

**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): **November 7, 2019**

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 November 7, 2019, Strongbridge Biopharma plc (the “Company”) issued a press release reporting third 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	<u>Press Release issued by Strongbridge Biopharma plc, dated November 7, 2019.</u>

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: November 7, 2019



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

~ KEVEYIS® (dichlorphenamide) Achieved \$5.7 Million in Revenue Along with a Positive Contribution Margin in Third Quarter of 2019; Strongbridge Remains On-Track to Meet or Exceed the Top End of Full-Year KEVEYIS Revenue Guidance of \$18 Million to \$20 Million ~

~ Phase 3 LOGICS Study of RECORLEV™ (levoketoconazole) has Achieved Approximately Two-Thirds Target Enrollment To-Date; Top-line Results Anticipated in Second or Third Quarter 2020 ~

~ Novo Nordisk Will Pay Strongbridge \$6 Million in Conjunction with Terminating the Services Agreement to Promote MACRILEN™ (macimorelin) in the U.S.; All Commercial Costs Related to MACRILEN to be Eliminated ~

~ Strongbridge Extends Cash Runway Guidance; Cash Sufficient to Fund Operations Through Second Quarter 2021 ~

Dublin, Ireland and Treviso, Pa., November 7, 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 third quarter of 2019 and provided a corporate update.

“As I step into the role of executive chairman, my initial key priorities are to identify a new chief executive officer, ensure a quality new drug application submission for RECORLEV™ (levoketoconazole), and improve the Company’s financial performance through cost savings initiatives,” said John H. Johnson, executive chairman of Strongbridge Biopharma. “Towards this goal, with the \$6 million expected from Novo Nordisk and anticipated KEVEYIS® (dichlorphenamide) sales growth and product profitability, we are now able to extend our cash runway through the second quarter of 2021.”

Fredric Cohen, M.D., chief medical officer of Strongbridge Biopharma commented with regard to the Company’s clinical development program for RECORLEV™ (levoketoconazole), “We have achieved approximately two-thirds of our target enrollment in the LOGICS trial to date, and while we are making progress, enrollment has been slower than anticipated. Based upon current projections, we believe that all of the remaining patients required to complete enrollment have been identified, with most in the titration and maintenance phase, and the remainder in screening.”

Third Quarter 2019 and Recent Corporate & Financial Highlights

Rare Neuromuscular Franchise: KEVEYIS® (dichlorphenamide)

- Achieved KEVEYIS net product sales of \$5.7 million during the third quarter of 2019, a 36 percent increase compared to \$4.2 million during the third quarter of 2018; Company remains on track to meet or exceed the top end of the full-year 2019 KEVEYIS revenue guidance range of \$18 million to \$20 million.
- Achieved a positive contribution margin for KEVEYIS in the third quarter, approximately six months ahead of previous projections.
- In October, long-term efficacy and safety characterization results for KEVEYIS were presented at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting in Austin, Texas.

Rare Endocrine Franchise: RECORLEV™ (levoketoconazole)

- Enrollment in the Phase 3 LOGICS study of RECORLEV™ (levoketoconazole) in endogenous Cushing's syndrome is approximately two-thirds complete. The Company projects that it has identified all of the remaining patients required to complete enrollment, with most in the titration and maintenance phase, and the remainder in screening. Top-line results are now anticipated in the second or third quarter of 2020.
- The Company plans to submit a New Drug Application for RECORLEV to the U.S. Food and Drug Administration approximately six months after reporting top-line LOGICS results.
- In October, the Company held a routine bi-annual data and safety monitoring board (DSMB) meeting for LOGICS, at which the DSMB recommended that the Phase 3 LOGICS study continue as planned.
- In September, comprehensive results from the positive pivotal Phase 3 SONICS study of RECORLEV for the potential treatment of endogenous Cushing's syndrome were published online in *The Lancet Diabetes & Endocrinology*.

Rare Endocrine Franchise: MACRILEN™ (macimorelin)

- Strongbridge and Novo Nordisk have reached an agreement in principle to terminate, effective December 1, 2019, the services agreement between the parties that provides for the use and funding by Novo Nordisk of Strongbridge's field team for the promotion of MACRILEN in the United States.
- In connection with the termination of this agreement, Novo Nordisk will pay Strongbridge \$6 million and the Company will no longer provide services to Novo Nordisk.
- Given that Strongbridge will no longer be supporting Novo Nordisk, Strongbridge will eliminate all commercial costs related to MACRILEN, including the approximately 23 Strongbridge field-based positions related to the MACRILEN sales efforts, effective December 1, 2019.

