



Assertio Therapeutics Announces First-Quarter 2019 Financial Results

May 8, 2019

- Reports Neurology Franchise Net Sales of \$26.3 million --
- Commercialization Agreement Revenues of \$30.9 million --
- Raises 2019 Earnings Guidance Range and Confirms Neurology Franchise Net Sales Guidance --
- Significant Debt Reduction --

LAKE FOREST, Ill., May 08, 2019 (GLOBE NEWSWIRE) -- Assertio Therapeutics, Inc. (NASDAQ: ASRT) today reported financial results for the quarter ended March 31, 2019, and provided an update on its business performance and strategic initiatives.

First-Quarter Financial Highlights: (unaudited)

<i>(in millions, except earnings per share)</i>	First-Quarter 2019	
	GAAP	Non-GAAP ⁽¹⁾
Total Revenues	\$57.9	\$59.7
Net Income/(Loss)	\$(14.3)	\$17.6
Earnings/(Loss) Per Share	\$(0.22)	\$0.23
Adjusted EBITDA	-	\$36.4

(1) All non-GAAP measures included in this earnings release are reconciled to the corresponding GAAP measures in the schedules attached.

"We're off to a strong start to the year," said Arthur Higgins, President and CEO of Assertio. "We continue to drive better performance from our business as we remain focused on operating efficiencies and improving momentum in our Neurology Franchise net sales. As a result of our strong start, today we are raising our adjusted EBITDA guidance range."

Business Highlights:

- **Favorable NUCYNTA[®] Patent Ruling:** On March 28, 2019, the Company announced that the United States Court of Appeals for the Federal Circuit ruled in favor of Assertio with respect to the Company's patent litigation against three filers of Abbreviated New Drug Applications (ANDAs) for the NUCYNTA franchise. The Federal Circuit's ruling affirms the decision of the United States District Court (D.N.J.), which found U.S. patent No. 7,994,364 (the '364 Patent) to be valid and infringed by the defendants. The '364 Patent covers the entire NUCYNTA franchise until December 2025.* The NUCYNTA franchise is commercialized by Collegium Pharmaceutical, Inc. (Collegium). The Company receives royalties from Collegium based on net sales of the franchise.

*Patent expiration dates reflect the addition of six months of pediatric patent term extension Assertio anticipates securing from the United States Food and Drug Administration.

- **FDA Accepted Filing of 505(b)(2) NDA Filing for Cosyntropin:** On February 19, 2019, the Company received notification of acceptance for filing from the U.S. Food and Drug Administration for its 505(b)(2) New Drug Application for its injectable formulation of long-acting cosyntropin (synthetic adrenocorticotrophic hormone, or ACTH). The Company, together with its partner, West Therapeutic Development, LLC, seeks approval for the use of long-acting cosyntropin as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.
- **Amended Senior Secured Credit Facility:** On January 8, 2019, the Company amended its Senior Secured Credit Facility, replacing the previous fixed adjusted EBITDA covenant with a trailing 12-month debt-to adjusted EBITDA ratio that declines over time as we make scheduled principal payments. The amendment gives the Company greater flexibility to continue to pay down debt and invest in the core business, including potential business development transactions.
- **Debt Reduction and Cash Position:** On January 15 and April 15, 2019, the Company made scheduled principal repayments of \$25.0 million and \$55.0 million, respectively, reducing the Company's secured debt to \$202.5 million as of today's date. On January 30, 2019, the Company received \$32.0 million, the balance of a \$62.0 million patent litigation settlement announced in the third quarter of 2018. As of March 31, 2019, the Company had cash and cash equivalents of \$109.7 million.

