
**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): **August 4, 2020**

STRONGBRIDGE BIOPHARMA plc
(Exact name of registrant as specified in its charter)

Ireland
(State or other
jurisdiction of incorporation)

001-37569
(Commission
File Number)

98-1275166
(I.R.S. Employer
Identification No.)

900 Northbrook Drive, Suite 200
Trevose, PA
(Address of principal executive offices)

19053
(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:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 August 4, 2020, 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 Disclosure.

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 August 4, 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: August 4, 2020



Strongbridge Biopharma plc Reports Second Quarter 2020 Financial Results and Provides Corporate Update

~ Reports KEVEYIS® (dichlorphenamide) Second Quarter 2020 Revenue of \$7.8 Million, a 28 Percent Increase Compared to \$6.1 Million During Second Quarter of 2019 ~

~ Company Expects to Report Top-Line Results from the Phase 3 LOGICS Study of RECORLEV™ (levoketoconazole) in Endogenous Cushing's Syndrome in September 2020 ~

~ Increased Cash Position and Extended Runway to Fund Operations Through the First Quarter of 2022 Following Completion of a \$30 Million Debt Facility ~

~ Appointed John H. Johnson as Chief Executive Officer in July 2020 ~

~ Strongbridge to Host Conference Call Today at 8:30 am ET ~

Dublin, Ireland and Trevese, Pa., August 4, 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 reported financial results for the second quarter of 2020 and provided a corporate update.

“Strongbridge had an impressive second quarter as we executed upon a number of critical milestones across our rare disease portfolio. We recently announced the achievement of the last participant completing the last study visit in the randomized withdrawal phase of the Phase 3 LOGICS study of RECORLEV™ (levoketoconazole), and we look forward to reporting top-line data in September 2020,” said John H. Johnson, chief executive officer of Strongbridge Biopharma. “Additionally, KEVEYIS® (dichlorphenamide) revenue grew by 38 percent in the first-half of 2020 compared to the same period in 2019. Importantly, this growth was achieved despite the challenges posed by the COVID-19 pandemic, which has impacted the biopharmaceutical industry as a whole. Given our strong first half performance, we expect to achieve, or potentially exceed, the higher end of our full-year 2020 KEVEYIS revenue guidance range of \$22 million to \$26 million.”

Corporate & Financial Highlights:

Rare Neuromuscular Franchise: KEVEYIS® (dichlorphenamide)

- The Company achieved KEVEYIS net product sales of \$14.4 million for the first half of 2020 ended June 30, 2020, representing a 38 percent increase over \$10.4 million in revenue from the first half of 2019. Second quarter 2020 revenue was \$7.8 million, a 28 percent increase over second quarter revenue of \$6.1 million in 2019.

- Second quarter 2020 KEVEYIS performance is attributed to new patient starts and high retention rates for existing patients on therapy. Our patient services team continues to work closely with new and existing patients to ensure access and minimize any interruptions or unnecessary discontinuations with therapy.
- The Company maintains KEVEYIS full-year revenue guidance for 2020 of \$22 million to \$26 million, and currently expects to achieve, or potentially exceed, the higher end of the range.

Rare Endocrine Franchise: RECORLEV® (levoketoconazole)

- In May, the Company announced that it had completed enrollment in the Phase 3 LOGICS study, with a total of 44 study participants enrolled in the randomized withdrawal phase of the study.
- In July, the Company announced that the last participant completed the last study visit in the randomized withdrawal phase of the LOGICS study, with a total of 43 patients completing the randomized withdrawal phase of the study.
- The Company anticipates that it will report top-line results from the LOGICS study in September 2020.
- The Company continues to anticipate submitting a New Drug Application (NDA) for RECORLEV to the FDA approximately six months after reporting top-line LOGICS results.

Corporate

- In May, the Company and its subsidiaries entered into a \$30 million debt facility with Avenue Venture Opportunities Fund, L.P. (Avenue), a fund within the Avenue Capital Group, and its affiliates, which under the terms of the loan agreement, allowed Strongbridge to borrow \$10 million at closing and provides Strongbridge with two potential additional tranches of up to \$10 million each.
- In July, Strongbridge announced the appointment of John H. Johnson as chief executive officer.
- Strongbridge had approximately \$60 million of cash, cash equivalents and marketable securities, \$10 million in debt, and \$20 million potentially available on its debt facility, as of June 30, 2020.
- Assuming the full draw-down of the \$30 million debt facility, the Company expects that it can fund operations through the first quarter of 2022.

Second Quarter 2020 Financial Results

The Company's net revenues from sales of KEVEYIS increased \$1.7 million or 28% from \$6.1 million for the three months ended June 30, 2019 to \$7.8 million for the three months ended June 30, 2020. The Company recorded cost of sales of \$0.4 million for the three months ended June 30, 2020, compared to cost of sales of \$1.0 million for the same period in 2019. Cost of sales decreased due to changes in the assumptions underlying the allocation between the purchase price of our inventory and the supply agreement. Our gross margins were 95% for three months ended June 30, 2020, compared to gross margins of 83% for the same period in 2019.

