
**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): **October 31, 2018**

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))

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 October 31, 2018, 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	Press Release issued by Strongbridge Biopharma plc. dated October 31, 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: /s/ A. Brian Davis
Name: A. Brian Davis
Title: Chief Financial Officer

Date: October 31, 2018



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

~ Financial Position to be Significantly Strengthened in Fourth Quarter 2018 by \$145 Million of Upfront Cash and \$36.7 Million Equity Investment from Separately Announced Transactions with Novo Nordisk; Company Intends to Utilize Portion of Proceeds to Repay Outstanding Debt of \$88 Million ~

~ Third Quarter 2018 Revenue of \$5.3 Million, Including KEVEYIS® (dichlorphenamide) Revenue of \$4.2 Million; KEVEYIS 2018 Revenue Guidance Revised to \$16 — \$17 Million ~

~ Presented Positive Results from the SONICS Study at the European Neuroendocrine Association Congress; Company Plans to Expand Enrollment in LOGICS, Bolstering Phase 3 Program In Anticipation of Forthcoming FDA Type C Meeting ~

~ Strongbridge to Host Conference Call Today at 8:45 a.m. ET to Discuss the Transaction Details and Third Quarter Financial Results and Corporate Highlights ~

Dublin, Ireland and Treviso, Pa., October 31, 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 third quarter 2018 financial results and provided a corporate update.

Third Quarter 2018 And Recent Corporate Highlights:

Rare Endocrine Franchise:

- Earlier today, Strongbridge announced in a separate press release that the Company entered into an agreement with Novo Nordisk to sell the U.S. and Canadian rights to MACRILEN™ (macimorelin) for an upfront payment of \$145 million plus tiered royalties on net sales. Strongbridge's current MACRILEN field organization will continue to promote the product in the U.S. under an up to three-year agreement with Novo Nordisk. In addition, Novo Nordisk agreed to purchase approximately 5.2 million ordinary shares of the Company at a purchase price of \$7.00 per share, resulting in gross proceeds of approximately \$36.7 million. These transactions are expected to close in December 2018.
 - Following the commercial launch of MACRILEN at the end of July, the Company achieved initial net product sales of \$1.1 million in the third quarter of 2018.
 - Detailed initial results from SONICS, presented at the 18th Annual Congress of the European Neuroendocrine Association, showed that: 1) RECORLEV™ (levoketoconazole) achieved statistically significant and clinically meaningful improvements in key secondary endpoints of cardiovascular risk biomarkers; 2) normalized mUFC initially in 81 percent of patients with Cushing's syndrome who advanced into the maintenance phase; and 3) nearly half of
-

patients who completed the six-month maintenance phase achieved a 50 percent or more decrease or normalization in mUFC regardless of a dose increase.

- Ongoing evaluation of the clinical data from the pivotal Phase 3 SONICS study of RECORLEV for the treatment of endogenous Cushing's syndrome continues to instill confidence in RECORLEV's potential to play an important role in individualized medical therapy, including consideration as a first-line treatment. Results from further SONICS analyses are planned for the International Congress of Endocrinology in December 2018 and for publication in a peer-reviewed journal in the first half of 2019.
- The Company will amend the clinical trial protocol for the ongoing Phase 3 LOGICS study to expand the randomized-patient target from 35 to 54 patients. The increase in randomized study participants will bolster the body of evidence for RECORLEV by including a larger patient population from this double-blind, placebo controlled, randomized withdrawal trial. Top-line results from the expanded LOGICS study are expected in the fourth quarter of 2019. The Company plans to conduct a Type C meeting with FDA in the first quarter of 2019 to discuss the path forward for the NDA filing for RECORLEV.

Rare Neuromuscular Franchise:

- Achieved KEVEYIS® (dichlorphenamide) net product sales of \$4.2 million in the third quarter of 2018, a 66 percent increase compared to \$2.5 million in the third quarter of 2017.
- Full-year 2018 KEVEYIS revenue guidance revised to \$16 — \$17 million from \$18 — \$20 million.

Corporate:

- Strongbridge had \$67.4 million of cash and cash equivalents and \$88.3 million in outstanding debt as of September 30, 2018.
- After giving effect to the anticipated net proceeds upon closing of the transactions separately announced today with Novo Nordisk and the anticipated repayment in full of outstanding debt, the Company's pro forma cash and cash equivalents as of September 30, 2018 was approximately \$148 million.

