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): **March 3, 2021**

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:

☐ 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 Act:

Title of each class	Trading Symbol(s)	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 March 3, 2021, Strongbridge Biopharma plc (the "Company") issued a press release reporting fourth quarter and year-end 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 March 3, 2021.
104	Cover Page Interactive Data File (formatted as inline XBRL)

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/ Stephen Long
Name: Stephen Long
Title: Chief Legal Officer

Date: March 3, 2021

Strongbridge Biopharma plc Reports Fourth Quarter and Full-Year 2020 Financial Results and Provides Corporate Update

~ Submitted New Drug Application (NDA) for RECORLEV® (levoketoconazole) for the Treatment of Endogenous Cushing's Syndrome to U.S. Food & Drug Administration ~

~ KEVEYIS® (dichlorphenamide) Full-Year 2020 Revenue of $30.7 Million, a 41.5 Percent Increase over 2019 Revenue of $21.7 Million ~

~ Full-Year 2021 KEVEYIS® (dichlorphenamide) Revenue Guidance of $34 Million to $36 Million ~

~ Company Reports $87.5 Million in Cash on Hand; Expects to Fund Operations Into and Potentially Beyond the First Quarter of 2023 ~

~ Strongbridge to Host Conference Call Today at 8:30 a.m. ET ~

Dublin, Ireland and Trevose, Pa., March 3, 2021 – 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 fourth quarter and full year ended December 31, 2020.

"With the successes of 2020 as a backdrop, we have begun 2021 with great momentum and optimism. Based upon the two positive and statistically significant Phase 3 SONICS and LOGICS studies, Strongbridge has submitted a New Drug Application to the U.S. Food and Drug Administration for RECORLEV® (levoketoconazole) for the treatment of endogenous Cushing's syndrome," said John H. Johnson, chief executive officer of Strongbridge Biopharma. "I am incredibly proud of our organization's accomplishments over the last year and the team's ability to execute against a number of strategic priorities that have set us up for long-term success. As we approach a number of transformational milestones in the year ahead, we remain focused on strengthening our organization through actively preparing for the potential approval and launch of RECORLEV, continued scientific exchange of results from the RECORLEV Phase 3 clinical program, and driving continued growth for KEVEYIS® (dichlorphenamide)."

Corporate & Financial Highlights

Rare Neuromuscular Franchise: KEVEYIS® (dichlorphenamide)

- Achieved KEVEYIS net product sales of $8.2 million for the fourth quarter ended, December 31, 2020, and $30.7 million for the full year ended December 31, 2020, exceeding its

projected $28 million to $29 million guidance range, and representing a 41.5 percent increase over 2019 revenue of $21.7 million.
- Full-year 2021 revenue guidance of $34 million to $36 million for KEVEYIS.

Rare Endocrine Franchise: RECORLEV® (levoketoconazole)

- On March 2, 2021, the Company announced it submitted a New Drug Application (NDA) for RECORLEV to the U.S. Food and Drug Administration; if approved, and assuming a projected 10-month review cycle, the launch of RECORLEV is anticipated in the first quarter of 2022.
- With regard to the clinical development program and medical affairs activities:
    - In November, secondary endpoints results from the Phase 3 SONICS study of RECORLEV for the potential treatment of endogenous Cushing's syndrome were published in the journal, *Pituitary.*
    - Interim safety and efficacy results, including new data analyses, from the Phase 3 LOGICS study have been accepted for poster presentation at the Endocrine Society's (ENDO) 2021 annual meeting, taking place virtually from March 20-23, 2021.

Corporate and Financial Updates

- On February 16, 2021, the Company announced the promotion of Richard S. Kollender, who has served as chief operating officer of Strongbridge since September 2019, to president and chief financial officer. In this expanded role, Mr. Kollender will succeed Robert Lutz as chief financial officer and also maintain the responsibilities he held as chief operating officer. Mr. Kollender previously served on Strongbridge's board of directors and also as chairman of the audit committee. These management changes are effective on March 3, 2021.
- Following completion in September 2020 of a $25 million equity raise and a recent year-end borrowing of an additional $10 million under the Company's existing debt facility, Strongbridge reports approximately $87.5 million of cash and cash equivalents as of December 31, 2020.
- Assuming the availability and full draw-down of the remaining $10 million from its debt facility, the Company believes it can fund operations as currently planned into, and potentially beyond, the first quarter of 2023.

Fourth Quarter 2020 Financial Results

The Company's net revenues from sales of KEVEYIS increased $2.6 million, or 47%, from $5.6 million for the three months ended December 31, 2019 to $8.2 million for the three months ended December 31, 2020. The Company recorded cost of sales of $0.4 million for the three months ended December 31, 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 our supply agreement. Our gross margins were 95% for three months ended December 31, 2020, compared to gross margins of 82% for the same period in 2019.

Selling, general and administrative expenses were $11.6 million for the three months ended December 31, 2020, compared to $12.0 million for the same period in 2019. The decrease during the current period was due to reduced personnel costs from headcount reductions and T&E savings from the prior period, partially offset by an increase in 3rd party expenses relating to our commercial activities.

