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): **November 18, 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))

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 7.01 Regulation FD

On November 18, 2019, Strongbridge Biopharma plc issued a press release announcing steps taken to improve operational efficiencies and the appointment of a new lead independent director. 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 7.01 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 in this Item 7.01 and 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Exhibit Table**
99.1	Press Release issued by Strongbridge Biopharma plc, dated November 18, 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/ Robert Lutz
Name: Robert Lutz
Title: Chief Financial Officer

Date: November 18, 2019

Strongbridge Biopharma plc Announces Additional Steps to Improve Operational Efficiencies and Appoints New Lead Independent Director

~ The Company Remains Focused on Completing the LOGICS Study and Submitting a New Drug Application (NDA) for RECORLEV™ (levoketoconazole), While Ensuring Continued Growth and Profitability of KEVEYIS® (dichlorphenamide) and Serving the Unmet Needs of the Primary Periodic Paralysis Community ~

Dublin, Ireland and Trevose, Pa., November 18, 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 that the Company is eliminating approximately 15 positions through a reduction in headcount across the organization. This reduction is in addition to the previously announced elimination of all commercial costs related to MACRILEN™ (macimorelin), including the approximately 23 Strongbridge field-based positions related to the MACRILEN sales efforts, effective December 1, 2019. Collectively, the total reduction of overall employee headcount is approximately 38 positions, or 34 percent.

Strongbridge intends to optimize its resources for completing the development of RECORLEV™ (levoketoconazole) and continuing to grow KEVEYIS® (dichlorphenamide), and expects to realize an estimated annualized cost savings of approximately $4.2 million beginning in 2020 based upon the elimination of these 15 positions. The Company estimates that it will incur approximately $1.4 million for severance and other costs related to this action.

“We believe that this reduction in force, coupled with the recent elimination of all commercial costs related to MACRILEN, will better align the Company’s resources with our long-term strategic priorities,” said John H. Johnson, executive chairman of Strongbridge Biopharma. “Our focus remains on completing the LOGICS study and submitting a new drug application for RECORLEV, while ensuring continued growth and profitability of KEVEYIS and serving the unmet needs of the Primary Periodic Paralysis community. We wish the best for the many talented employees affected by this decision and thank them for their contributions to the organization.”

Strongbridge also today announced the appointment of Garheng Kong, M.D., Ph.D., to Lead Independent Director of the Company’s Board of Directors.

“Garheng has exceptional experience in creating and building high-growth and innovation-based healthcare businesses. On behalf of the board of directors, we are pleased to welcome him to this new role,” Johnson added.

Dr. Kong is founder and managing partner of HealthQuest Capital and has served as a member of Strongbridge's board of directors since September 2015. He brings more than 20 years of clinical, technical, and business experience in the healthcare industry, and currently serves on the board of directors of Alimera Sciences; Avedro, Inc.; and Laboratory Corporation of America. He previously served as a general partner at Sofinnova Ventures and Intersouth Partners. His early career included positions at GlaxoSmithKline, McKinsey, and TherOx before he started his investing career. Dr. Kong earned his M.D., Ph.D., and MBA from Duke University and received two undergraduate degrees in chemical engineering and biological sciences from Stanford University.

As previously reported in Strongbridge's third quarter 2019 financial results:

- John H. Johnson, who has served as chairman of Strongbridge since 2015, recently assumed the position of executive chairman, and is leading the organization while the board of directors conducts a formal search to identify a new chief executive officer;
- The Company remains on track to meet or exceed the top end of the full-year 2019 KEVEYIS® revenue guidance range of $18 million to $20 million;
- The Company had $79.6 million of cash and cash equivalents and no debt outstanding as of September 30, 2019; and
- The Company extended its cash runway guidance by at least three months, and now believes it can fund operations as currently planned through the second quarter of 2021.

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 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.

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.

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 potential organizational changes and related cost savings, charges related to organizational changes, expected revenues, future cash balances, Strongbridge's strategy, plans, status 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 a product, the adoption of a product 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.

Contacts:

Corporate and Investor Relations
Strongbridge Biopharma plc
Marcy Nanus
+1 484-312-3744
m.nanus@strongbridgebio.com

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