"We are pleased with the transactions announced earlier today with Novo Nordisk. Our financial position will be significantly strengthened, with not only substantially more cash on our balance sheet, but also the full repayment of outstanding debt. Importantly, the agreement affords us the ability to further our rare endocrine commercial presence as we continue to develop RECORLEV for endogenous Cushing's syndrome, while also sustaining our leadership position and focus on organizing the Primary Periodic Paralysis market and driving KEVEYIS uptake," said Matthew Pauls, president and chief executive officer of Strongbridge Biopharma. "Additionally, given the strength of the RECORLEV clinical development program — as evidenced by the continued positive data from our pivotal Phase 3 SONICS study — we are maximizing the potential of the LOGICS study through expanding the number of participants in order to optimize the overall data package that will support the RECORLEV NDA submission in the U.S."

Third Quarter 2018 Financial Results

For the three months ended September 30, 2018, basic net loss attributable to ordinary shareholders on a GAAP basis was \$20.6 million, or \$0.44 per share, compared to a basic net loss attributable to ordinary shareholders of \$35.1 million, or \$0.98 per share, for the same period in

2017. Net loss for the three months ended September 30, 2018 was lower than the same period in 2017 primarily due to a non-cash intangible asset impairment charge of \$20.7 million related to in-process research and development recorded for the veldoreotide program in 2017, an unrealized gain of \$7.1 million on the fair value of warrants recorded in 2018, compared to an unrealized gain of \$2.0 million on the fair value of warrants recorded in the same period of 2017, increased net revenues recorded in 2018 from sales of KEVEYIS and MACRILEN, which was launched in July 2018, as well as a \$3.5 million loss on extinguishment of debt recorded in 2017, offset in part by increased operating expenses associated with the commercialization of KEVEYIS and MACRILEN, higher research and development expenses primarily associated with the continued development of RECORLEV, and higher interest expense.

For the three months ended September 30, 2018, non-GAAP basic net loss attributable to ordinary shareholders was \$22.2 million, or \$0.47 per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of \$13.1 million, or \$0.35 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 and MACRILEN, higher research and development expenses primarily associated with the continued development of RECORLEV, and higher interest expense, offset in part by net revenues recorded from KEVEYIS and MACRILEN product sales.

The Company recorded net revenues from sales of KEVEYIS of \$4.2 million for the three months ended September 30, 2018, compared to net revenues of \$2.5 million for the same period in 2017. As a result of the July 2018 MACRILEN launch, the Company recorded net revenues of \$1.1 million for the three months ended September 30, 2018. No MACRILEN revenue was recognized for the same period of 2017. The Company recorded cost of goods sold of \$1.4 million for the three months ended September 30, 2018, compared to cost of goods sold of \$0.6 million for the same period in 2017.

Selling, general and administrative expenses were \$19.6 million for the three months ended September 30, 2018, compared to \$8.5 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 commercialization of KEVEYIS and MACRILEN.

Research and development expenses were \$7.2 million for the three months ended September 30, 2018, compared to \$4.5 million for the same period in 2017. The increase during the 2018 period was primarily due to expenses related to the RECORLEV LOGICS and OPTICS clinical trials.

Year-to-Date September 2018 Financial Results

For the nine months ended September 30, 2018, basic net loss attributable to ordinary shareholders on a GAAP basis was \$52.2 million, or \$1.14 per share, compared to a basic net loss attributable to ordinary shareholders of \$94.7 million, or \$2.67 per share, for the same period in 2017. Net loss for the nine months ended September 30, 2018 was lower than the same period in 2017 primarily due to a non-cash intangible asset impairment charge of \$20.7 million related to in-process research and development recorded for the veldoreotide program in 2017, an unrealized gain of \$16.4 million on the fair value of warrants recorded in 2018, compared to an unrealized loss of \$28.2 million on the fair value of warrants recorded in the same period of 2017, increased net revenues recorded in 2018

from sales of KEVEYIS and MACRILEN, which was launched in July 2018, as well as a \$3.5 million loss on extinguishment of debt recorded in 2017, compared to a \$0.5 million loss recorded in 2018, offset in part by increased operating expenses associated with the commercialization of KEVEYIS and MACRILEN, higher research and development expenses primarily associated with the continued development of RECORLEV, and higher interest expense.

For the nine months ended September 30, 2018, non-GAAP basic net loss attributable to ordinary shareholders was \$53.2 million, or \$1.16 per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of \$35.6 million, or \$1.00 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 and MACRILEN, higher research and development expenses primarily associated with the continued development of RECORLEV, and higher interest expense, offset in part by net revenues recorded from KEVEYIS and MACRILEN product sales.

