
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 8, 2019**

NEOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-37508
(Commission File No.)

27-0395455
(IRS Employer Identification No.)

2940 N. Highway 360
Grand Prairie, TX 75050

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(972) 408-1300**

Not applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common stock, par value \$0.001 per share	NEOS	The Nasdaq Stock Market LLC

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.

The information under this caption and contained in the press release attached hereto as Exhibit 99.1 is furnished by Neos Therapeutics, Inc. (the "Company") in accordance with Securities Exchange Commission Release No. 33-8216. This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date of this Current Report, except as shall be expressly set forth by specific reference in such a filing.

On November 8, 2019, the Company issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Number</u>	<u>Description</u>
99.1	Press Release dated November 8, 2019

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press Release dated November 8, 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.

NEOS THERAPEUTICS, INC.

Date: November 8, 2019

By: /s/ Richard Eisenstadt
Richard Eisenstadt
Chief Financial Officer

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Exhibit 99.1

Neos Therapeutics Reports Third Quarter 2019 Financial Results

— Company to host conference call today at 8:30am EDT —

DALLAS and FORT WORTH, Texas, November 8, 2019 — Neos Therapeutics, Inc. (Nasdaq: NEOS), a commercial-stage pharmaceutical company utilizing its novel microparticle delivery technology to develop and manufacture central nervous system-focused products, today reported financial results for the third quarter ended September 30, 2019 and provided a business update.

“During the third quarter of 2019, we reported 40 percent year-over-year revenue growth, which, combined with our continued improvement in quarterly operating net loss, highlights the strong progress we have made toward our goal of achieving profitability,” said Jerry McLaughlin, President and Chief Executive Officer. “In addition, we continued to increase the number of pharmacies included in our Neos RxConnect patient assistance program, and believe the further expansion of this network will be an important future growth driver for our business. We are also very excited about the progress we have made with our lead pipeline candidate, NT0502, which we expect to enter Phase 1 clinical trials shortly. There is a large unmet need for new treatments for sialorrhea, and we believe that we can uniquely meet this need with a novel mechanism that leverages our microparticle technology. We believe NT0502 has the potential to become the standard of treatment for sialorrhea and truly improve the lives of patients and their caregivers.”

ADHD Commercial Franchise

- **Growth in Net Revenue Per Pack Reflects Successful Shift to More Profitable Business Channels and Market Segments:** Neos reported growth in net product sales and net revenue per pack for its two core commercial attention deficit hyperactivity disorder (ADHD) products, Adzenys XR-ODT® and Cotempla XR-ODT®, for the three months ended September 30, 2019 compared to the same period in 2018.

	Net Revenue per Pack		
	Q3 2019	Q3 2018	% Change
Adzenys XR-ODT	\$ 122	\$ 108	13 %
Cotempla XR-ODT	\$ 128	\$ 108	19 %

- **Executing on Back-to-School Commercial Strategy and Expanding Availability of Neos RxConnect Network Pharmacies:** During the third quarter of 2019, the Company actively deployed new marketing campaigns for its two core products and substantially expanded the number of participating pharmacies in the Neos RxConnect network. With the pending addition of a large regional grocery store chain, the Company expects that there will be approximately 460 pharmacies in the network at the end of November 2019, representing more than a 200% increase since the end of the third quarter of 2019.
- **Prescriptions for ADHD Products:** In the third quarter of 2019, as reported by IQVIA, aggregate prescriptions for Adzenys XR-ODT and Cotempla XR-ODT decreased by 6 percent compared to the third quarter of 2018, consistent with the change in commercial strategy the Company unveiled in late 2018. Specifically, Adzenys XR-ODT and Cotempla XR-ODT prescriptions totaled 52,321 and 36,174, respectively, in the third quarter of 2019 compared to 58,873 and 35,690, respectively, in the third quarter of 2018.

Financial and Pipeline Highlights

- **Substantial Progress Toward Operational Profitability:** For the fifth consecutive fiscal quarter, the Company reduced its quarterly net loss. For the third quarter of 2019, net loss narrowed to \$2.1 million, down from \$12.7 million in the third quarter of 2018, reflecting the evolution of the commercial strategy from volume-based to profitable growth and the Company's focus on both operational productivity and expense management.
 - **NT0502 to Enter Phase 1 Clinical Trials Near-Term:** The Company's lead pipeline candidate, NT0502, is a new chemical entity and a selective muscarinic receptor antagonist that utilizes the same microparticle
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technology used in the Company's four commercial products. NT0502 is being developed to address the significant unmet medical need for the treatment of chronic sialorrhea (excessive drooling) in adult and pediatric patients with neurological conditions, including Parkinson's disease, cerebral palsy, mental retardation and amyotrophic lateral sclerosis. The Company plans to initiate a Phase 1 trial in the first quarter of 2020.

Select Financial Results for the Third Quarter Ended September 30, 2019

- Total product revenues were \$17.5 million for the three months ended September 30, 2019, compared to \$12.5 million for the same period in 2018.

	Q3 2019	Q3 2018	% Change
Adzenys XR-ODT	\$ 8.8MM	\$ 7.0MM	26 %
Cotempla XR-ODT	\$ 7.2MM	\$ 4.9MM	48 %
Adzenys ER	\$ 0.2MM	\$ *	N/A
Generic Tussionex	\$ 1.3MM	\$ 0.6MM	117 %
Total	\$17.5MM	\$12.5MM	40 %

* Adzenys ER revenue was negligible in Q3 2018.

