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): **May 1, 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 2.02 Results of Operations and Financial Condition.

On May 1, 2019, Strongbridge Biopharma plc (the "Company") issued a press release reporting first quarter financial results and providing a corporate update. 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 May 1, 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: May 1, 2019

Exhibit 99.1

Strongbridge Biopharma plc Reports First Quarter 2019 Financial Results and Provides Corporate Update

~ Following Type C Meeting with the U.S. Food & Drug Administration (FDA), Strongbridge Plans to Submit its New Drug Application (NDA) for RECORLEV™ (levoketoconazole) in the Third Quarter of 2020; Submission to Include Data From the Phase 3 SONICS and LOGICS Studies ~

~ Newly Presented Data from the Phase 3 SONICS Study Reinforce the Potential Clinical Benefit and Role of RECORLEV in the Treatment of Patients with Endogenous Cushing's Syndrome ~

~ KEVEYIS® (dichlorphenamide) First Quarter 2019 Revenue of $4.3 Million On Track with Full-Year 2019 KEVEYIS® Revenue Guidance of $18 to $20 Million ~

Dublin, Ireland and Trevose, Pa., May 1, 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 reported financial results for the first quarter of 2019 and provided a corporate update.

"During the first quarter of 2019, we held a Type C meeting with the FDA to seek their guidance on the regulatory pathway for RECORLEV™ (levoketoconazole). In line with feedback from the FDA, we have concluded that submitting a New Drug Application (NDA) inclusive of data from both the Phase 3 SONICS and LOGICS studies is the optimal path forward," said Matthew Pauls, president and chief executive officer of Strongbridge Biopharma. "The LOGICS study is progressing well; however, due to slower than anticipated enrollment, we now expect to receive top-line results by the end of the first quarter of 2020. Despite this shift in timing, we are pleased to report that with the additional clarity from the FDA and review of our timelines, we now plan to submit an NDA by the end of the third quarter of 2020."

First Quarter 2019 and Recent Corporate & Financial Highlights

Rare Endocrine Franchise: RECORLEV™ (levoketoconazole)

- The Company held a Type C meeting with the FDA to seek guidance on the regulatory path forward to obtain U.S. marketing approval for RECORLEV for the treatment of endogenous Cushing's syndrome. In line with the Agency's feedback, Strongbridge plans to submit its New Drug Application (NDA) with data from both the Phase 3 SONICS and LOGICS studies by the end of the third quarter of 2020.

- As a result of slower than anticipated enrollment, Strongbridge now plans on receiving LOGICS top-line data by the end of the first quarter of 2020, which will support an NDA submission by the end of the third quarter of 2020.
- In March and April of 2019, Strongbridge announced:

    - Top-line findings from the extended evaluation phase of the Phase 3 SONICS study, in which RECORLEV met its objective of showing a positive, long-term benefit-risk profile.
    - A subgroup analysis showing potential clinical benefits of treatment with RECORLEV in patients with diabetes mellitus was presented at the Annual Meeting of the Endocrine Society (ENDO).
    - Secondary endpoint results from the SONICS study demonstrating clinically meaningful improvements in cortisol control were presented at the 16th Annual International Pituitary Congress (IPC).
    - Additional secondary endpoint results from the SONICS study showing meaningful improvements in the clinical signs and symptoms of Cushing's syndrome were presented at the 2019 American Association of Clinical Endocrinologists (AACE) Annual Scientific and Clinical Congress.

Rare Neuromuscular Franchise: KEVEYIS® (dichlorphenamide)

- Achieved KEVEYIS net product sales of $4.3 million during the first quarter of 2019, a 12 percent increase compared to $3.9 million during the first quarter of 2018.
- Reiterated full-year 2019 revenue guidance for KEVEYIS of $18 to $20 million; based upon current assumptions, the Company anticipates a positive KEVEYIS contribution margin by the end of the first quarter of 2020.
- In May, Strongbridge will present long-term efficacy data for KEVEYIS for the treatment of Primary Periodic Paralysis at the 71st annual meeting of the American Academy of Neurology (AAN).

Corporate:

- Strongbridge had $104.3 million of cash and cash equivalents and no debt outstanding as of March 31, 2019.

First Quarter 2019 Financial Results

For the three months ended March 31, 2019, basic and diluted net loss attributable to ordinary shareholders on a GAAP basis was $18.4 million, or $0.34 per share, compared to a basic and diluted net loss attributable to ordinary shareholders of $28.7 million, or $0.66 per share, for the same period in 2018. Net loss for the three months ended March 31, 2019 was lower than the same period in 2018 primarily due to an unrealized loss of $1.8 million on the fair value of warrants recorded in 2019 (compared to an unrealized loss of $9.7 million on the fair value of warrants recorded in the same period of 2018), offset in part by higher research and development expenses associated with the continued development of RECORLEV and $0.7 million of income tax expense recorded during

the three months ended March 31, 2019. In addition, during the three months ended March 31, 2018, the Company recorded $2.9 million of interest expense and a $0.5 million loss on extinguishment of debt. The debt was fully repaid in the fourth quarter of 2018 and, therefore, the Company recorded no interest expense or loss on extinguishment on debt during the three months ended March 31, 2019.

For the three months ended March 31, 2019, non-GAAP basic net loss attributable to ordinary shareholders was $13.0 million, or $0.25 per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of $14.3 million, or $0.33 per share, for the same period in 2018. The decrease in non-GAAP net loss during the three months ended March 31, 2019 was primarily due to interest expense and a loss on extinguishment of debt in 2018, lower selling, general, and administrative expenses in 2019, and higher net revenues from KEVEYIS product sales in 2019, offset in part by higher research and development expenses in 2019 primarily associated with the continued development of RECORLEV and higher income tax expense in 2019.