Corporate:

- Strongbridge had \$79.6 million of cash and cash equivalents and no debt outstanding as of September 30, 2019.
 - The Company extended its cash runway guidance by at least three months, and now believes it can fund operations as currently planned through the second quarter of 2021.
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- In September, the Company appointed Richard S. Kollender, who previously served on the Company's board of directors, to chief operating officer and promoted Robert Lutz from chief business officer to chief financial officer. Additionally, David Gill was appointed to the board of directors and as chairman of the audit committee following Richard's resignation from the Board.
- On November 5, the Company announced that Matthew Pauls stepped down as president, chief executive officer (CEO) and director. John H. Johnson, who has served as chairman of Strongbridge since 2015, assumed the position of executive chairman, and is leading the organization while the Board of Directors conducts a formal search to identify a new CEO.

Third Quarter 2019 Financial Results

For the three months ended September 30, 2019, basic net loss attributable to ordinary shareholders on a GAAP basis was \$13.8 million, or (\$0.25) per share, compared to a basic net loss attributable to ordinary shareholders of \$20.6 million, or (\$0.44) per share, for the same period in 2018. Net loss for the three months ended September 30, 2019 was lower than the same period in 2018 primarily due to higher KEVEYIS net revenues for the three months ended September 30, 2019 and lower selling, general, and administrative expenses primarily due to MACRILEN launch preparation activities in 2018 and lower expenses related to KEVEYIS. In addition, during the three months ended September 30, 2018, the Company recorded \$3.4 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 September 30, 2019. This was offset in part by an unrealized gain of \$7.1 million on the fair value of warrants recorded in 2018 (compared to an unrealized gain of \$3.2 million on the fair value of warrants recorded in the same period of 2019). In addition, for the three months ended September 30, 2018, the Company recorded \$1.1 million of MACRILEN net revenue. The Company sold its rights to MACRILEN to Novo Nordisk Healthcare AG in December 2018.

For the three months ended September 30, 2019, non-GAAP basic net loss attributable to ordinary shareholders was \$13.6 million, or (\$0.25) per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of \$22.2 million, or (\$0.47) per share, for the same period in 2018. The decrease in non-GAAP net loss during the three months ended September 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 MACRILEN net revenue recorded in 2018.

Net revenues were \$5.7 million for the three months ended September 30, 2019, an increase of \$0.3 million compared to the same period in 2018. The Company recorded net revenues from sales of KEVEYIS of \$5.7 million for the three months ended September 30, 2019, a 36 percent increase compared to net revenues of \$4.2 million for the same period in 2018. For the three months ended September 30, 2018, the Company recorded \$1.1 million of net revenues from sales of MACRILEN.

Selling, general and administrative expenses were \$12.8 million for the three months ended September 30, 2019, compared to \$19.6 million for the same period in 2018. The decrease during the 2019 period was primarily due to MACRILEN launch preparation activities conducted in 2018, as well as a reduction in expenses related to KEVEYIS.

Research and development expenses were \$7.6 million for the three months ended September 30, 2019, compared to \$7.2 million for the same period in 2018.

Year-to-Date September 2019 Financial Results

For the nine months ended September 30, 2019, basic net loss attributable to ordinary shareholders on a GAAP basis was \$40.5 million, or (\$0.75) per share, compared to a basic net loss attributable to ordinary shareholders of \$52.2 million, or (\$1.14) per share, for the same period in 2018. Net loss for the nine months ended September 30, 2019 was lower than the same period in 2018 primarily due to \$9.6 million of interest expense and a \$0.5 million loss on extinguishment of debt recorded during the nine months ended September 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 on debt during the nine months ended September 30, 2019. In addition, KEVEYIS revenues were higher for the nine months ended September 30, 2019 compared to the same period in 2018. Finally, selling, general, and administrative expenses during the nine months ended September 30, 2019 were lower compared to the same period in 2018, primarily due to MACRILEN launch preparation activities in 2018 and lower expenses related to KEVEYIS. These factors were offset in part by an unrealized gain of \$16.4 million on the fair value of warrants recorded in 2018 (compared to an unrealized gain of \$10.1 million on the fair value of warrants recorded in the same period of 2019) and \$1.1 million of MACRILEN net revenues recorded in 2018. The Company sold its rights to MACRILEN to Novo Nordisk Healthcare AG in December 2018.

