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 10, 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 2.02 Results of Operations and Financial Condition.

On May 10, 2018, 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 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, or otherwise subject to the liabilities of that section. The information in this Current Report on Form 8-K 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.

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 10, 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: _____
Name: A. Brian Davis
Title: Chief Financial Officer

Date: May 10, 2018

Exhibit 99.1

Strongbridge Biopharma plc Reports First Quarter 2018 Financial Results and Provides Corporate Update

~ KEVEYIS® (dichlorphenamide) First Quarter 2018 Revenue of $3.9 Million ~

~ Increased Full-Year 2018 Revenue Guidance for KEVEYIS from $16 to $19 Million to $18 to $20 Million ~

~ MACRILEN™ (macimorelin) Product Launch on Track for July 2018 ~

~ Development Program for RECORLEV™ (levoketoconazole) Progressing with Top-line Results for SONICS Planned for Mid-2018 and LOGICS for First Quarter 2019 ~

Dublin, Ireland and Trevose, Pa., May 10, 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, today reported first quarter 2018 financial results.

"The first quarter of 2018 was highly productive for Strongbridge as we began preparing for the commercial launch in July of MACRILEN™ (macimorelin), the first and only FDA-approved oral drug indicated for the diagnosis of Adult Growth Hormone Deficiency (AGHD). The interest from the endocrinology community across the United States has been significant; the enthusiasm to adopt a safe, simple and accurate drug to use in their assessment of AGHD has reinforced our optimism about the market potential for MACRILEN," said Matthew Pauls, president and chief executive officer of Strongbridge Biopharma. "We also delivered solid first quarter revenues for KEVEYIS® (dichlorphenamide) and given these results, along with our expectation for continued strong commercial execution for the balance of the year, we increased our full year KEVEYIS revenue guidance for 2018."

First Quarter 2018 & Recent Company Highlights:

Corporate & Commercial:

- Achieved KEVEYIS net product sales of $3.9 million in the first quarter of 2018, a 30 percent increase compared to $3.0 million in the fourth quarter of 2017.
- Increased full-year 2018 revenue guidance for KEVEYIS from $16 to $19 million to $18 to $20 million.
- Acquired the U.S. and Canadian rights to MACRILEN in January 2018 expanding the Company's footprint in the rare endocrine therapeutic category.
- In preparation for the planned MACRILEN launch in July, hired 15 of 16 sales representatives; in the process of hiring two regional business directors and four field reimbursement managers.

- Strengthened intellectual property portfolio with second method of use patent issued for RECORLEV by the United States Patent and Trademark Office.

Clinical Development and Medical Affairs:

- Presented new clinical analyses for KEVEYIS at the 70th American Academy of Neurology (AAN) Annual Meeting.
- Hired two of three medical science liaisons in preparation for the planned MACRILEN launch.
- Top-line results for SONICS remain on track for mid-year 2018.
- Held Data and Safety Monitoring Board (DSMB) meeting at the end of April at which the DSMB recommended that the Phase 3 SONICS study continue as planned with no protocol changes.
- Dosed the initial patients and continued activating sites for the Phase 3 LOGICS study.
- Presented results from an in vitro study of levoketoconazole, the active ingredient in RECORLEV, at ENDO 2018, the Annual Meeting of the Endocrine Society; these data demonstrated that levoketoconazole is the clinically active half of ketoconazole with regard to cortisol and androgen synthesis inhibition.

First Quarter 2018 Financial Results

For the three months ended March 31, 2018, basic and diluted net loss attributable to ordinary shareholders on a GAAP basis was $28.7 million, or $0.66 per share, compared to a basic net loss attributable to ordinary shareholders of $29.5 million, or $0.83 per share, for the same period in 2017. Net loss for the three months ended March 31, 2018 was lower than the same period in 2017 primarily due to net revenues recorded in 2018 from sales of KEVEYIS, which was launched in April 2017, and a lower unrealized loss on the fair value of warrants recorded in 2018, offset in part by increased operating expenses associated with the commercialization of KEVEYIS.

For the three months ended March 31, 2018, non-GAAP basic and diluted net loss attributable to ordinary shareholders was $14.3 million, or $0.33 per share, compared to a non-GAAP basic and diluted net loss attributable to ordinary shareholders of $10.4 million, or $0.28 per share, for the same period in 2017. The increase in non-GAAP net loss was primarily due to increased operating expenses associated with the commercialization of KEVEYIS, which was launched in April 2017, offset in part by net revenues recorded from KEVEYIS product sales.

The Company recorded net revenues from sales of KEVEYIS, which was launched in April 2017, of $3.9 million and cost of goods sold of $0.7 million for the three months ended March 31, 2018. No revenue or cost of goods sold was recognized for the same period in 2017.

Research and development expenses were $4.9 million for the three months ended March 31, 2018, compared to $3.5 million for the same period in 2017. The increase during the 2018 period was primarily due to expenses related to the RECORLEV LOGICS clinical trial.

Selling, general and administrative expenses were $12.4 million for the three months ended March 31, 2018, compared to $7.4 million for the same period in 2017. The increase during the 2018 period

was primarily due to costs incurred to establish the commercial and corporate infrastructure necessary to support the launch and ongoing commercialization of KEVEYIS.