Selling, general and administrative expenses were \$9.6 million for the three months ended June 30, 2020, compared to \$12.2 million for the same period in 2019. The decrease during the current period was due to reduced personnel costs from headcount reductions and from reduced spending due to COVID-19.

Research and development expenses were \$6.2 million for the three months ended June 30, 2020, compared to \$8.7 million for the same period in 2019. The decrease was due to decreases in product development and supporting activities resulting from the completion of our SONICS trial in 2019 and higher costs related to our LOGICS trial in 2019 offset by an increase in costs from our OPTICS trial in 2020.

For the three months ended June 30, 2020, basic net loss attributable to ordinary shareholders on a GAAP basis was (\$17.3 million), or (\$0.32) per share, compared to a basic net loss attributable to ordinary shareholders of (\$8.2) million, or (\$0.15) per share, for the same period in 2019. Net loss for the three months ended June 30, 2020 was higher than the same period in 2019 due to an unrealized loss of \$7.4 million on the fair value of warrants recorded in 2020, compared to an unrealized gain of \$8.7 million in 2019. This amount was offset by an increase in KEVEYIS revenue of \$1.7 million and the reduction in selling, general and administrative and research and development expenses during the three months ended June 30, 2020 compared to the same period in 2019.

For the three months ended June 30, 2020, non-GAAP basic net loss attributable to ordinary shareholders was (\$6.7 million), or (\$0.12) per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of (\$13.1 million), or (\$0.24) per share, for the same period in 2019. The decrease in non-GAAP net loss during the three months ended June 30, 2020 was primarily due to increase in KEVEYIS revenue of \$1.7 million. In addition, selling, general and administrative and research and development expenses decreased during the three months ended June 30, 2020 compared to the same period in 2019.

Year-to-Date 2020 Financial Results

The Company's net revenues from sales of KEVEYIS increased \$4.0 million or 38% from \$10.4 million for the six months ended June 30, 2019 to \$14.4 million for the six months ended June 30, 2020. The Company recorded cost of sales of \$1.4 million for the six months ended June 30, 2020, compared to cost of sales of \$1.8 million for the same period in 2019. Cost of sales decreased due to changes in the assumptions underlying the allocation between the purchase price of our inventory and the supply agreement. Our gross margins were 91% for six months ended June 30, 2020, compared to gross margins of 82% for the same period in 2019.

Selling, general and administrative expenses were \$20.0 million for the six months ended June 30, 2020, compared to \$24.3 million for the same period in 2019. The decrease during the current period was due to reduced personnel costs from headcount reductions and from reduced spending due to COVID-19.

Research and development expenses were \$13.7 million for the six months ended June 30, 2020, compared to \$15.3 million for the same period in 2019. The decrease was due to decreases in product development and supporting activities resulting from the completion of our SONICS trial in 2019 and higher costs related to our LOGICS trial in 2019 offset by an increase in costs from our OPTICS trial in 2020.

For the six months ended June 30, 2020, basic net loss attributable to ordinary shareholders on a GAAP basis was (\$30.0 million), or (\$0.55) per share, compared to a basic net loss attributable to ordinary shareholders of (\$26.7) million, or (\$0.49) per share, for the same period in 2019. Net loss for the six months ended June 30, 2020 was higher than the same period in 2019 due to an unrealized loss of \$6.8 million on the fair value of warrants recorded in 2020, compared to an unrealized gain of \$6.9 million in 2019. This amount was offset by increase in KEVEYIS revenue of \$4.0 million and the reduction in selling, general and administrative and research and development expenses during the six months ended June 30, 2020 compared to the same period in 2019.

For the six months ended June 30, 2020, non-GAAP basic net loss attributable to ordinary shareholders was (\$17.0 million), or (\$0.31) per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of (\$26.2 million), or (\$0.48) per share, for the same period in 2019. The decrease in non-GAAP net loss during the six months ended June 30, 2020 was primarily due to an increase in KEVEYIS revenue of \$4.0 million. In addition, selling, general and administrative and research and development expenses decreased during the six months ended June 30, 2020 compared to the same period in 2019.

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

	June 30, 2020	December 31, 2019
Consolidated Balance Sheet Data:		
Cash and cash equivalents	\$ 59,909	\$ 57,032
Marketable securities	—	21,072
Total assets	97,634	117,638
Long-term debt, net	7,003	—
Total liabilities	49,765	45,447
Total stockholders' equity	47,869	72,191

