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 12, 2018**

STRONGBRIDGE BIOPHARMA plc

(Exact name of registrant as specified in its charter)

Ireland	**001-37569**	**98-1275166**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

900 Northbrook Drive **Suite 200** **Trevose, PA**	**19053**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(610)254-9200**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition.

On March 12, 2018, Strongbridge Biopharma plc (the "Company") issued a press release reporting fourth quarter and year-end 2017 financial results and providing a corporate update. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information contained in this Current Report on Form 8-K and Exhibit 99.1 is being furnished to the Commission and shall not be deemed "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Current Report on Form 8-K and Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 7.01 Regulation FD.

The response to Item 2.02 is incorporated herein by reference to this Item 7.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Table
99.1	Press Release issued by Strongbridge Biopharma plc, dated March 12, 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: March 12, 2018

Exhibit 99.1

Strongbridge Biopharma plc Reports Full-Year 2017 Financial Results

~ KEVEYIS® (dichlorphenamide) Fourth Quarter and Full-Year 2017 Revenue of $3.0 Million and $7.0 Million, Respectively ~

~ Full-Year 2018 KEVEYIS Revenue Guidance of $16 to $19 Million ~

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

~ RECORLEV™ (levoketoconazole) Phase 3 Clinical Program Progressing with SONICS Top-line Results Expected in Mid-Year 2018 ~

~ Investor & Analyst Day in New York City Planned for April 5, 2018 to Discuss Clinical Development and Commercial Progress ~

Dublin, Ireland and Trevose, Pa., March 12, 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 financial results for the full year and fourth quarter ended December 31, 2017.

"2017 was a defining year for Strongbridge, marked by rapid transformation and growth as we became a revenue-generating rare disease company. As a result of the early launch uptake of KEVEYIS, the first and only FDA-approved treatment for Primary Periodic Paralysis (PPP), we made the decision to more than double our field-based team in the fourth quarter to meet growing market demand and position us for success in 2018 and beyond. This expanded investment reflects the significant opportunity in the market, the need to raise awareness of this ultra-rare disease and our commitment to patient communities, such as PPP, that may otherwise go ignored," said Matthew Pauls, president and chief executive officer of Strongbridge Biopharma.

"In 2017, we completed enrollment in SONICS, our pivotal Phase 3 study of RECORLEV™ (levoketoconazole) in Cushing's syndrome and look forward to top-line results in mid-2018. We are also excited to launch our second rare disease product, MACRILEN™ (macimorelin), in the middle of the year," Pauls added.

Full-Year 2017 Corporate & Financial Highlights

Early Launch Success with KEVEYIS Demonstrates Significant Market Opportunity:

- Achieved net product sales of $3.0 million during the fourth quarter of 2017, a 20% increase compared to $2.5 million in the third quarter.

- Expanded the Company's rare neuromuscular field-based team from 12 to 21 sales representatives, along with the addition of three regional business directors and three patient access managers.

- Launched the no-cost *Uncovering Periodic Paralysis* genetic testing program at the end of the third quarter.

- Full-year 2018 revenue guidance for KEVEYIS of $16 to $19 million.

RECORLEV Phase 3 Clinical Development Program Continues to Progress

- Completed target enrollment in the Phase 3 SONICS study in the second quarter of 2017. Top-line results from SONICS are anticipated in mid-2018.

- Began activating sites for the Phase 3 LOGICS study in the fourth quarter of 2017, with dosing of the first patients anticipated in the first quarter of 2018 and availability of top-line data expected in the first quarter of 2019.

- Two Data and Safety Monitoring Board (DSMB) reviews were held in 2017. In each case, the DSMB recommended that the Phase 3 SONICS study continue as planned with no protocol changes.

Strongbridge Financial and Marketplace Position Strengthened by a Number of Recent Key Events:

- Acquired the U.S. and Canadian rights to MACRILEN in January 2018. In conjunction, completed a public offering of ordinary shares raising net proceeds of $33.3 million and amended the Company's existing senior credit facility with CRG LP to increase total potential borrowing from $50 million to $100 million.

- Completed a public offering of ordinary shares in October 2017, raising net proceeds of $23.4 million.

- Company added to the Russell 3000®Index in June 2017 and the NASDAQ Biotech Index in December 2017.

Strongbridge will host an Investor and Analyst Day in New York City on Thursday, April 5, 2018 in which management and external opinion leaders will discuss the Company's clinical development progress and commercial priorities for 2018.