Revenue Summary: *(in thousands, unaudited)*

Three Months Ended March 31,

	2019	2018
Product sales, net:		
Gralise	\$ 13,278	\$ 14,827
CAMBIA	8,808	6,416
Zipsor	4,231	4,746
Total neurology product sales, net	26,317	25,989
Nucynta products	62	18,145
Lazanda	71	220
Total product sales, net	26,450	44,354
Commercialization agreement:		
Commercialization rights and facilitation services, net	30,856	28,095
Revenue from transfer of inventory	—	55,705
Royalties and milestone revenue	623	250
Total revenues	\$ 57,929	\$ 128,404

2019 Financial Guidance:

The Company is raising its previous 2019 earnings guidance range and confirming its previous Neurology Franchise net sales guidance:

	Prior 2019 Guidance	Current 2019 Guidance
Neurology Franchise Net Sales	Low to Mid-Single Digit Growth	Low to Mid-Single Digit Growth
GAAP Net Loss⁽¹⁾⁽²⁾	(\$71) to (\$61) million	(\$68) to (\$58) million
Non-GAAP Adjusted EBITDA⁽¹⁾⁽²⁾	\$115 to \$125 million	\$118 to \$128 million

(1) Guidance includes \$2.8 million of non-cash Collegium warrant related income.

(2) Guidance excludes any future mark-to-market adjustments, which cannot be estimated.

Conference Call and Webcast:

Assertio will host a conference call today, Wednesday, May 8, 2019 beginning at 4:30 p.m. ET to discuss its results. This event can be accessed in three ways:

- From the Assertio website: <http://investor.assertiotx.com>. Please access the website 15 minutes prior to the start of the call to download and install any necessary audio software.
- By telephone: Participants can access the call by dialing (877) 550-3745 (United States) or (281) 973-6277 (International) referencing Conference ID 5347358.
- By replay: A replay of the webcast will be located under the Investor Relations section of Assertio's website approximately two hours after the conclusion of the live call.

About Assertio Therapeutics, Inc.

Assertio Therapeutics is committed to providing responsible solutions to advance patient care in the Company's core areas of neurology, orphan and specialty medicines. Assertio currently markets three FDA-approved products and continues to identify, license and develop new products that offer enhanced options for patients that may be under served by existing therapies. To learn more about Assertio, visit www.assertiotx.com.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This news release contains forward-looking statements. These statements involve inherent risks and uncertainties that could cause actual results to differ materially from those projected or anticipated, including risks related to regulatory approval and clinical development of long-acting cosyntropin, expectations regarding royalties to be received based on sales of NUCYNTA and NUCYNTA ER, expectations regarding potential business opportunities and other risks outlined in the Company's public filings with the Securities and Exchange Commission, including the Company's most recent annual report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. All information provided in this news release speaks as of the date hereof. Except as otherwise required by law, the Company undertakes no obligation to update or revise its forward-looking statements.

Investor and Media Contact:

John B. Thomas
Senior Vice President, Investor Relations and Corporate Communications
jthomas@assertiotx.com

Non-GAAP Financial Measures

To supplement the Company's financial results presented on a U.S. generally accepted accounting principles (GAAP) basis, the Company has included information about non-GAAP revenue, non-GAAP adjusted earnings, non-GAAP adjusted diluted earnings per share, non-GAAP adjusted EBITDA and other non-GAAP financial measures as useful operating metrics. The Company believes that the presentation of these non-GAAP financial measures, when viewed with results under GAAP and the accompanying reconciliation, provides supplementary information to analysts, investors, lenders, and the Company's management in assessing the Company's performance and results from period to period. The Company uses these non-GAAP measures internally to understand, manage and evaluate the Company's performance, and in part, in the determination of bonuses for executive officers and employees. These non-GAAP financial measures should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP. Non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, non-GAAP measures used by other companies.

Specified Items

Non-GAAP measures presented within this release exclude specified items. The Company considers specified items to be significant income/expense items not indicative of current operations, including the related tax effect. Specified items include non-cash adjustment to Collegium agreement revenue and cost of sales, release of NUCYNTA and Lazanda sales reserves for products the Company is no longer selling, interest income, interest expense, amortization, acquired in-process research and development and non-cash adjustments related to product acquisitions, stock-based compensation expense, non-cash interest expense related to debt, depreciation, taxes, transaction costs, CEO transition, restructuring costs, adjustments to net sales related to reserves recorded prior to the Company's exit of opioid commercialization activities, legal costs and expenses incurred in connection with opioid-related litigation, investigations and regulations pertaining to the company's historical commercialization of opioid products, certain types of legal settlements, disputes, fees and costs, and to adjust for the tax effect related to each of the non-GAAP adjustments.

