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): August 6, 2019

Sage Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	001-36544	27-4486580
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

215 First Street Cambridge, MA	02142
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (617) 299-8380

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 $0.0001 per share	**SAGE**	**The Nasdaq Global Market**

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 August 6, 2019, Sage Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on August 6, 2019, furnished herewith.

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.

Date: August 6, 2019

SAGE THERAPEUTICS, INC.

By: /s/ Anne Marie Cook
Anne Marie Cook
Senior Vice President, General Counsel

Exhibit 99.1

Sage Therapeutics Announces Second Quarter 2019 Financial Results and Highlights Pipeline and Business Progress

ZULRESSO™ (brexanolone) injection CIV, the first treatment specifically indicated for postpartum depression, commercially launched in the U.S. in late-June, with first patients treated in July 2019

Commercial execution is progressing as expected and on-track across key focus areas including enabling pathways to care, facilitating patient access in the treatment of PPD, and supporting women through Sage Central

Strong data signals from depression, neurology, and neuropsych franchises presented at FutureCast

Conference call today at 8:00 a.m. EDT

CAMBRIDGE, Mass., August 6, 2019 — Today, Sage Therapeutics (NASDAQ: SAGE), a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain, reported business highlights and financial results for the second quarter ended June 30, 2019.

"Eight years ago, Sage laid the foundation to become the leading brain health company during a time when there was tremendous skepticism about the ability to develop novel medicines," said Jeff Jonas, M.D., chief executive officer at Sage. "Today, our first compound is now our first commercially launched drug and our track record of success is a direct result of our unique approach to R&D and clinical development programs. Sage's deliberate decision-making approach around pipeline management has allowed us to build what I think is a leading multi-franchise company focused on getting patients better, sooner."

Portfolio Updates:

Sage is advancing a portfolio of novel and differentiated product candidates designed to improve brain health by targeting the GABA and NMDA receptor systems. Dysfunction in these systems is thought to be at the core of numerous neurological and neuropsychiatric disorders.

Depression Franchise:

Led by ZULRESSO™ (brexanolone) injection CIV, approved by the U.S. Food and Drug Administration (FDA) in March 2019 as the first treatment specifically indicated for postpartum depression (PPD), and SAGE-217, Sage's next-generation positive allosteric modulator (PAM) of GABA$_A$ receptors being evaluated in clinical development as a treatment for various affective disorders. SAGE-217 has received breakthrough therapy designation from the U.S. FDA for the treatment of major depressive disorder (MDD).

- **ZULRESSO:** The U.S. commercial launch of ZULRESSO commenced on June 24, 2019 following scheduling by the U.S. Drug Enforcement Administration (DEA) and finalization of the product label. ZULRESSO is administered in a healthcare setting certified under the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS) program.

Sites of Care:

- More than 100 healthcare facilities, including hospitals, infusion centers, wellness centers, and fertility centers are ZULRESSO REMS certified, covering 55 of the top 140 Metropolitan Statistical Areas in the U.S.
- ZULRESSO REMS certification is one step in the process for sites of care to be treatment ready. Given the need to achieve formulary approval, establish protocols for administering ZULRESSO and secure satisfactory reimbursement, full activation of sites can take an estimated 6 to 9 months or more. Sage anticipates launch momentum to build in 4Q 2019 into 2020.

Payer Coverage and Access:

- As of August 1, 2019, plans representing more than 65 percent of all covered lives have committed to favorable coverage with either light or no restrictions.
- Plans covering approximately 30 percent of covered lives are still reviewing ZULRESSO, with decisions expected in the coming months. We expect these payers to cover ZULRESSO on a medical exception basis until a policy is in place.

Patient Support:

- Sage Central, Sage's patient support center, officially opened in June and is providing a range of patient resources to assist women with PPD and their families, including: dedicated case managers who can provide information to help navigate the treatment journey; personalized support to assist with understanding insurance and coverage options; financial assistance programs for eligible patients; and access to educational resources and assistance through connections to more than 60 national and local advocacy groups.