Research and development expenses were $5.3 million for the three months ended December 31, 2020, compared to $8.0 million for the same period in 2019. The decrease was primarily due to reduced support activities and materials for our LOGICS trial, offset by a small increase in costs from our OPTICS trial in 2020.

For the three months ended December 31, 2020, basic net loss attributable to ordinary shareholders on a GAAP basis was ($11.9 million), or ($0.18) per share, compared to a basic net loss attributable to ordinary shareholders of ($9.0 million), or ($0.17) per share, for the same period in 2019. Net loss for the three months ended December 31, 2020 was higher than the same period in 2019 due to the prior period including income from the termination of a contract offset by an increase in net revenue in the current period. Additionally, there was a $2.3 million change in the revaluation of the fair value of our liability classified warrants recorded in 2020 compared to 2019 due to the increase in our stock price.

For the three months ended December 31, 2020, non-GAAP basic net loss attributable to ordinary shareholders was ($7.6 million), or ($0.11) per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of ($13.5 million), or ($0.25) per share, for the same period in 2019. The decrease in non-GAAP net loss during the three months ended December 31, 2020 due to the increase in KEVEYIS revenues and overall lower expenses.

Year-to-Date 2020 Financial Results

The Company's net revenues from sales of KEVEYIS increased $9.0 million, or 41.5%, from $21.7 million for the twelve months ended December 31, 2019 to $30.7 million for the twelve months ended December 31, 2020. The Company recorded cost of sales of $2.2 million for the twelve months ended December 31, 2020, compared to cost of sales of $3.8 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 our supply agreement. Our gross margins were 93% for twelve months ended December 31, 2020, compared to gross margins of 82% for the same period in 2019.

Selling, general and administrative expenses were $40.9 million for the twelve months ended December 31, 2020, compared to $49.1 million for the same period in 2019. The decrease during the current period was due to reduced personnel costs from headcount reductions, reduced spending due to COVID-19, and lower third-party expenses. Additionally, the prior period had $3.2 million in one-time charges for severance expense.

Research and development expenses were $25.8 million for the twelve months ended December 31, 2020, compared to $30.9 million for the same period in 2019. The spending reduction was primarily 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 in part by an increase in costs from our OPTICS trial in 2020.

For the twelve months ended December 31, 2020, basic net loss attributable to ordinary shareholders on a GAAP basis was ($45.1 million), or ($0.78) per share, compared to a basic net loss attributable to ordinary shareholders of ($49.5) million, or ($0.91) per share, for the same period in 2019. Net loss for the twelve months ended December 31, 2020 was lower than the same period in 2019 due to the increase in KEVEYIS revenue of $9.0 million and the reduction in selling, general and administrative and research and development expenses during the twelve months ended December 31, 2020 compared to the same period in 2019. Those decreases were offset by a $12.2 million change in the revaluation of the fair value of our liability classified warrants due to the increase in our stock price and income from termination of a contract which was recorded in the prior period.

For the twelve months ended December 31, 2020, non-GAAP basic net loss attributable to ordinary shareholders was ($31.1 million), or ($0.54) per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of ($53.2 million), or ($0.98) per share, for the same period in 2019. The decrease in non-GAAP net loss during the twelve months ended December 31, 2020 was due to an increase in KEVEYIS revenue of $9.0 million and selling, general and administrative and research and development expenses decreasing during the twelve months ended December 31, 2020 compared to the same period in 2019.

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 87,522	$ 57,032
Marketable securities	—	21,072
Total assets	121,100	117,638
Long-term debt, net	17,114	—
Total liabilities	55,495	45,447
Total shareholders' equity	65,605	72,191

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

	Three Months Ended December 31		Year Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Net product sales	$ 8,053	$ 5,677	$ 30,670	$ 21,676
Royalty revenue	18	7	61	36
Total revenues	8,071	5,684	30,731	21,712
Cost and expenses:				
Cost of sales (excluding amortization of intangible asset)	$ 408	$ 1,001	$ 2,212	$ 3,822
Selling, general and administrative	9,221	12,806	40,867	49,058
Research and development	6,771	7,552	25,795	30,903
Amortization of intangible asset	1,255	1,255	5,022	5,022
Total cost and expenses	17,655	22,614	73,896	88,805
Operating loss	(9,584)	(16,930)	(43,165)	(67,093)
Other (expense) income, net:				
Interest expense	—	1,725	(1,336)	—
Unrealized (loss) gain on fair value of warrants	6,949	3,202	(814)	11,386
Income from field services agreement			—	12,616
Expense from field services agreement			—	(6,652)
Loss on extinguishment of debt			—	—
Gain on sale of subsidiary	—	(1,672)	—	—
Other income, net	(1)	576	225	2,060
Total other (expense) income, net	6,948	2,106	(1,925)	19,410
(Loss) income before income taxes	(2,636)	(14,824)	(45,090)	(47,683)
Income tax benefit (expense)	—	(691)	15	(1,768)
Net (loss) income	$ (2,636)	$ (15,515)	(45,075)	(49,451)
Other comprehensive loss:				
Unrealized (loss) gain on marketable securities	—	—	(3)	3
Comprehensive (loss) income	$ (2,636)	$ (15,515)	$ (45,078)	$ (49,448)
Net (loss) income attributable to ordinary shareholders:				
Basic	$ (2,636)	$ (15,515)	$ (45,075)	$ (49,451)
Diluted	$ (9,585)	$ (16,992)	$ (45,075)	$ (60,837)
Net (loss) income per share attributable to ordinary shareholders:				
Basic	$ (0.06)	$ (0.25)	$ (0.78)	$ (0.91)
Diluted	$ (0.18)	$ (0.31)	$ (0.78)	$ (1.10)
Weighted-average shares used in computing net (loss) income per share attributable to ordinary shareholders:				
Basic	56,105,155	54,192,710	57,976,472	54,182,499
Diluted	57,404,652	54,540,646	57,976,472	55,383,030