The Company recorded net revenues from sales of KEVEYIS of \$12.4 million for the nine months ended September 30, 2018, compared to net revenues of \$4.1 million for the same period in 2017. As a result of the July 2018 MACRILEN launch, the Company recorded net revenues of \$1.1 million for the nine months ended September 30, 2018. No MACRILEN revenue was recognized for the same period of 2017. The Company recorded cost of goods sold of \$2.9 million for the nine months ended September 30, 2018, compared to cost of goods sold of \$1.0 million for the same period in 2017.

Selling, general and administrative expenses were \$47.1 million for the nine months ended September 30, 2018, compared to \$26.1 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 and MACRILEN.

Research and development expenses were \$17.5 million for the nine months ended September 30, 2018, compared to \$12.1 million for the same period in 2017. The increase during the 2018 period was primarily due to expenses related to the RECORLEV LOGICS and OPTICS clinical trials.

Conference Call Details

Strongbridge will host a conference call on Wednesday, October 31 at 8:45 a.m. ET. To access the live call, dial 844-285-7153 (domestic) or 478-219-0180 (international) with conference ID 9775249. 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 9775249.

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 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 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 the FDA at 1-800-FDA-1088. Please see Full Prescribing Information for additional important MACRILEN safety information.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws. The words "anticipate," "estimate," "expect," "intend," "may," "plan," "potential," "project," "target," "will," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All statements, other than statements of historical facts, contained in this press release, are forward-looking statements, including statements related to the potential advantages of RECORLEV, the potential for RECORLEV as a first-line treatment, discussions with regulators regarding the approval process for RECORLEV, the release of additional planned analyses of the SONICS study, Strongbridge's strategy, plans, status and results of SONICS and other 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, and risks related to our ability to repay funds under our

credit facility. 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, 2017 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:

Corporate and Media Relations

Elixir Health Public Relations
Lindsay Rocco
+1 862-596-1304
lrocco@elixirhealthpr.com

Investor Relations

U.S.:
Solebury Trout
Marcy Nanus
+1 646-378-2927
mnanus@soleburytrout.com

Europe:
First House
Geir Arne Drangeid
+47 913 10 458
strongbridgebio@firsthouse.no

USA

900 Northbrook Drive
Suite 200
Trevose, PA 19053
Tel. +1 610-254-9200
Fax. +1 215-355-7389

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

	September 30,		December 31,
	2018		2017
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 67,383	\$	57,510
Total assets	140,849		103,925
Long-term debt, net	79,061		37,794
Total liabilities	147,105		115,839
Total stockholders' deficit	(6,256)		(11,914)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Consolidated Statement of Operations Data:				
Revenues:				
Net product sales	\$ 5,347	\$ 2,533	\$ 13,513	\$ 4,062
Total revenues	<u>5,347</u>	<u>2,533</u>	<u>13,513</u>	<u>4,062</u>
Cost and expenses:				
Cost of sales (excluding amortization of intangible assets)	\$ 1,441	\$ 591	\$ 2,861	\$ 968
Selling, general and administrative	19,564	8,484	47,137	26,068
Research and development	7,198	4,504	17,532	12,113
Amortization of intangible assets	1,876	1,256	5,517	3,767
Impairment of intangible asset	—	20,723	—	20,723
Total cost and expenses	<u>30,079</u>	<u>35,558</u>	<u>73,047</u>	<u>63,639</u>
Operating loss	(24,732)	(33,025)	(59,534)	(59,577)
Other income (expense), net:				
Unrealized gain (loss) on fair value of warrants	7,131	1,953	16,448	(28,194)
Interest expense	(3,387)	(1,364)	(9,550)	(2,838)
Foreign exchange loss	(15)	(11)	(22)	(36)
Loss on extinguishment of debt	—	(3,545)	(500)	(3,545)
Other income, net	445	82	954	107
Total other income (expense), net	<u>4,174</u>	<u>(2,885)</u>	<u>7,330</u>	<u>(34,506)</u>
Loss before income taxes	(20,558)	(35,910)	(52,204)	(94,083)
Income tax benefit (expense)	—	850	(1)	(652)
Net loss	<u>(20,558)</u>	<u>(35,060)</u>	<u>(52,205)</u>	<u>(94,735)</u>
Net loss attributable to ordinary shareholders:				
Basic	\$ (20,558)	\$ (35,060)	\$ (52,205)	\$ (94,735)
Diluted	<u>\$ (27,690)</u>	<u>\$ (35,060)</u>	<u>\$ (68,653)</u>	<u>\$ (94,735)</u>
Net loss per share attributable to ordinary shareholders:				
Basic	\$ (0.44)	\$ (0.98)	\$ (1.14)	\$ (2.67)
Diluted	<u>\$ (0.55)</u>	<u>\$ (0.98)</u>	<u>\$ (1.37)</u>	<u>\$ (2.67)</u>
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:				
Basic	46,978,472	35,716,247	45,916,177	35,463,496
Diluted	<u>50,317,423</u>	<u>35,716,247</u>	<u>49,985,483</u>	<u>35,463,496</u>