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
Revenues:		
Product sales, net	\$ 26,450	\$ 44,354
Commercialization agreement, net	30,856	83,800
Royalties and milestones	623	250
Total revenues	57,929	128,404
Costs and expenses:		
Cost of sales (excluding amortization of intangible assets)	2,575	12,044
Research and development expenses	1,793	1,528
Selling, general and administrative expenses	25,045	29,033
Amortization of intangible assets	25,444	25,444
Restructuring charges	—	9,017
Total costs and expenses	54,857	77,066
Income from operations	3,072	51,338
Interest income and other (expense) income, net	(609)) 229
Interest (expense)	(16,554)) (18,068)
Income taxes (expense) benefit	(210)) 325
Net (loss) income	\$ (14,301)) \$ 33,824
Basic net (loss) income per share	\$ (0.22)) \$ 0.53
Diluted net (loss) income per share	\$ (0.22)) \$ 0.48
Shares used in computing basic net (loss) income per share	64,239	63,503
Shares used in computing diluted net (loss) income per share	64,239	81,877

CONSOLIDATED CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 109,691	\$ 110,949
Accounts receivable, net	43,488	37,211
Inventories, net	3,077	3,396
Property and equipment, net	16,625	13,064
Intangible assets, net	666,655	692,099
Investments	10,362	11,784
Prepaid and other assets	33,566	64,363
Total assets	\$ 883,464	\$ 932,866
Accounts payable	\$ 5,421	\$ 6,138
Interest payable	8,794	11,645
Accrued liabilities	19,976	31,361
Accrued rebates, returns and discounts	71,655	75,759
Senior notes	251,418	278,309
Convertible notes	292,604	287,798
Contingent consideration liability	1,066	1,038
Other liabilities	23,985	20,483
Shareholders' equity	208,545	220,335

Total liabilities and shareholders' equity

\$ 883,464

\$ 932,866

RECONCILIATION OF GAAP NET INCOME (LOSS) TO NON-GAAP ADJUSTED EBITDA
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
GAAP net (loss)/income	\$ (14,301) \$ 33,824
Commercialization agreement revenues ⁽¹⁾	1,930	(52,486)
Commercialization agreement cost of sales ⁽²⁾	—	6,200
Nucynta sales reserve ⁽³⁾	—	(10,711)
Nucynta and Lazanda revenue reserves ⁽⁴⁾	(133) —
Expenses for opioid-related litigation, investigations and regulations ⁽⁵⁾	2,500	1,076
Intangible amortization related to product acquisitions	25,444	25,444
Contingent consideration related to product acquisitions	—	(202)
Stock-based compensation	2,702	1,976
Interest and other income	(501) (94)
Interest expense	16,554	18,015
Depreciation	337	1,475
Income taxes (expense) benefit	210	(325)
Restructuring and related costs ⁽⁶⁾	—	8,330
Other costs	—	362
Change in fair value of warrants	\$ 1,629	\$ —
Non-GAAP adjusted EBITDA	\$ 36,371	\$ 32,884

(1) For the period from January 8, 2018 through November 8, 2018, the adjustment relates to the non-cash value assigned to inventory transferred to Collegium. As of the date of the amendment, on November 8, 2018, the Company ceased recognition of fixed revenues and began the recognition of variable revenues when they become due beginning in January 2019. The adjustment for the three months ended March 31, 2019 relates to non-cash expense for third-party royalties, which are expected to have no net impact for the full year period, as well as the amortization of the contract asset.

(2) Represents the cash received for inventory transferred to Collegium at the commencement of the Commercialization Agreement.

(3) Represents a \$12.5 million benefit related to the release of sales reserves for which the Company is no longer financially responsible, net of \$1.8 million in royalties payable to a third party during the three months ended March 31, 2018.

(4) Removal of the impact of revenue adjustment estimates related to products that we are no longer commercializing.