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

	Three Months Ended December 31, 2020			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (10,397)	$ (11,961)	$ (11,946)	$ (0.18)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 1,256	$ 1,256	$ 1,256	
Stock-based compensation - Selling, General & Admin. (b)	$ 1,318	$ 1,318	$ 1,318	
Stock-based compensation - Research & Development (b)	$ 469	$ 469	$ 469	
Unrealized loss on fair value of warrants (c)	—	$ 976	$ 976	
Non-cash interest expense (d)	—	$ 308	$ 308	
Adjusted	$ (7,354)	$ (7,634)	$ (7,619)	$ (0.11)

	Three Months Ended December 31, 2019			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (16,635)	$ (8,980)	$ (8,980)	$ (0.17)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 1,256	$ 1,256	$ 1,256	
Stock-based compensation - Selling, General & Admin. (b)	$ 1,076	$ 1,076	$ 1,076	
Stock-based compensation - Research & Development (b)	$ 450	$ 450	$ 450	
Unrealized gain on fair value of warrants (c)	—	$ (1,307)	$ (1,307)	
Gain on settlement of field agreement (e)	—	$ (6,000)	$ (6,000)	
Adjusted	$ (13,853)	$ (13,505)	$ (13,505)	$ (0.25)

(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 or loss on fair value of warrants are excluded due to the nature of this item, 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.

(e) The gain on settlement of field services agreement is excluded due to the non-recurring nature of this gain. We believe such exclusion facilitates investors' ability to more accurately compare our operating results to those of our peer companies and is reflective of how management internally manages the business.

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

	Year Ended December 31, 2020			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (43,165)	$ (45,090)	$ (45,075)	$ (0.78)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 5,022	$ 5,022	$ 5,022	
Stock-based compensation - Selling, General & Admin. (b)	$ 5,448	$ 5,448	$ 5,448	
Stock-based compensation - Research & Development (b)	$ 1,933	$ 1,933	$ 1,933	
Unrealized loss on fair value of warrants (c)	—	$ 814	$ 814	
Non-cash interest expense (d)	—	$ 714	$ 714	
Adjusted	$ (30,762)	$ (31,159)	$ (31,144)	$ (0.54)

	Year Ended December 31, 2019			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (67,093)	$ (47,683)	$ (49,451)	$ (0.91)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 5,022	$ 5,022	$ 5,022	
Stock-based compensation - Selling, General & Admin. (b)	$ 6,552	$ 6,552	$ 6,552	
Stock-based compensation - Research & Development (b)	$ 2,045	$ 2,045	$ 2,045	
Unrealized gain on fair value of warrants (c)	—	$ (11,386)	$ (11,386)	
Gain on settlement of field services agreement (e)	—	$ (6,000)	$ (6,000)	
Adjusted	$ (53,474)	$ (51,450)	$ (53,218)	$ (0.98)

(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 or loss on fair value of warrants are excluded due to the nature of this item, 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.

(e) The gain on settlement of field services agreement is excluded due to the non-recurring nature of this gain. We believe such exclusion facilitates investors' ability to more accurately compare our operating results to those of our peer companies and is reflective of how management internally manages the business.

Conference Call Details

Strongbridge will host a conference call on Wednesday, March 3, 2021 at 8:30 a.m. ET. To access the live call, dial (844) 285-7153 (domestic) or (478) 219-0180 (international) with conference ID 2452827. The conference call will also be 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 2452827.

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 preclinical 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 has demonstrated in two successful Phase 3 studies to significantly suppress serum cortisol and has the potential to be a next-generation cortisol inhibitor.

The Phase 3 program for RECORLEV includes 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 LOGICS study, which met its primary endpoint, 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. The ongoing long-term open label OPTICS study will gather further useful information related to the long-term use of RECORLEV.

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 2021 KEVEYIS revenue guidance, expected cash balances and cash runway, potential advantages of RECORLEV, the anticipated timing for the review of the NDA for RECORLEV and the potential launch of RECORLEV (if approved), Strongbridge's strategy, plans, 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, 2020 and its subsequent Quarterly Reports on Form 10-Q, as well as its other 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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