Fourth Quarter 2017 Financial Results

For the three months ended December 31, 2017, basic and diluted net loss attributable to ordinary shareholders on a GAAP basis was $18.7 million, or $0.47 per share, compared to a basic net loss attributable to ordinary shareholders of $16.0 million, or $0.71 per share, for the same period in 2016. Net loss for the three months ended December 31, 2017 was higher than the same period in 2016 primarily due to increased operating expenses associated with the commercialization of KEVEYIS, which was launched in April 2017, and an unrealized loss on the fair value of warrants, offset in part by net revenues recorded from KEVEYIS product sales and a non-cash impairment charge recorded in 2016 related to in-process research and development recorded for the veldoreotide program.

For the three months ended December 31, 2017, non-GAAP basic and diluted net loss attributable to ordinary shareholders was $12.3 million, or $0.31 per share, compared to a non-GAAP basic net

loss attributable to ordinary shareholders of $6.0 million, or $0.27 per share, for the same period in 2016. The increase in non-GAAP net loss was primarily due to increased operating expenses associated with the commercialization of KEVEYIS, which was launched in April 2017, offset in part by net revenues recorded from KEVEYIS product sales.

Non-GAAP net loss for the three months ended December 31, 2017 excludes $1.3 million of non-cash intangible asset amortization, $1.3 million of non-cash stock-based compensation expense, $0.6 million of non-cash interest expense, $2.0 million of non-cash unrealized losses on fair value of warrants, and a $1.2 million non-cash income tax expense. Non-GAAP net loss for the three months ended December 31, 2016 excludes a $10.6 million non-cash intangible asset impairment charge, $1.1 million of non-cash stock-based compensation expense and a $1.7 million non-cash income tax benefit.

As a result of the April 2017 KEVEYIS launch, the Company recorded net revenues of $3.0 million and cost of goods sold of $0.5 million for the three months ended December 31, 2017. No revenue or cost of goods sold was recognized for the same period of 2016.

Research and development expenses were $5.1 million for the three months ended December 31, 2017, compared to $4.1 million for the same period in the prior year. The increase during the 2017 period was primarily due to the RECORLEV LOGICS clinical trial.

Selling, general and administrative expenses were $10.2 million for the three months ended December 31, 2017, compared to $3.6 million for the same period in the prior year. The increase during the 2017 period was primarily due to costs incurred to establish the commercial and corporate infrastructure necessary to support the launch and ongoing commercialization of KEVEYIS.

Full-Year 2017 Financial Results

For the twelve months ended December 31, 2017, basic and diluted net loss attributable to ordinary shareholders on a GAAP basis was $113.5 million, or $3.11 per share, compared to a basic net loss attributable to ordinary shareholders of $48.6 million, or $2.26 per share, for the same period in 2016. The net loss for the twelve months ended December 31, 2017 included $54.4 million in charges consisting of a non-cash unrealized loss of $30.2 million on the fair value of the Company's warrant liability, a non-cash impairment charge of $20.7 million related to in-process research and development recorded for the veldoreotide program, and a loss of $3.5 million on the early extinguishment of debt that was repaid in July 2017 in connection with establishing a new credit facility. The net loss for the twelve months ended December 31, 2016 included non-cash intangible asset impairment charges of $15.8 million. Net loss for the twelve months ended December 31, 2017 was also higher than the same period in 2016 due to increased operating expenses associated with the commercialization of KEVEYIS, which was launched in April 2017, offset in part by net revenues recorded from KEVEYIS product sales.

For the twelve months ended December 31, 2017, non-GAAP basic and diluted net loss attributable to ordinary shareholders was $47.9 million, or $1.31 per share, compared to a non-GAAP basic net loss attributable to ordinary shareholders of $31.4 million, or $1.46 per share, for the same period

in 2016. The increase in non-GAAP net loss was primarily due to increased operating expenses associated with the commercialization of KEVEYIS, which was launched in April 2017, offset in part by net revenues recorded from KEVEYIS product sales and lower research and development expenses.

Non-GAAP net loss for the twelve months ended December 31, 2017 excludes $5.0 million of non-cash intangible asset amortization, a $20.7 million non-cash intangible asset impairment charge, $5.2 million of non-cash stock-based compensation expense, $30.2 million of non-cash unrealized losses on fair value of warrants, $2.8 million of non-cash interest and debt extinguishment expense, and $1.6 million of non-cash income tax expense. Non-GAAP net loss for the twelve months ended December 31, 2016 excludes $15.8 million of non-cash intangible asset impairment charges, $4.6 million of non-cash stock-based compensation expense, $0.6 million of non-cash unrealized gains on fair value of warrants, and a $2.6 million non-cash income tax benefit.

As a result of the April 2017 KEVEYIS launch, the Company recorded net revenues of $7.0 million and cost of goods sold of $1.5 million for the twelve months ended December 31, 2017. No revenue or cost of goods sold was recognized for the same period of 2016.

Research and development expenses were $17.3 million for the twelve months ended December 31, 2017, compared to $20.0 million for the same period in the prior year. The decrease during the 2017 period was primarily due to a planned decrease in development activity for veldoreotide, and decreased development spend related to programs discontinued during 2016.

