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): **July 31, 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 2.02 Results of Operations and Financial Condition.

On July 31, 2019, Strongbridge Biopharma plc (the "Company") issued a press release reporting second 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 July 31, 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: July 31, 2019

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

~ KEVEYIS® (dichlorphenamide) Second Quarter 2019 Revenue of $6.1 Million ~

~ Company on Track to Meet Full-Year 2019 KEVEYIS® Revenue Guidance of $18 to $20 Million ~

~ Enrollment in Phase 3 LOGICS Study for RECORLEV™ (levoketoconazole) Progressing with Top-Line Data Anticipated at the End of the First Quarter 2020 ~

Dublin, Ireland and Trevose, Pa., July 31, 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 second quarter of 2019 and provided a corporate update.

"We are encouraged by the quarter-over-quarter revenue growth achieved with KEVEYIS® (dichlorphenamide) during the second quarter of 2019. These results reflect the progress the Company has made in more fully addressing the unmet needs of the primary periodic paralysis community," said Matthew Pauls, president and chief executive officer of Strongbridge Biopharma. "Additionally, the knowledge we are gaining from our experience with KEVEYIS will be instrumental as we prepare for the potential approval and launch of RECORLEV™ (levoketoconazole) for endogenous Cushing's syndrome."

Second Quarter 2019 and Recent Corporate & Financial Highlights

Rare Neuromuscular Franchise: KEVEYIS® (dichlorphenamide)

- Achieved KEVEYIS net product sales of $6.1 million during the second quarter of 2019, a 42 percent increase compared to $4.3 million during the second 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 presented long-term efficacy results for KEVEYIS at the 71st American Academy of Neurology Annual Meeting. The results demonstrated that long-term treatment with KEVEYIS is efficacious and provides durable reduction in attack frequency and severity in patients with primary periodic paralysis.

Rare Endocrine Franchise: RECORLEV™ (levoketoconazole)

- Top-line data from the Phase 3 LOGICS study anticipated at the end of the first quarter of 2020; these data will support a New Drug Application (NDA) submission to the U.S. Food and Drug Administration projected at the end of the third quarter of 2020.
- In April, Strongbridge presented secondary endpoint results from the Phase 3 SONICS study demonstrating meaningful improvements in the clinical signs and symptoms of Cushing's syndrome at the 2019 American Association of Clinical Endocrinologists Annual Scientific and Clinical Congress.

Corporate:

- In July, Strongbridge was added to the U.S. broad-market Russell 3000® and Microcap® Indexes.
- In June, Strongbridge announced that it strengthened its senior leadership team with the promotion of Scott Wilhoit to chief commercial officer and the appointment of Marcy Nanus to vice president of corporate affairs.
- Strongbridge had $86.2 million of cash and cash equivalents and no debt outstanding as of June 30, 2019. The Company believes the combination of existing cash resources, along with anticipated KEVEYIS revenues and payments from Novo Nordisk, are sufficient to fund operations as currently planned at least through the first quarter of 2021.

Second Quarter 2019 Financial Results

For the three months ended June 30, 2019, basic net loss attributable to ordinary shareholders on a GAAP basis was $8.2 million, or $0.15 per share, compared to a basic net loss attributable to ordinary shareholders of $2.9 million, or $0.06 per share, for the same period in 2018. Net loss for the three months ended June 30, 2019 was higher than the same period in 2018 primarily due to an unrealized gain of $19.0 million on the fair value of warrants recorded in 2018 (compared to an unrealized gain of $8.7 million on the fair value of warrants recorded in the same period of 2019) and higher research and development expenses associated with the continued development of RECORLEV, offset in part by lower selling, general, and administrative expenses primarily due to MACRILEN™ (macimorelin) launch preparation activities in 2018, as well as higher KEVEYIS net revenues for the three months ended June 30, 2019. In addition, during the three months ended June 30, 2018, the Company recorded $3.3 million of interest expense on previously outstanding long-term debt. The debt was fully repaid in the fourth quarter of 2018 and, therefore, the Company recorded no interest expense during the three months ended June 30, 2019.

