
**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 13, 2020**

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 March 13, 2020, the Company issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 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 March 13, 2020

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated March 13, 2020

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: March 13, 2020

By: /s/ Richard Eisenstadt

Richard Eisenstadt

Chief Financial Officer

Neos Therapeutics Reports Fourth Quarter and Year-End 2019 Financial Results

— Full year 2019 net revenues increased by 29% and operating loss decreased by \$33M —

— Neos RxConnect rapidly expanded with ~500 pharmacies in network at year-end —

— NT0502 Phase 1 ascending dose trial initiation planned in 2H20 following top-line PK data —

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

DALLAS and FORT WORTH, Texas, March 13, 2020 — Neos Therapeutics, Inc. (Nasdaq: NEOS), a commercial-stage pharmaceutical company developing and manufacturing central nervous system-focused products, today reported financial results for the fourth quarter and fiscal year ended December 31, 2019 and provided a business update.

“We made tremendous strides in 2019, following the reset of our commercial strategy for our ADHD portfolio, which resulted in an improvement to the financial foundation of the company. In particular, we realized a 29% increase in net revenues for the full year of 2019 compared to 2018 and through our focus on operational productivity and expense management, we reduced our operating loss by approximately \$33 million compared to 2018. During the year, we established and rapidly grew our proprietary Neos RxConnect patient support program to approximately 500 pharmacies. As we look forward, we are confident in the outlook for 2020 and beyond,” said Jerry McLaughlin, president and chief executive officer. “We are also extremely pleased to now have top-line results from the NT0502 Phase 1 pilot pharmacokinetic study, and we plan to initiate an ascending dose study in the second half of the year. We believe NT0502 has the potential to address a significantly underserved patient population of individuals struggling with chronic sialorrhea, otherwise known as excessive drooling, across numerous debilitating CNS disorders.”

ADHD Commercial Franchise

- **Increased net revenue per pack by over 30 percent:** 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 Cotelpla XR-ODT®, for the three months ended December 31, 2019 compared to the same period in 2018.

	Net Revenue per Pack		
	Q4 2019	Q4 2018	% Change
Adzenys XR-ODT	\$ 128	\$ 97	32 %
Cotelpla XR-ODT	\$ 126	\$ 95	33 %

- **Strong growth in Neos RxConnect patient support program:** During the fourth quarter of 2019, the company substantially expanded the number of participating pharmacies in the Neos RxConnect network to approximately 500 pharmacies, including one regional pharmacy chain, as of December 31, 2019. In mid-March, the company added a second regional pharmacy chain with approximately 250 pharmacies to the network, and it remains in active discussions with a number of other regional pharmacies strategically aligned in Neos territories.
- **Planned 2Q 2020 commercial launch of ADHD portfolio in Puerto Rico:** Neos recently entered into an agreement with a third-party to commercialize Neos’ ADHD portfolio in Puerto Rico. The commercial launch is anticipated to occur in the second quarter of 2020.

Advancing Clinical Pipeline

- **Phase 1 pilot pharmacokinetic top-line data for NT0502:** The company has completed a Phase 1 pilot study evaluating the pharmacokinetic profile of multiple formulations of NT0502 in 30 healthy adult volunteers. The top-line data confirms a formulation for further clinical development.

- **NT0502 Phase 1 ascending dose trial to begin in second half of 2020:** The company plans to initiate a Phase 1 clinical trial of NT0502 in the second half of 2020. The multi-part study will include single ascending and multiple ascending dose cohorts.

Financial Highlights and Select Financial Results

- For the fourth quarter of 2019, net loss narrowed to \$3.5 million, down from \$9.3 million in the fourth quarter of 2018, reflecting the evolution of the commercial strategy and the company's focus on both operational productivity and expense management.
- Total product revenues were \$16.8 million for the three months ended December 31, 2019, compared to \$15.4 million for the same period in 2018. For the fiscal year ended December 31, 2019, total product revenues were \$64.6 million, compared to \$50.0 million for the fiscal year ended December 31, 2018.

	Fourth Quarter			Fiscal Year		
	2019	2018	% Change	2019	2018	% Change
Adzenys XR-ODT	\$ 8.5MM	\$ 8.1MM	4.9 %	\$ 31.2MM	\$ 26.6MM	17.3 %
Cotempla XR-ODT	\$ 6.1MM	\$ 6.1MM	0 %	\$ 25.6MM	\$ 19.0MM	34.7 %
Adzenys ER	\$ 0.3MM	\$ *	*	\$ 0.8MM	\$ *	*
Generic Tussionex	\$ 1.9MM	\$ 1.4MM	35.7 %	\$ 7.0MM	\$ 4.3MM	62.8 %
Total	\$ 16.8MM	\$ 15.4MM	9.1 %	\$ 64.6MM	\$ 50.0MM	29.2 %

* Adzenys ER revenue was negligible in Q4 and fiscal year 2018.