Selling, general and administrative expenses were $36.3 million for the twelve months ended December 31, 2017, compared to $14.9 million for the same period in the prior year. The increase during the 2017 period was primarily due to costs incurred to establish the necessary commercial and corporate infrastructure to support the launch and ongoing commercialization of KEVEYIS.

Strongbridge had $57.5 million of cash and cash equivalents and $40.0 million in outstanding debt as of December 31, 2017, compared to $66.8 million of cash and cash equivalents and $20.0 million in outstanding debt as of December 31, 2016. After adjusting for the net proceeds of the debt and equity financings completed in the first quarter of 2018 and the costs to acquire MACRILEN in January 2018, Strongbridge had pro forma cash and cash equivalents of $110.6 million and pro forma outstanding debt of $85.0 million as of December 31, 2017. The Company believes the combination of existing cash resources and anticipated additional borrowings available under its credit facility will provide sufficient cash resources under its current operating plan, which includes the commercial launch of MACRILEN and the potential U.S. regulatory approval and launch of RECORLEV, to achieve consistent positive cash flows from operating activities.

Conference Call Information

Strongbridge will host a conference call on Monday, March 12 at 8:30 a.m. ET. To access the live call, dial 844-285-7153 (domestic) or 478-219-0180 (international) with conference ID 6497969. 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 6497969.

About Strongbridge Biopharma

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

About KEVEYIS

KEVEYIS® (dichlorphenamide) is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants. In clinical studies, the most common side effects of KEVEYIS were a numbness or tingling, difficulty thinking and paying attention, changes in taste, and confusion. These are not all of the possible side effects that you may experience with KEVEYIS. Talk to your doctor if you have any symptoms that bother you or do not go away. You are encouraged to report side effects to Strongbridge Biopharma at 1-855-324-8912, or to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch/. For additional KEVEYIS important safety information and the full prescribing information visit www.keveyis.com.

About MACRILEN

MACRILEN™ (macimorelin) is a prescription oral solution that is used to test for adult growth hormone deficiency (AGHD). In clinical studies, the most common side effects of MACRILEN were changed sense of taste, dizziness, headache, fatigue, nausea, hunger, diarrhea, upper respiratory tract infection, feeling hot, excessive sweating, sore nose and throat, and decreased heart rate. These are not all of the possible side effects that you may experience with MACRILEN. Call your healthcare provider for medical advice about side effects. You are encouraged to report side effects to Strongbridge at 1-855-324-8912, or to the FDA at 1-800-FDA-1088 or visit www.strongbridgebio.com/products/macrilen/. Please see Full Prescribing Information for additional important MACRILEN safety information.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, are forward-looking statements. These statements relate to future events and involve known and unknown risks, including, without limitation, uncertainties regarding Strongbridge's strategy, plans, future financial position, anticipated investments, costs and results, outcomes of

product development efforts, status and results of clinical trials, and objectives of management for future operations. The words "anticipate," "estimate," "expect," "intend," "may," "plan," "potential," "project," "target," "will," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on current expectations, estimates, forecasts and projections and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors. The forward-looking statements contained in this press release are made as of the date of this press release, and Strongbridge Biopharma does not assume any obligation to update any forward-looking statements except as required by applicable law.

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

	December 31, 2017	December 31, 2016
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 57,510	$ 66,837
Total assets	103,925	137,531
Long-term debt, net	37,794	18,434
Total liabilities	115,839	70,559
Total stockholders' (deficit) equity	(11,914)	66,972

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Consolidated Statement of Operations Data:				
Revenues:				
Net product sales	$ 2,984	$ —	$ 7,046	$ —
Total revenues	2,984	—	7,046	—
Cost and expenses:				
Cost of sales (excluding amortization of intangible asset)	$ 515	$ —	$ 1,483	$ —
Selling, general and administrative	10,224	3,615	36,292	14,875
Research and development	5,155	4,141	17,268	20,023
Amortization of intangible asset	1,255	—	5,022	—
Impairment of intangible assets	—	10,600	20,723	15,828
Total cost and expenses	17,149	18,356	80,788	50,726
Operating loss	(14,165)	(18,356)	(73,742)	(50,726)
Other income (expense), net:				
Unrealized gain (loss) on fair value of warrants	(2,024)	—	(30,218)	638
Interest expense	(1,475)	(20)	(4,313)	(20)
Foreign exchange gain (loss)	(5)	638	(41)	(69)
Loss on early extinguishment of debt	—	(5)	(3,545)	—
Other income (expense), net	41	30	147	(1,180)
Total other income (expense), net	(3,463)	643	(37,970)	(631)
Loss before income taxes	(17,628)	(17,713)	(111,712)	(51,357)
Income tax (expense) benefit	(1,119)	1,712	(1,771)	2,638
Net loss	(18,747)	(16,001)	(113,483)	(48,719)
Net loss attributable to non-controlling interest	—	—	—	122
Net loss attributable to Strongbridge Biopharma	$ (18,747)	$ (16,001)	$ (113,483)	$ (48,597)
Net loss attributable to ordinary shareholders:				
Basic	$ (18,747)	$ (16,001)	$ (113,483)	$ (48,597)
Diluted	$ (18,747)	$ (16,639)	$ (113,483)	$ (49,236)
Net loss per share attributable to ordinary shareholders:				
Basic	$ (0.47)	$ (0.71)	$ (3.11)	$ (2.26)
Diluted	$ (0.47)	$ (0.73)	$ (3.11)	$ (2.27)
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:				
Basic	39,753,550	22,577,766	36,544,825	21,550,353
Diluted	39,753,550	22,682,977	36,544,825	21,655,564