For the three months ended June 30, 2019, non-GAAP basic net loss attributable to ordinary shareholders was $13.1 million, or $0.24 per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of $16.7 million, or $0.36 per share, for the same period in 2018. The decrease in non-GAAP net loss during the three months ended June 30, 2019 was primarily due to interest expense recorded 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.

The Company recorded net revenues from sales of KEVEYIS of $6.1 million for the three months ended June 30, 2019, compared to net revenues of $4.3 million for the same period in 2018. The Company recorded cost of goods sold of $1.0 million for the three months ended June 30, 2019, compared to cost of goods sold of $0.8 million for the same period in 2018.

Selling, general and administrative expenses were $12.2 million for the three months ended June 30, 2019, compared to $15.2 million for the same period in 2018. The decrease during the 2019 period was primarily due to MACRILEN launch preparation activities conducted in 2018.

Research and development expenses were $8.7 million for the three months ended June 30, 2019, compared to $5.5 million for the same period in 2018. The increase during the 2019 period was primarily due to expenses related to the RECORLEV LOGICS clinical trial and other RECORLEV development activities.

Year-to-Date June 2019 Financial Results

For the six months ended June 30, 2019, basic net loss attributable to ordinary shareholders on a GAAP basis was $26.7 million, or $0.49 per share, compared to a basic net loss attributable to ordinary shareholders of $31.6 million, or $0.69 per share, for the same period in 2018. Net loss for the six months ended June 30, 2019 was lower than the same period in 2018 primarily due to $6.2 million of interest expense and a $0.5 million loss on extinguishment of debt recorded during the six months ended June 30, 2018. The debt was fully repaid in the fourth quarter of 2018 and, therefore, the Company recorded no interest expense or loss on extinguishment of debt during the six months ended June 30, 2019. In addition, selling, general, and administrative expenses during the six months ended June 30, 2019 were lower compared to the same period in 2018, primarily due to MACRILEN launch preparation activities in 2018. Finally, KEVEYIS revenues were higher for the six months ended June 30, 2019 compared to the same period in 2018. This was offset in part by higher research and development expenses recorded for the six months ended June 30, 2019 associated with the continued development of RECORLEV.

For the six months ended June 30, 2019, non-GAAP basic net loss attributable to ordinary shareholders was $26.2 million, or $0.48 per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of $31.0 million, or $0.68 per share, for the same period in 2018. The decrease in non-GAAP net loss during the six months ended June 30, 2019 was primarily due to interest expense recorded 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.

The Company recorded net revenues from sales of KEVEYIS of $10.4 million for the six months ended June 30, 2019, compared to net revenues of $8.2 million for the same period in 2018. The Company recorded cost of goods sold of $1.8 million for the six months ended June 30, 2019, compared to cost of goods sold of $1.4 million for the same period in 2018.

Selling, general and administrative expenses were $24.3 million for the six months ended June 30, 2019, compared to $27.6 million for the same period in 2018. The decrease during the 2019 period was primarily due to MACRILEN launch preparation activities conducted in 2018.

Research and development expenses were $15.3 million for the six months ended June 30, 2019, compared to $10.3 million for the same period in 2018. The increase during the 2019 period was primarily due to expenses related to the RECORLEV LOGICS clinical trial and other RECORLEV development activities.

Conference Call Details

Strongbridge will host a conference call on Wednesday, July 31 at 8:30 a.m. ET. To access the live call, dial 844-285-7153 (domestic) or 478-219-0180 (international) with conference ID 8196543. 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 8196543.

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 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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STRONGBRIDGE BIOPHARMA plc
Select Consolidated Balance Sheet Information (unaudited)
(in thousands, except share and per share data)

	June 30, 2019	December 31, 2018
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 86,167	$ 122,490
Total assets	135,156	170,285
Total liabilities	43,867	57,330
Total stockholders' equity	91,289	112,955