(5) Legal costs/expenses related to opioid-related litigation, investigations and regulations pertaining to the Company's historical commercialization of opioid products.

(6) Restructuring and other costs represents non-recurring costs associated with the Company's restructuring, reincorporation, headquarters relocation and CEO transition.

RECONCILIATION OF GAAP NET INCOME/(LOSS) TO NON-GAAP ADJUSTED EARNINGS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
GAAP net (loss)/income	\$ (14,301) \$ 33,824
Commercialization agreement revenues ⁽¹⁾	1,930	(52,486)
Commercialization agreement cost of sales ⁽²⁾	—	6,200
Nucynta sales reserve ⁽³⁾	—	(10,711)
Nucynta and Lazanda revenue reserves ⁽⁴⁾	(133) —
Expenses for opioid-related litigation, investigations and regulations ⁽⁵⁾	2,500	1,076
Intangible amortization related to product acquisitions	25,444	25,444
Contingent consideration related to product acquisitions	—	(202)
Stock-based compensation	2,702	1,976
Restructuring and related costs ⁽⁶⁾	—	8,330
Non-cash interest expense on debt	6,164	5,418
Other income (expenses)	(332) —
Change in fair value of warrants	1,629	—

Third party royalties	—	—	—	—	—	—	—	—	—	—
Nucynta sales reserve	—	—	—	—	—	—	—	—	—	—
Non-cash interest expense on debt	—	—	—	—	—	—	—	6,164	—	—
Nucynta and Lazanda revenue reserves	—	(133)	—	—	—	—	—	—	—	—
Expenses for opioid-related litigation, investigations and regulations	—	—	—	—	—	(2,500)	—	—	—	—
Intangible amortization related to product acquisitions	—	—	—	—	—	—	(25,444)	—	—	—
Contingent consideration related to product acquisitions	—	—	—	—	—	—	—	—	—	—
Stock based compensation	—	—	—	(273)	(2,429)	—	—	—	—	—
Restructuring and other costs	—	—	—	—	—	—	—	—	—	—
Change in fair value of warrants	—	—	—	—	—	—	—	—	1,629	—
Other income (expense)	—	—	—	—	—	—	—	—	(332)	—
Income tax effect of non-GAAP adjustments	—	—	—	—	—	—	—	—	—	(8,039)
Non-GAAP adjusted	\$ 32,786	\$ 26,317	\$ 623	\$ 2,575	\$ 1,520	\$ 20,116	\$ —	\$ (10,390)	\$ 688	\$ (8,249)

RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
For the three months ended March 31, 2018
(in thousands)
(unaudited)

	Commercialization agreement revenues	Product Sales	Cost of sales	Research and development expense	Selling, general and administrative expense	Restructuring Charges	Amortization of intangible assets	Interest expense	Benefits from (provision for) income taxes
GAAP as reported	\$ 83,800	\$ 44,354	\$ 12,044	\$ 1,528	\$ 29,033	\$ 9,022	\$ 25,444	\$ (18,068)	\$ 325
Non-cash adjustment to commercial agreement revenues and cost of sales ⁽¹⁾	(52,486)	—	(6,200)	—	—	—	—	—	—
Release of NUCYNTA sales reserves ⁽²⁾	—	(12,455)	(1,744)	—	—	—	—	—	—
Expenses for opioid-related litigation, investigations and regulations	—	—	—	—	(1,076)	—	—	—	—
Non-cash interest expense on debt	—	—	—	—	—	—	—	5,418	—

Intangible amortization related to product acquisitions	—	—	—	—	—	—	(25,444)	—	—
Contingent consideration related to product acquisitions	—	—	—	—	242	—	—	—	40	—
Stock based compensation	—	—	(14)	(53)	(1,909)	—	—
Restructuring and other costs ⁽³⁾	—	—	—	—	691	(9,022)	—	—	—
Income tax effect of non-GAAP adjustments	—	—	—	—	—	—	—	—	—	3,616
Non-GAAP adjusted	\$ 31,314	\$ 31,899	\$ 4,086	\$ 1,475	\$ 26,981	\$ —	\$ —	\$ —	\$ (12,610)	\$ 3,941

(1) Adjustment for the non-cash value assigned to inventory transferred to Collegium.

