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): **April 9, 2020**

NEOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37508	**27-0395455**
(Commission File No.)	(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 8.01. Other Events.

On April 9, 2020, Neos Therapeutics, Inc. (the "Company") issued a press release announcing that the United States Patent and Trademark Office has issued U.S. Patent No. 10,610,507, which is directed to methods of treating sialorrhea by administering N-desethyloxbutynin, the active pharmaceutical ingredient in the Company's clinical compound, NT0502. The patent, assigned to the Company, is not expected to expire before November 2032.

A copy of the press release is furnished hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are included with this Current Report on Form 8-K:

Number	Description
99.1	Press release dated April 9, 2020

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated April 9, 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: April 9, 2020

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

Exhibit 99.1

Neos Therapeutics Announces Issuance of New U.S. Methods of Use Patent for N-desethyloxybutynin

— N-desethyloxybutynin is the active ingredient in NT0502, the company's development candidate for the treatment of sialorrhea —

Dallas and Fort Worth, Texas, April 9, 2020 — Neos Therapeutics, Inc. (NASDAQ: NEOS), a commercial-stage pharmaceutical company developing and manufacturing central nervous system-focused products, today announced that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 10,610,507, which is directed to methods of treating sialorrhea by administering N-desethyloxybutynin, the active pharmaceutical ingredient in NT0502. NT0502 is currently in Phase 1 clinical development for the treatment of sialorrhea in patients with neurological conditions. The patent, assigned to Neos Therapeutics, is not expected to expire before November 2032.

"We are very pleased to have secured this important method of use patent from the USPTO. The issuance of this patent further supports our efforts to explore the potential of NT0502 to treat sialorrhea in patients with neurological disorders, particularly Parkinson's Disease, given the significant psychosocial and medical impact they experience," said Jerry McLaughlin, President and Chief Executive Officer. "We remain on track to initiate a Phase 1 single ascending and multiple ascending dose clinical trial of NT0502 in the second half of 2020, and look forward to reporting the data from this trial."

About NT0502

NT0502 (N-desethyloxybutynin) is a new chemical entity being developed as an oral, once- or twice-daily treatment to reduce chronic sialorrhea in patients with neurological and other conditions associated with excess saliva and drooling. Based on preclinical data, the company believes that NT0502 offers the potential for an improved tolerability profile and an easier-to-dose oral formulation, without the need for complex titration, compared to existing treatment options. N-desethyloxybutynin is an active metabolite of oxybutynin, an approved drug to treat a urological condition.

About Sialorrhea

Sialorrhea is defined as prevalent and excessive drooling from the mouth as a result of limitations in a person's ability to control and swallow oral secretions[1,2]. Sialorrhea can lead to significant physical and psychosocial complications, including perioral chapping, aspiration, dehydration, infection, foul odor, stigmatization, and increased dependency and level of care, all of which can create an additional burden for these medically complicated patients[1,3]. In the U.S., more than 1.4 million patients – including those suffering from Parkinson's disease[4,5], cerebral palsy[6,7], stroke[8,9], traumatic brain injury[10], ALS[11] and other neurological conditions[12,13] – experience sialorrhea due to neuromuscular/sensory dysfunction. Many of these patients remain untreated today because existing non-selective anticholinergic agents are associated with treatment-limiting side effects and cumbersome dosing schedules.

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

Certain statements in this press release constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. Forward-looking statements may involve statements 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, intellectual property, 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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the impact of COVID-19, including with respect to the clinical development of NT0502; 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; the uncertainties inherent in conducting clinical trials, including any potential impact on timing resulting from COVID-19; expectations for regulatory interactions, submissions and approvals; the financial condition and outlook for the Company; 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, including with respect to the U.S. patent covering methods of treating sialorrhea; other matters that could affect the availability or commercial potential of the Company's commercial products or therapeutic candidates, including whether NT0502 offers the potential for an improved tolerability profile and an easier-to-dose oral formulation, without the need for complex titration, compared to existing treatment options; 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.

References

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