For the nine months ended September 30, 2019, non-GAAP basic net loss attributable to ordinary shareholders was \$39.7 million, or (\$0.73) per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of \$53.2 million, or (\$1.16) per share, for the same period in 2018. The decrease in non-GAAP net loss during the nine months ended September 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 recorded for the nine months ended September 30, 2019 associated with the continued development of RECORLEV and MACRILEN net revenue recorded in 2018.

Net revenues were \$16.1 million for the nine months ended September 30, 2019, an increase of \$2.6 million compared to the same period in 2018. The Company recorded net revenues from sales of KEVEYIS of \$16.1 million for the nine months ended September 30, 2019, a 30 percent increase compared to net revenues of \$12.4 million for the same period in 2018. For the nine months ended September 30, 2018, the Company recorded \$1.1 million of net revenues from sales of MACRILEN.

Selling, general and administrative expenses were \$37.1 million for the nine months ended September 30, 2019, compared to \$47.1 million for the same period in 2018. The decrease during the 2019 period was primarily due to MACRILEN launch preparation activities conducted in 2018, as well as a reduction in expenses related to KEVEYIS.

Research and development expenses were \$22.9 million for the nine months ended September 30, 2019, compared to \$17.5 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

Conference Call Details

Strongbridge will host a conference call on Thursday, November 7 at 8:30 a.m. ET. To access the live call, dial 844-285-7153 (domestic) or 478-219-0180 (international) with conference ID 1074065. 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 1074065.

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, discussions with regulators regarding the approval process for RECORLEV, the anticipated timing for the release of top-line data from the LOGICS study and the submission of an NDA for RECORLEV to the FDA, Strongbridge’s strategy, plans, status and results of clinical trials, outcomes of product development efforts and objectives of management for future operations. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed in such statement, including risks and uncertainties associated with clinical development and the regulatory approval process, the reproducibility of any reported results showing the benefits of RECORLEV, the adoption of RECORLEV by physicians, if approved, as treatment for any disease and the emergence of unexpected adverse events following regulatory approval and use of the product by patients. Additional risks and uncertainties relating to Strongbridge and its business can be found under the heading “Risk Factors” in Strongbridge’s Annual Report on Form 10-K for the year ended December 31, 2018 and subsequent filings with the SEC. These forward-looking statements are based on current expectations, estimates, forecasts and projections and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors. The forward-looking statements contained in this press release are made as of the date of this press release, and Strongbridge Biopharma does not assume any obligation to update any forward-looking statements except as required by applicable law.

Contacts:

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

	September 30, 2019	December 31, 2018
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	\$ 79,608	\$ 122,490
Total assets	122,960	170,285
Total liabilities	43,319	57,330
Total stockholders' equity	79,641	112,955