The Company recorded net revenues from sales of KEVEYIS of $4.3 million for the three months ended March 31, 2019, compared to net revenues of $3.9 million for the same period in 2018. The Company recorded cost of goods sold of $0.8 million for the three months ended March 31, 2019, compared to cost of goods sold of $0.7 million for the same period in 2018.

Selling, general and administrative expenses were $12.1 million for the three months ended March 31, 2019, compared to $12.4 million for the same period in 2018.

Research and development expenses were $6.6 million for the three months ended March 31, 2019, compared to $4.9 million for the same period in 2018. The increase during the 2019 period was primarily due to expenses related to the RECORLEV OPTICS clinical trial and other RECORLEV development activities.

Conference Call Details

Strongbridge will host a conference call on Wednesday, May 1 at 8:30 a.m. ET. To access the live call, dial 844-285-7153 (domestic) or 478-219-0180 (international) with conference ID 1396930. The conference call will also be audio webcast from the Company's website at www.strongbridgebio.com under the "Investor/Webcasts and Presentations" section. A replay of the call will be made available for one week following the conference call. To hear a replay of the call, dial 855-859-2056 (domestic) or 404-537-3406 (international) with conference ID 1396930.

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 endpoint, 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 will 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 the potential advantages of RECORLEV, discussions with regulators regarding the approval process for 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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STRONGBRIDGE BIOPHARMA plc
Select Consolidated Balance Sheet Information (unaudited)
(in thousands, except share and per share data)

	March 31 2019	December 31, 2018
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 104,306	$ 122,490
Total assets	153,482	170,285
Total liabilities	56,499	57,330
Total stockholders' equity	96,983	112,955

STRONGBRIDGE BIOPHARMA plc
Consolidated Statement of Operations (unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	**2018**
Consolidated Statement of Operations Data:		
Revenues:		
Net product sales	$ 4,333	$ 3,870
Royalty revenues	10	—
Total revenues	4,343	3,870
Cost and expenses:		
Cost of sales (excluding amortization of intangible assets)	$ 813	$ 667
Selling, general and administrative	12,100	12,362
Research and development	6,583	4,881
Amortization of intangible assets	1,256	1,769
Total cost and expenses	20,752	19,679
Operating loss	(16,409)	(15,809)
Other expense, net		
Income from field services agreement	2,016	—
Expense from field services agreement	(2,229)	—
Unrealized loss on fair value of warrants	(1,820)	(9,700)
Interest expense	—	(2,874)
Loss on extinguishment of debt	—	(500)
Other income, net	685	160
Total income, net	(1,348)	(12,914)
Loss before income taxes	(17,757)	(28,723)
Income tax expense	(677)	—
Net loss	(18,434)	(28,723)
Net loss attributable to ordinary shareholders:		
Basic and diluted	$ (18,434)	$ (28,723)
Net loss per share attributable to ordinary shareholders:		
Basic and diluted	$ (0.34)	$ (0.66)
Weighted-average shares used in computing net income (loss) per share attributable to ordinary shareholders:		
Basic and diluted	54,155,034	43,620,746

STRONGBRIDGE BIOPHARMA plc
Reconciliation of Non-GAAP Financial Measures (unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31, 2019			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (16,409)	$ (17,757)	$ (18,434)	$ (0.34)
Non-GAAP Adjustments:				
Amortization of intangible assets (a)	$ 1,256	$ 1,256	$ 1,256	$ 0.02
Stock-based compensation - Research & Development (b)	$ 512	$ 512	$ 512	$ 0.01
Stock-based compensation - Selling, General & Admin. (b)	$ 1,811	$ 1,811	$ 1,811	$ 0.03
Unrealized loss on fair value of warrants (c)	—	$ 1,820	$ 1,820	$ 0.03
Adjusted	$ (12,830)	$ (12,358)	$ (13,035)	$ (0.25)

	Three Months Ended March 31, 2018			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (15,809)	$ (28,723)	$ (28,723)	$ (0.66)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 1,769	$ 1,769	$ 1,769	$ 0.04
Stock-based compensation - Research & Development (b)	$ 408	$ 408	$ 408	$ 0.01
Stock-based compensation - Selling, General & Admin. (b)	$ 1,280	$ 1,280	$ 1,280	$ 0.03
Unrealized loss on fair value of warrants (c)	—	$ 9,700	$ 9,700	$ 0.22
Non-cash interest expense (d)	—	$ 1,232	$ 1,232	$ 0.03
Adjusted	$ (12,352)	$ (14,334)	$ (14,334)	$ (0.33)

(a) The effects of amortization of the intangible assets and charges related to the impairment of the intangible assets are excluded because these charges are non-cash, and we believe such exclusion facilitates investors' ability to more accurately compare our operating results to those of our peer companies.

(b) The effects of non-cash employee stock-based compensation are excluded because of varying available valuation methodologies and subjective assumptions. We believe this is a useful measure for investors because such exclusion facilitates comparison to peer companies who also provide similar non-GAAP disclosures and is reflective of how management internally manages the business.

(c) The unrealized loss on fair value of warrants are excluded due to the nature of this charge, which is non-cash and related primarily to the effect of changes in the company's stock price at a point in time. We believe such exclusion facilitates investors' ability to more accurately compare our operating results to those of our peer companies.

(d) The effects of non-cash interest charges are excluded. We believe such exclusion facilitates an understanding of the effects of the debt service obligations on the Company's liquidity and comparisons to peer group companies and is reflective of how management internally manages the business.