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

	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	\$ 0.04
Stock-based compensation - Research & Development (b)	\$ 468	\$ 468	\$ 468	\$ 0.01
Stock-based compensation - Selling, General & Admin. (b)	\$ 1,649	\$ 1,649	\$ 1,649	\$ 0.04
Unrealized gain on fair value of warrants (c)	—	\$ (7,131)	\$ (7,131)	\$ (0.15)
Non-cash interest and debt extinguishment expenses (d)	—	\$ 1,488	\$ 1,488	\$ 0.03
Adjusted	<u>\$ (20,739)</u>	<u>\$ (22,208)</u>	<u>\$ (22,208)</u>	<u>\$ (0.47)</u>
	Three Months Ended September 30, 2017			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	\$ (33,025)	\$ (35,910)	\$ (35,060)	\$ (0.98)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	\$ 1,256	\$ 1,256	\$ 1,256	\$ 0.04
Impairment of intangible asset (a)	\$ 20,723	\$ 20,723	\$ 20,723	\$ 0.58
Stock-based compensation - Research & Development (b)	\$ 324	\$ 324	\$ 324	\$ 0.01
Stock-based compensation - Selling, General & Admin. (b)	\$ 1,007	\$ 1,007	\$ 1,007	\$ 0.03
Unrealized gain on fair value of warrants (c)	—	\$ (1,953)	\$ (1,953)	\$ (0.05)
Non-cash interest expense (d)	—	\$ 1,501	\$ 1,501	\$ 0.04
Non-cash income tax benefit (e)	—	—	\$ (850)	\$ (0.02)
Adjusted	<u>\$ (9,715)</u>	<u>\$ (13,052)</u>	<u>\$ (13,052)</u>	<u>\$ (0.35)</u>

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

	Nine 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	\$ (59,534)	\$ (52,204)	\$ (52,205)	\$ (1.14)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	\$ 5,517	\$ 5,517	\$ 5,517	\$ 0.12
Stock-based compensation - Research & Development (b)	\$ 1,339	\$ 1,339	\$ 1,339	\$ 0.03
Stock-based compensation - Selling, General & Admin. (b)	\$ 4,450	\$ 4,450	\$ 4,450	\$ 0.10
Unrealized gain on fair value of warrants (c)	—	\$ (16,448)	\$ (16,448)	\$ (0.36)
Non-cash interest and debt extinguishment expenses (d)	—	\$ 4,150	\$ 4,150	\$ 0.09
Adjusted	<u>\$ (48,228)</u>	<u>\$ (53,196)</u>	<u>\$ (53,197)</u>	<u>\$ (1.16)</u>

	Nine Months Ended September 30, 2017			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	\$ (59,577)	\$ (94,083)	\$ (94,735)	\$ (2.67)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	\$ 3,767	\$ 3,767	\$ 3,767	\$ 0.11
Impairment of intangible asset (a)	\$ 20,723	\$ 20,723	\$ 20,723	\$ 0.58
Stock-based compensation - Research & Development (b)	\$ 822	\$ 822	\$ 822	\$ 0.02
Stock-based compensation - Selling, General & Admin. (b)	\$ 3,041	\$ 3,041	\$ 3,041	\$ 0.09
Unrealized loss on fair value of warrants (c)	—	\$ 28,194	\$ 28,194	\$ 0.80
Non-cash interest expense (d)	—	\$ 2,213	\$ 2,213	\$ 0.06
Non-cash income tax expense (e)	—	—	\$ 397	\$ 0.01
Adjusted	<u>\$ (31,224)</u>	<u>\$ (35,323)</u>	<u>\$ (35,578)</u>	<u>\$ (1.00)</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 the Company believes 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. The Company believes 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 charge, which is non-cash and related primarily to the effect of changes in the company's stock price at a point in time. The Company believes 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. The Company believes 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. The Company believes such exclusion facilitates investor's ability to more accurately compare our operating results to those of our peer companies.