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2020	2019	2020	2019
Consolidated Statement of Operations Data:				
Revenues:				
Net product sales	\$ 7,752	\$ 6,073	\$ 14,415	\$ 10,406
Royalty revenue	8	6	19	16
Total revenues	<u>7,760</u>	<u>6,079</u>	<u>14,434</u>	<u>10,422</u>
Cost and expenses:				
Cost of sales (excluding amortization of intangible asset)	\$ 393	\$ 1,022	\$ 1,362	\$ 1,835
Selling, general and administrative	9,638	12,182	20,041	24,282
Research and development	6,152	8,739	13,704	15,322
Amortization of intangible asset	1,255	1,255	2,511	2,511
Total cost and expenses	<u>17,438</u>	<u>23,198</u>	<u>37,618</u>	<u>43,950</u>
Operating loss	<u>(9,678)</u>	<u>(17,119)</u>	<u>(23,184)</u>	<u>(33,528)</u>
Other (expense) income, net:				
Unrealized (loss) gain on fair value of warrants	(7,367)	8,697	(6,787)	6,877
Income from field services agreement	—	1,725	—	3,741
Expense from field services agreement	—	(1,758)	—	(3,987)
Interest expense	(253)	—	(253)	—
Other income, net	26	608	254	1,293
Total other (expense) income, net	<u>(7,594)</u>	<u>9,272</u>	<u>(6,786)</u>	<u>7,924</u>
Loss before income taxes	<u>(17,272)</u>	<u>(7,847)</u>	<u>(29,970)</u>	<u>(25,604)</u>
Income tax expense	—	(400)	—	(1,077)
Net loss	<u>\$ (17,272)</u>	<u>\$ (8,247)</u>	<u>\$ (29,970)</u>	<u>\$ (26,681)</u>
Other comprehensive income				
Unrealized gain on marketable securities	(6)	—	(3)	—
Comprehensive loss	<u>\$ (17,278)</u>	<u>\$ (8,247)</u>	<u>\$ (29,973)</u>	<u>\$ (26,681)</u>
Net loss attributable to ordinary shareholders:				
Basic	<u>\$ (17,272)</u>	<u>\$ (8,247)</u>	<u>\$ (29,970)</u>	<u>\$ (26,681)</u>
Diluted	<u>\$ (17,272)</u>	<u>\$ (16,944)</u>	<u>\$ (29,970)</u>	<u>\$ (33,558)</u>
Net loss per share attributable to ordinary shareholders:				
Basic	<u>\$ (0.32)</u>	<u>\$ (0.15)</u>	<u>\$ (0.55)</u>	<u>\$ (0.49)</u>
Diluted	<u>\$ (0.32)</u>	<u>\$ (0.30)</u>	<u>\$ (0.55)</u>	<u>\$ (0.60)</u>
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:				
Basic	<u>54,302,325</u>	<u>54,175,731</u>	<u>54,266,675</u>	<u>54,165,439</u>
Diluted	<u>54,302,325</u>	<u>55,781,078</u>	<u>54,266,675</u>	<u>56,262,936</u>

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

	Three Months Ended June 30, 2020			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	\$ (9,678)	\$ (17,272)	\$ (17,272)	\$ (0.32)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	\$ 1,255	\$ 1,255	\$ 1,255	
Stock-based compensation - Research & Development (b)	\$ 493	\$ 493	\$ 493	
Stock-based compensation - Selling, General & Admin. (b)	\$ 1,280	\$ 1,280	\$ 1,280	
Unrealized loss on fair value of warrants (c)	-	\$ 7,367	\$ 7,367	
Non-cash interest expense (d)	-	\$ 135	\$ 135	
Adjusted	\$ (6,650)	\$ (6,742)	\$ (6,742)	\$ (0.12)

	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 asset (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)

- (a) The effects of amortization of the intangible asset 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 (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.
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STRONGBRIDGE BIOPHARMA plc
Reconciliation of Non-GAAP Financial Measures (unaudited)
(in thousands, except share and per share data)

	Six Months Ended June 30, 2020			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	\$ (23,184)	\$ (29,970)	\$ (29,970)	\$ (0.55)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	\$ 2,511	\$ 2,511	\$ 2,511	
Stock-based compensation - Research & Development (b)	\$ 974	\$ 974	\$ 974	
Stock-based compensation - Selling, General & Admin. (b)	\$ 2,550	\$ 2,550	\$ 2,550	
Unrealized loss on fair value of warrants (c)	-	\$ 6,787	\$ 6,787	
Non-cash interest expense (d)	-	\$ 135	\$ 135	
Adjusted	\$ (17,149)	\$ (17,013)	\$ (17,013)	\$ (0.31)

	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 asset (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)

- (a) The effects of amortization of the intangible asset 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 (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.

Conference Call Details

Strongbridge will host a conference call on Tuesday, August 4 at 8:30 a.m. ET. To access the live call, dial 844-285-7153 (domestic) or 478-219-0180 (international) with conference ID 4461399. 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 4461399.

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 2020 revenue guidance, expected cash runway, future cash balances, the potential advantages of RECORLEV, status of clinical trials, the anticipated timing for completion of enrollment and the release of top-line data from the LOGICS study and the submission of an NDA for RECORLEV to the FDA, the anticipated effects of the coronavirus (COVID-19) pandemic on our business, operating results and financial condition, 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, 2019 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:

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