(2) \$12.5 million benefit from the release of sales reserves for which the Company is no longer financially responsible, net of \$1.7 million in royalties payable to Grunenthal.

(3) Restructuring and other costs represents non-recurring costs associated with the Company's restructuring, headquarters relocation and CEO transition.

RECONCILIATION OF GAAP NET INCOME (LOSS) TO NON-GAAP ADJUSTED EBITDA
ROLLING TWELVE MONTHS
(unaudited)

The below reconciliation is presented to disclose the calculation of Adjusted EBITDA (as defined in our Senior Notes) on a rolling 12 month basis to support covenant compliance for our Senior Notes.

	Twelve Month Period Ended March 31, 2019 (unaudited)
GAAP net (loss)/income	\$ (11,217)
Commercialization agreement revenues (1)	29,252
Nucynta and Lazanda revenue reserves (2)	(1,695)
Expenses for opioid-related litigation, investigations and regulations (3)	9,321
Intangible amortization related to product acquisitions	101,774
Contingent consideration related to product acquisitions	(313)
Stock-based compensation	11,165
Purdue Litigation	(62,000)
Interest and other income	(1,604)
Interest expense	67,420
Depreciation	793
Income taxes (expense) benefit	1,602
Restructuring and related costs (4)	12,934
Other costs	(239)
Fair value for warrants	1,629
Adjusted EBITDA	\$ 158,822

(1) For the period from January 8, 2018 through November 8, 2018, the adjustment relates to the non-cash value assigned to inventory transferred to Collegium. As of the date of the amendment, on November 8, 2018, the Company ceased recognition of fixed revenues and began the recognition of variable revenues when they become due beginning in January 2019. The adjustment for the three months ended March 31, 2019 relates to non-cash expense for third-party royalties, which are expected to have no net impact for the full year period, as well as the amortization of the contract asset.

(2) Removal of the impact of revenue adjustment estimates related to products that we are no longer commercializing.

(3) Legal costs/expenses related to opioid-related litigation, investigations and regulations pertaining to the Company's historical commercialization of opioid products.

(4) Restructuring and other costs represents non-recurring costs associated with the Company's restructuring, reincorporation, headquarters relocation and CEO transition.

FIRST-QUARTER RECONCILIATION OF GAAP to NON-GAAP REVENUES
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2019	2018 ⁽¹⁾
Total revenues (GAAP basis)	\$ 57.9	\$ 128.4
Non-cash adjustment to commercialization agreement revenues ⁽²⁾	1.8	(52.5)
Release of NUCYNTA sales reserves ⁽³⁾	—	(12.5)
Total revenues (non-GAAP basis)	\$ 59.7	\$ 63.5

(1) First quarter 2018 total GAAP revenues include one-time items described in our quarterly report on Form 10-Q for the fiscal period ended March 31, 2018.

(2) The adjustment for the three months ended March 31, 2019 relates to non-cash adjustments for third-party royalties, which were an expense in Q1 2019 but are expected to have no net impact for the full year period, the amortization of the contract asset, and the impact of revenue adjustment estimates related to products that we are no longer commercializing. For the three months ended March 31, 2018 the adjustment relates to the non-cash value assigned to inventory transferred to Collegium.

(3) \$12.5 million benefit from the release of sales reserves for which the Company is no longer financially responsible.

FULL-YEAR 2019 NON-GAAP GUIDANCE RECONCILIATION
(in millions)
(unaudited)

	Earnings ⁽¹⁾	
	Low End	High End
GAAP	\$ (68)	\$ (58)
Specified Items⁽²⁾	\$ 186	\$ 186
Non-GAAP	\$ 118	\$ 128

(1) GAAP net income guidance refers to GAAP net income and non-GAAP earnings guidance refers to non-GAAP adjusted EBITDA.

(2) For purposes of this forward-looking reconciliation, a description of the categories of specified items included in this reconciliation are detailed in the tables above.



Source: Assertio Therapeutics, Inc.