalents and no outstanding debt as of December 31, 2019.
- The Company has further extended its cash runway guidance by an additional three months, and now believes it can fund operations as currently planned through the third quarter of 2021, at least one-year following anticipated receipt of LOGICS top-line results.

Key Corporate Priorities for 2020

- Complete enrollment in the Phase 3 LOGICS study of RECORLEV in endogenous Cushing's syndrome. To date, the trial is more than 70 percent enrolled. The Company projects that all of the remaining patients required to complete enrollment are currently in the titration and maintenance phase.
- Report top-line results for the Phase 3 LOGICS study in the second or third quarter of 2020 and submit a New Drug Application (NDA) for RECORLEV to the U.S. Food and Drug Administration approximately six months after reporting top-line LOGICS results.
- Continue our efforts to pursue life cycle extension opportunities for KEVEYIS and grow the primary periodic paralysis market.

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.

About KEVEYIS

KEVEYIS® (dichlorphenamide) is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants. In clinical studies, the most common side effects of KEVEYIS were a numbness or tingling, difficulty thinking and paying attention, changes in taste, and confusion. These are not all of the possible side effects that you may experience with KEVEYIS. Talk to your doctor if you have any symptoms that bother you or do not go away. You are encouraged to report side effects to Strongbridge Biopharma at 1-855-324-8912,

or to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch. For additional KEVEYIS important safety information and the full prescribing information visit www.keveyis.com.

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 is believed to significantly suppress serum cortisol in healthy subjects and has the potential to be a next-generation cortisol inhibitor.

The Phase 3 program for RECORLEV consists of 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 ongoing LOGICS study 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.

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

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 Company's anticipated fourth quarter and full year 2019 financial results, 2020 revenue guidance and expected cash runway, future cash balances, the potential advantages of RECORLEV, the anticipated timing for the release of top-line data from the LOGICS study and the submission of an NDA for RECORLEV to the FDA, Strongbridge's strategy, plans, status and results of 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, 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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