- The Company reported a gross profit of \$11.1 million for the three months ended September 30, 2019, compared to a gross profit of \$5.5 million for the same period in 2018.
- Research and development expenses were \$1.6 million for the three months ended September 30, 2019, compared to \$2.0 million for the same period in 2018.
- Selling and marketing expenses were \$7.1 million for the three months ended September 30, 2019, compared to \$10.4 million for the same period in 2018.
- General and administrative expenses were \$2.8 million for the three months ended September 30, 2019, compared to \$3.5 million for the same period in 2018.
- The Company reported a net loss of \$2.1 million, or \$0.04 per share, for the three months ended September 30, 2019, compared to a net loss of \$12.7 million, or \$0.43 per share, for the same period in 2018.
- At September 30, 2019, the Company held \$25.3 million in cash and cash equivalents and short-term investments. As previously announced, on October 2, 2019, the Company entered into a senior secured credit agreement with certain lenders that provides the Company with up to \$25.0 million in loans based on accounts receivables.

Conference Call Details

Neos management will host a conference call and live audio webcast to discuss results and provide a Company update at 8:30 a.m. EDT today. The live call may be accessed by dialing (877) 388-8985 for domestic calls, or +1 (562) 912-2654 for international callers, and referencing conference ID number 1674997. A live audio webcast for the conference call will be available on the Investor Relations page of the Company's website at <http://investors.neostx.com/>. Following the conclusion of the call, the webcast will be available for replay for 30 days.

About Neos Therapeutics

Neos Therapeutics, Inc. (NASDAQ: NEOS) is a commercial-stage pharmaceutical company utilizing its novel microparticle delivery technology to develop and manufacture central nervous system (CNS)-focused products. Adzenys XR-ODT[®] (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), Cotempla XR-ODT[®] (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), and Adzenys-ER[®] (amphetamine) extended-release oral suspension (see Full Prescribing Information, including Boxed WARNING), all for the treatment of ADHD, are three

approved products utilizing the Company's novel microparticle delivery technology. Additional information about Neos is available at www.neostx.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, commercial products, clinical development of its therapeutic candidates, plans for potential future product candidates, financial condition and outlook, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the net sales, profitability, and growth of the Company's commercial products, including whether the Company's third quarter 2019 revenue growth compared to the third quarter of 2018 highlights strong progress towards achieving profitability and whether the continued expansion of the Neos RxConnect network will be an important future growth driver for the Company's business; the status, timing, costs, results and interpretation of the Company's clinical trials or any future trials, including whether the Company will commence a Phase 1 study of NT0502 in the first half of 2020 and whether NT0502 has the potential to become the standard of treatment for sialorrhea and truly improve the lives of patients and caregivers; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals; the financial condition and outlook for the Company, including whether the Company will continue to make progress towards its goal of achieving profitability; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties related to the Company's intellectual property; other matters that could affect the availability or commercial potential of the Company's commercial products or therapeutic candidates; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(unaudited)

	September 30, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 23,284	\$ 46,478
Short-term investments	1,992	—
Accounts receivable, net of allowances for chargebacks and cash discounts of \$3,986 and \$1,865, respectively	28,877	27,801
Inventories	11,676	10,367
Other current assets	1,757	4,032
Total current assets	67,586	88,678
Property and equipment, net	7,517	7,914
Operating lease right-of-use assets	3,161	—
Intangible assets, net	13,187	14,616
Other assets	304	149
Total assets	\$ 91,755	\$ 111,357
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	\$ 6,548	\$ 12,730
Accrued expenses	37,848	35,818
Current portion of operating lease liabilities	638	—
Current portion of long-term debt	16,108	8,557
Total current liabilities	61,142	57,105
Long-Term Liabilities:		
Long-term debt, net of current portion	28,788	43,217
Operating lease liabilities	3,434	—
Derivative liability	1,239	2,017
Deferred rent	—	989
Other long-term liabilities	180	184
Total long-term liabilities	33,641	46,407
Stockholders' (Deficit) Equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized at September 30, 2019 and December 31, 2018; 49,764,909 and 49,731,108 shares issued and outstanding, respectively, at September 30, 2019; 49,710,104 and 49,676,303 shares issued and outstanding, respectively, at December 31, 2018	50	50
Treasury stock, at cost, 33,801 shares at September 30, 2019 and December 31, 2018	(352)	(352)
Additional paid-in capital	327,671	325,130
Accumulated deficit	(330,397)	(316,983)
Total stockholders' (deficit) equity	(3,028)	7,845
Total liabilities and stockholders' (deficit) equity	\$ 91,755	\$ 111,357

Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Net product sales	\$ 17,540	\$ 12,503	\$ 47,817	\$ 34,595
Cost of goods sold	6,447	6,957	17,942	19,165
Gross profit	11,093	5,546	29,875	15,430
Research and development expenses	1,551	2,037	6,757	6,109
Selling and marketing expenses	7,125	10,446	21,463	34,993
General and administrative expenses	2,850	3,537	10,355	10,588
Loss from operations	(433)	(10,474)	(8,700)	(36,260)
Interest expense	(1,869)	(2,260)	(5,971)	(6,712)
Other income, net	251	39	1,257	634
Net loss	\$ (2,051)	\$ (12,695)	\$ (13,414)	\$ (42,338)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	49,730,755	29,625,792	49,720,780	29,212,856
Net loss per share of common stock, basic and diluted	\$ (0.04)	\$ (0.43)	\$ (0.27)	\$ (1.45)

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