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Consolidated Statement of Operations Data:				
Revenues:				
Net product sales	$ 6,073	$ 4,296	$ 10,406	$ 8,166
Royalty revenues	6	—	16	—
Total revenues	6,079	4,296	10,422	8,166
Cost and expenses:				
Cost of sales (excluding amortization of intangible assets)	$ 1,022	$ 753	$ 1,835	$ 1,420
Selling, general and administrative	12,182	15,210	24,282	27,572
Research and development	8,739	5,453	15,322	10,334
Amortization of intangible assets	1,255	1,872	2,511	3,641
Total cost and expenses	23,198	23,288	43,950	42,967
Operating loss	(17,119)	(18,992)	(33,528)	(34,801)
Other income, net				
Income from field services agreement	1,725	—	3,741	—
Expense from field services agreement	(1,758)	—	(3,987)	—
Unrealized gain on fair value of warrants	8,697	19,017	6,877	9,317
Interest expense	—	(3,289)	—	(6,163)
Loss on extinguishment of debt	—	—	—	(500)
Other income, net	608	342	1,293	502
Total income, net	9,272	16,070	7,924	3,156
Loss before income taxes	(7,847)	(2,922)	(25,604)	(31,645)
Income tax expense	(400)	(1)	(1,077)	(1)
Net loss	(8,247)	(2,923)	(26,681)	(31,646)
Net loss attributable to ordinary shareholders:				
Basic	$ (8,247)	$ (2,923)	$ (26,681)	$ (31,646)
Diluted	$ (16,944)	$ (21,940)	$ (33,558)	$ (40,963)
Net loss per share attributable to ordinary shareholders:				
Basic	$ (0.15)	$ (0.06)	$ (0.49)	$ (0.69)
Diluted	$ (0.30)	$ (0.43)	$ (0.60)	$ (0.81)
Weighted-average shares used in computing net income (loss) per share attributable to ordinary shareholders:				
Basic	54,175,731	45,829,600	54,165,439	45,728,793
Diluted	55,781,078	50,437,716	56,262,936	50,363,801

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

	Three Months Ended June 30, 2019			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (17,119)	$ (7,847)	$ (8,247)	$ (0.15)
Non-GAAP Adjustments:				
Amortization of intangible assets (a)	$ 1,255	$ 1,255	$ 1,255	
Stock-based compensation - Research & Development (b)	$ 592	$ 592	$ 592	
Stock-based compensation - Selling, General & Admin. (b)	$ 1,981	$ 1,981	$ 1,981	
Unrealized gain on fair value of warrants (c)	—	$ (8,697)	$ (8,697)	
Adjusted	$ (13,291)	$ (12,716)	$ (13,116)	$ (0.24)

	Three Months Ended June 30, 2018			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (18,992)	$ (2,922)	$ (2,923)	$ (0.06)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 1,872	$ 1,872	$ 1,872	
Stock-based compensation - Research & Development (b)	$ 463	$ 463	$ 463	
Stock-based compensation - Selling, General & Admin. (b)	$ 1,521	$ 1,521	$ 1,521	
Unrealized gain on fair value of warrants (c)	—	$ (19,017)	$ (19,017)	
Non-cash interest expense (d)	—	$ 1,430	$ 1,430	
Adjusted	$ (15,136)	$ (16,653)	$ (16,654)	$ (0.36)

	Six Months Ended June 30, 2019			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (33,528)	$ (25,604)	$ (26,681)	$ (0.49)
Non-GAAP Adjustments:				
Amortization of intangible assets (a)	$ 2,511	$ 2,511	$ 2,511	
Stock-based compensation - Research & Development (b)	$ 1,104	$ 1,104	$ 1,104	
Stock-based compensation - Selling, General & Admin. (b)	$ 3,792	$ 3,792	$ 3,792	
Unrealized gain on fair value of warrants (c)	—	$ (6,877)	$ (6,877)	
Adjusted	$ (26,121)	$ (25,074)	$ (26,151)	$ (0.48)

	Six Months Ended June 30, 2018			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (34,801)	$ (31,645)	$ (31,646)	$ (0.69)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 3,641	$ 3,641	$ 3,641	
Stock-based compensation - Research & Development (b)	$ 871	$ 871	$ 871	
Stock-based compensation - Selling, General & Admin. (b)	$ 2,801	$ 2,801	$ 2,801	
Unrealized gain on fair value of warrants (c)	—	$ (9,317)	$ (9,317)	
Non-cash interest and debt extinguishment expense (d)	—	$ 2,662	$ 2,662	
Adjusted	$ (27,488)	$ (30,987)	$ (30,988)	$ (0.68)

(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 gain 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.