Strongbridge had $92.4 million of cash and cash equivalents and $86.5 million in outstanding debt as of March 31, 2018, compared to $57.5 million of cash and cash equivalents and $40.0 million in outstanding debt as of December 31, 2017. The Company believes the combination of existing cash resources and potential additional borrowings available under its credit facility will provide sufficient cash resources under its current operating plan, which includes the commercial launch of MACRILEN and the potential U.S. regulatory approval and launch of RECORLEV, to achieve consistent positive cash flows from operating activities.

Conference Call Information
Strongbridge will host a conference call on Thursday, May 10 at 8:30 a.m. ET. To access the live call, dial 844-285-7153 (domestic) or 478-219-0180 (international) with conference ID 4674956. 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 4674956.

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 commercial portfolio within its rare neuromuscular and rare endocrine franchises includes KEVEYIS®(dichlorphenamide), the first and only FDA-approved treatment for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis, and MACRILEN™ (macimorelin), the first and only FDA-approved oral drug indicated for the diagnosis of adult growth hormone deficiency. The Company's rare endocrine franchise also includes a clinical-stage pipeline of therapies: RECORLEV™ (levoketoconazole), a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome, and veldoreotide, a next-generation somatostatin analog being investigated for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation.

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 MACRILEN
MACRILEN™ (macimorelin) is a prescription oral solution that is used to test for adult growth hormone deficiency (AGHD). In clinical studies, the most common side effects of MACRILEN were

changed sense of taste, dizziness, headache, fatigue, nausea, hunger, diarrhea, upper respiratory tract infection, feeling hot, excessive sweating, sore nose and throat, and decreased heart rate. These are not all of the possible side effects that you may experience with MACRILEN. Call your healthcare provider for medical advice about side effects. You are encouraged to report side effects to Strongbridge at 1-855-324-8912, or to the FDA at 1-800-FDA-1088 or visit www.strongbridgebio.com/products/macrilen/. Please see Full Prescribing Information for additional important MACRILEN safety information.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, are forward-looking statements. These statements relate to future events and involve known and unknown risks, including, without limitation, uncertainties regarding Strongbridge's strategy, plans, future financial position, anticipated investments, costs and results, outcomes of product development efforts, status and results of clinical trials, and objectives of management for future operations. 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. 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 2018	December 31, 2017
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 92,405	$ 57,510
Total assets	163,527	103,925
Long-term debt, net	76,142	37,794
Total liabilities	161,674	115,839
Total stockholders' equity (deficit)	1,853	(11,914)

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

	Three Months Ended	
	2018	2017
Consolidated Statement of Operations Data:		
Revenues:		
Net product sales	$ 3,870	$ —
Total revenues	3,870	—
Cost and expenses:		
Cost of sales (excluding amortization of intangible assets)	$ 667	$ —
Selling, general and administrative	12,362	7,442
Research and development	4,881	3,481
Amortization of intangible assets	1,769	1,256
Total cost and expenses	19,679	12,179
Operating loss	(15,809)	(12,179)
Other expense, net:		
Unrealized loss on fair value of warrants	(9,700)	(14,928)
Interest expense	(2,874)	(737)
Foreign exchange loss	(20)	(12)
Loss on extinguishment of debt	(500)	—
Other income (expense), net	180	(35)
Total other expense, net	(12,914)	(15,712)
Loss before income taxes	(28,723)	(27,891)
Income tax expense	—	(1,594)
Net loss	(28,723)	(29,485)
Net loss attributable to ordinary shareholders:		
Basic and diluted	$ (28,723)	$ (29,485)
Net loss per share attributable to ordinary shareholders:		
Basic and diluted	$ (0.66)	$ (0.83)
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:		
Basic and diluted	43,620,746	35,335,026

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

	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 assets (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 and debt extinguishment expenses (d)	—	$ 1,232	$ 1,232	$ 0.03
Adjusted	$ (12,352)	$ (14,334)	$ (14,334)	$ (0.33)

	Three Months Ended March 31, 2017			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (12,179)	$ (27,891)	$ (29,485)	$ (0.83)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 1,256	$ 1,256	$ 1,256	$ 0.04
Stock-based compensation - Research & Development (b)	$ 217	$ 217	$ 217	$ 0.01
Stock-based compensation - Selling, General & Admin. (b)	$ 952	$ 952	$ 952	$ 0.03
Unrealized loss on fair value of warrants (c)	—	$ 14,928	$ 14,928	$ 0.42
Non-cash interest expense (d)	—	$ 442	$ 442	$ 0.01
Non-cash income tax (benefit) expense (e)	—	—	$ 1,339	$ 0.04
Adjusted	$ (9,754)	$ (10,096)	$ (10,351)	(0.28)

(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 and debt extinguishment 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.

(e) The effect of non-cash tax expense or benefit related to valuation allowance adjustments of the deferred income tax asset is excluded because of its non-recurring nature. We believe such exclusion facilitates investor's ability to more accurately compare our operating results to those of our peer companies.