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Consolidated Statement of Operations Data:				
Revenues:				
Net product sales	\$ 5,677	\$ 5,347	\$ 16,083	\$ 13,513
Royalty revenues	7	—	23	—
Total revenues	<u>5,684</u>	<u>5,347</u>	<u>16,106</u>	<u>13,513</u>
Cost and expenses:				
Cost of sales (excluding amortization of intangible assets)	\$ 1,001	\$ 1,441	\$ 2,836	\$ 2,861
Selling, general and administrative	12,806	19,564	37,088	47,137
Research and development	7,552	7,198	22,874	17,532
Amortization of intangible assets	1,255	1,876	3,766	5,517
Total cost and expenses	<u>22,614</u>	<u>30,079</u>	<u>66,564</u>	<u>73,047</u>
Operating loss	(16,930)	(24,732)	(50,458)	(59,534)
Other income, net				
Income from field services agreement	1,725	—	5,466	—
Expense from field services agreement	(1,672)	—	(5,659)	—
Unrealized gain on fair value of warrants	3,202	7,131	10,079	16,448
Interest expense	—	(3,387)	—	(9,550)
Loss on extinguishment of debt	—	—	—	(500)
Other income, net	576	430	1,869	932
Total income, net	<u>3,831</u>	<u>4,174</u>	<u>11,755</u>	<u>7,330</u>
Loss before income taxes	(13,099)	(20,558)	(38,703)	(52,204)
Income tax expense	(691)	—	(1,768)	(1)
Net loss	<u>(13,790)</u>	<u>(20,558)</u>	<u>(40,471)</u>	<u>(52,205)</u>
Net loss attributable to ordinary shareholders:				
Basic	\$ (13,790)	\$ (20,558)	\$ (40,471)	\$ (52,205)
Diluted	\$ (16,992)	\$ (27,690)	\$ (50,550)	\$ (68,653)
Net loss per share attributable to ordinary shareholders:				
Basic	\$ (0.25)	\$ (0.44)	\$ (0.75)	\$ (1.14)
Diluted	\$ (0.31)	\$ (0.55)	\$ (0.91)	\$ (1.37)
Weighted-average shares used in computing net income (loss) per share attributable to ordinary shareholders:				
Basic	54,192,710	46,978,472	54,174,629	45,916,177
Diluted	<u>54,540,646</u>	<u>50,317,423</u>	<u>55,844,719</u>	<u>49,985,483</u>

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

	Three Months Ended September 30, 2019			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	\$ (16,930)	\$ (13,099)	\$ (13,790)	\$ (0.25)
Non-GAAP Adjustments:				
Amortization of intangible assets (a)	\$ 1,255	\$ 1,255	\$ 1,255	
Stock-based compensation - Research & Development (b)	\$ 491	\$ 491	\$ 491	
Stock-based compensation - Selling, General & Admin. (b)	\$ 1,684	\$ 1,684	\$ 1,684	
Unrealized gain on fair value of warrants (c)	—	\$ (3,202)	\$ (3,202)	
Adjusted	<u>\$ (13,500)</u>	<u>\$ (12,871)</u>	<u>\$ (13,562)</u>	<u>\$ (0.25)</u>

	Three Months Ended September 30, 2018			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	\$ (24,732)	\$ (20,558)	\$ (20,558)	\$ (0.44)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	\$ 1,876	\$ 1,876	\$ 1,876	
Stock-based compensation - Research & Development (b)	\$ 467	\$ 467	\$ 467	
Stock-based compensation - Selling, General & Admin. (b)	\$ 1,649	\$ 1,649	\$ 1,649	
Unrealized gain on fair value of warrants (c)	—	\$ (7,131)	\$ (7,131)	
Non-cash interest expense (d)	—	\$ 1,488	\$ 1,488	
Adjusted	<u>\$ (20,740)</u>	<u>\$ (22,209)</u>	<u>\$ (22,209)</u>	<u>\$ (0.47)</u>

Six Months Ended September 30, 2019

	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	\$ (50,458)	\$ (38,703)	\$ (40,471)	\$ (0.75)
Non-GAAP Adjustments:				
Amortization of intangible assets (a)	\$ 3,766	\$ 3,766	\$ 3,766	
Stock-based compensation - Research & Development (b)	\$ 1,595	\$ 1,595	\$ 1,595	
Stock-based compensation - Selling, General & Admin. (b)	\$ 5,475	\$ 5,475	\$ 5,475	
Unrealized gain on fair value of warrants (c)	—	\$ (10,079)	\$ (10,079)	
Adjusted	<u>\$ (39,622)</u>	<u>\$ (37,946)</u>	<u>\$ (39,714)</u>	<u>\$ (0.73)</u>

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	\$ (59,534)	\$ (52,204)	\$ (52,205)	\$ (1.14)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	\$ 5,517	\$ 5,517	\$ 5,517	
Stock-based compensation - Research & Development (b)	\$ 1,339	\$ 1,339	\$ 1,339	
Stock-based compensation - Selling, General & Admin. (b)	\$ 4,450	\$ 4,450	\$ 4,450	
Unrealized gain on fair value of warrants (c)	—	\$ (16,448)	\$ (16,448)	
Non-cash interest and debt extinguishment expense (d)	—	\$ 4,150	\$ 4,150	
Adjusted	<u>\$ (48,228)</u>	<u>\$ (53,196)</u>	<u>\$ (53,197)</u>	<u>\$ (1.16)</u>

- (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