- Gross profit was \$9.7 million for the three months ended December 31, 2019, compared to \$7.6 million for the same period in 2018. For the fiscal year ended December 31, 2019, gross profit was \$39.5 million, compared to \$23.1 million for the fiscal year ended December 31, 2018.
- Research and development expenses were \$1.8 million for the three months ended December 31, 2019, compared to \$2.4 million for the same period in 2018. For the fiscal year ended December 31, 2019, research and development expenses were \$8.6 million, compared to \$8.5 million for the fiscal year ended December 31, 2018.
- Selling and marketing expenses were \$6.7 million for the three months ended December 31, 2019, compared to \$9.1 million for the same period in 2018. For the fiscal year ended December 31, 2019, selling and marketing expenses were \$28.1 million, compared to \$44.1 million for the fiscal year ended December 31, 2018.
- General and administrative expenses were \$2.9 million for the three months ended December 31, 2019, compared to \$3.3 million for the same period in 2018. For the fiscal year ended December 31, 2019, general and administrative expenses were \$13.2 million, compared to \$13.9 million for the fiscal year ended December 31, 2018.
- Net loss for the three months ended December 31, 2019 was \$3.5 million, or \$0.07 per share, compared to a net loss of \$9.3 million, or \$0.23 per share, for the same period in 2018. For the fiscal year ended December 31, 2019, net loss was \$16.9 million, or \$0.34 per share, compared to a net loss of \$51.7 million, or \$1.60 per share for the fiscal year ended December 31, 2018.
- At December 31, 2019, the company held \$24.9 million in cash and cash equivalents and short-term investments.

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. ET 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 5454889. 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 the Company's confidence in the outlook for 2020 and beyond, the Company's future expansion of the Neos RxConnect network and the expected launch of the Company's ADHD products in Puerto Rico; the status, timing, costs, results and interpretation of the Company's clinical trials or any future trials, including whether the Company will initiate a Phase 1 ascending dose study of NT0502 in the second half of 2020 and whether NT0502 has the potential to address a significantly underserved patient population; the uncertainties inherent in conducting clinical trials, including whether the Phase 1 pilot study of NT0502 confirms a formulation for further clinical development; 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 operational 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)

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 16,830	\$ 46,478
Short-term investments	8,064	—
Accounts receivable, net of allowances for chargebacks and cash discounts of \$4,848 and \$1,865 at December 31, 2019 and 2018, respectively	26,563	27,801
Inventories	11,010	10,367
Prepaid expenses and other current assets	4,092	4,032
Total current assets	66,559	88,678
Property and equipment, net	7,345	7,914
Operating lease right-of-use assets	3,044	—
Intangible assets, net	12,543	14,616
Other assets	1,382	149
Total assets	\$ 90,873	\$ 111,357
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	\$ 6,650	\$ 12,730
Accrued expenses	40,188	35,818
Current portion of operating lease liabilities	681	—
Current portion of long-term debt	15,836	8,557
Total current liabilities	63,355	57,105
Long-Term Liabilities:		
Long-term debt, net of current portion	29,099	43,217
Operating lease liabilities	3,254	—
Derivative liability	1,135	2,017
Deferred rent	—	989
Other long-term liabilities	160	184
Total long-term liabilities	33,648	46,407
Stockholders' (Deficit) Equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized at December 31, 2019 and 2018; 49,766,472 and 49,732,671 shares issued and outstanding, respectively, at December 31, 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 December 31, 2019 and 2018	(352)	(352)
Additional paid-in capital	328,056	325,130
Accumulated deficit	(333,885)	(316,983)
Accumulated other comprehensive income	1	—
Total stockholders' (deficit) equity	(6,130)	7,845
Total liabilities and stockholders' (deficit) equity	\$ 90,873	\$ 111,357

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Net product sales	\$ 16,832	\$ 15,393	\$ 64,649	\$ 49,988
Cost of goods sold	7,181	7,763	25,123	26,928
Gross profit	9,651	7,630	39,526	23,060
Research and development expenses	1,825	2,399	8,582	8,508
Selling and marketing expenses	6,659	9,140	28,122	44,133
General and administrative expenses	2,882	3,327	13,237	13,915
Loss from operations	(1,715)	(7,236)	(10,415)	(43,496)
Interest expense	(2,038)	(2,262)	(8,009)	(8,974)
Other income, net	276	161	1,533	795
Loss before income taxes	(3,477)	(9,337)	(16,891)	(51,675)
Income tax expense (benefit)	11	—	11	—
Net loss	\$ (3,488)	\$ (9,337)	\$ (16,902)	\$ (51,675)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	49,732,654	41,415,358	49,723,772	32,288,555
Net loss per share of common stock, basic and diluted	\$ (0.07)	\$ (0.23)	\$ (0.34)	\$ (1.60)

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