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

	Three Months Ended December 31, 2017			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (14,165)	$ (17,628)	$ (18,747)	$ (0.47)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 1,255	$ 1,255	$ 1,255	$ 0.03
Stock-based compensation - Research & Development (b)	$ 318	$ 318	$ 318	$ 0.01
Stock-based compensation - Selling, General & Admin. (b)	$ 986	$ 986	$ 986	$ 0.02
Unrealized loss on fair value of warrants (c)	—	$ 2,024	$ 2,024	$ 0.05
Non-cash interest and debt extinguishment expenses (d)	—	$ 599	$ 599	$ 0.02
Non-cash income tax expense (e)	—	—	$ 1,247	$ 0.03
Adjusted	$ (11,606)	$ (12,446)	$ (12,318)	$ (0.31)

	Three Months Ended December 31, 2016			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (18,356)	$ (17,713)	$ (16,001)	$ (0.71)
Non-GAAP Adjustments:				
Impairment of intangible asset (a)	$ 10,600	$ 10,600	$ 10,600	$ 0.47
Stock-based compensation - Research & Development (b)	$ 200	$ 200	$ 200	$ 0.01
Stock-based compensation - Selling, General & Admin. (b)	$ 886	$ 886	$ 886	$ 0.04
Non-cash income tax benefit (e)	—	—	$ (1,712)	$ (0.08)
Adjusted	$ (6,670)	$ (6,027)	$ (6,027)	$ (0.27)

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

	Twelve Months Ended December 31, 2017			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (73,742)	$ (111,712)	$ (113,483)	$ (3.11)
Non-GAAP Adjustments:				
Amortization of intangible asset (a)	$ 5,022	$ 5,022	$ 5,022	$ 0.14
Impairment of intangible asset (a)	$ 20,723	$ 20,723	$ 20,723	$ 0.57
Stock-based compensation - Research & Development (b)	$ 1,140	$ 1,140	$ 1,140	$ 0.03
Stock-based compensation - Selling, General & Admin. (b)	$ 4,027	$ 4,027	$ 4,027	$ 0.11
Unrealized loss on fair value of warrants (c)	—	$ 30,218	$ 30,218	$ 0.83
Non-cash interest expense and loss on early extinguishment of debt (d)	—	$ 2,812	$ 2,812	$ 0.08
Non-cash income tax expense (e)	—	—	$ 1,644	$ 0.04
Adjusted	$ (42,830)	$ (47,770)	$ (47,897)	$ (1.31)

	Twelve Months Ended December 31, 2016			
	Operating loss	Loss before income taxes	Net loss attributable to ordinary shareholders	Net loss per share attributable to ordinary shareholders
GAAP	$ (50,726)	$ (51,357)	$ (48,597)	$ (2.26)
Non-GAAP Adjustments:				
Impairment of intangible asset (a)	$ 15,828	$ 15,828	$ 15,828	$ 0.73
Stock-based compensation - Research & Development (b)	$ 601	$ 601	$ 601	$ 0.03
Stock-based compensation - Selling, General & Admin. (b)	$ 4,006	$ 4,006	$ 4,006	$ 0.19
Unrealized gain on fair value of warrants (c)		$ (638)	$ (638)	$ (0.03)
Non-cash income tax benefit (e)	—	—	$ (2,638)	$ (0.12)
Adjusted	$ (30,291)	$ (31,560)	$ (31,438)	$ (1.46)

(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 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. We believe such exclusion facilitates investors' ability to more accurately compare our operating results to those of our peer companies.

(d) The effects of non-cash interest and debt extinguishment charges are excluded. We believe such exclusion facilitates an understanding of the effects of the debt service obligations on the Company's liquidity and comparisons to peer group companies, and is reflective of how management internally manages the business.

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