- **SAGE-217:** In July 2019, Sage announced clinical findings from an open-label Phase 2 clinical trial of SAGE-217 in bipolar depression (ARCHWAY Study), as well as analysis of datasets from previously completed clinical studies in MDD and PPD showing positive signals for potential development of SAGE-217 in generalized anxiety disorder and treatment-resistant depression (TRD). Sage plans to initiate a clinical study evaluating SAGE-217 in TRD. Timing for initiation of this study will be provided in 2H 2019.
  - *ARCHWAY Study:* Results from this open-label Phase 2 clinical trial evaluating the safety and activity of SAGE-217 in 35 adult men and women with moderate to severe bipolar I/II disorder with a major depressive episode demonstrated a rapid and durable response to treatment as measured by the Montgomery–Åsberg Depression Rating Scale (MADRS) and a statistically significant improvement compared to baseline at Day 15; the effect was maintained through the end of the follow-up period at Day 42. The most common adverse events (AEs) in the trial were somnolence, headache, diarrhea, and sedation. There were two cases of transient hypomania off-treatment; no mania or serious AEs were reported in the trial.
  - *SAGE-217 in patients who did not respond to anti-depressant therapy at baseline:* Results from a post-hoc analysis of 51 patients from the MDD-201B and ROBIN (PPD) studies with ongoing symptoms of depression despite receiving standard anti-depressant pharmacotherapy demonstrated a rapid response to treatment and

reduction in depressive symptoms in the SAGE-217-treated group compared to the placebo group which was durable over the follow-up period. The most common (>5%) AEs in the MDD-201B study were headache, dizziness, nausea, and somnolence; the most common (>5%) AEs in the ROBIN study were somnolence, headache, dizziness, upper respiratory tract infection, diarrhea, and sedation.

- *SAGE-217 in anxiety:* Analysis evaluating response on the Hamilton Anxiety Rating Scale (HAM-A) in 89 patients from the MDD-201B study and 151 patients from the ROBIN (PPD) study demonstrated rapid onset of a clinically meaningful anxiolytic effect in the SAGE-217-treated group compared to the placebo group which was durable past initial treatment over the study period.
- The SAGE-217 clinical program evaluating the potential of SAGE-217 as a short-course episodic, rapidly-acting oral treatment for MDD and PPD is progressing as expected. In addition to the two completed, positive pivotal studies, one in MDD and one in PPD, there are four additional ongoing or planned studies, including:
    - *MOUNTAIN Study:* Evaluating a dosing regimen of two weeks of 20mg or 30mg SAGE-217 treatment compared to placebo in patients with MDD, with four weeks of blinded follow-up. Top-line data from this pivotal study are expected in 4Q 2019 or 1Q 2020.
    - *Retreatment studies:* These studies are designed to provide longer-term retreatment and follow-up safety and tolerability data.
        - *REDWOOD Study (MDD-302):* Placebo-controlled pivotal trial to evaluate fixed interval SAGE-217 monotherapy maintenance treatment (without traditional antidepressants) for up to a year. The trial is expected to commence in 3Q 2019.
        - *SHORELINE Study:* Open-label pivotal trial evaluating SAGE-217 in treatment-free intervals and as-needed over the course of up to a year. Patients receive an initial two-week course of SAGE-217 therapy and are assessed every eight weeks for potential relapse of depressive symptoms. Top-line data are expected in 2020.
    - *RAINFOREST Study*: Phase 3 clinical trial evaluating two weeks of 30mg SAGE-217 treatment compared to placebo in patients with MDD and comorbid insomnia. Top-line data are expected in 2020.

Neurology Franchise:

SAGE-324, a next-generation PAM of GABAA receptors, is in development as a potential therapy for neurological conditions, such as essential tremor (ET), epilepsy and Parkinson's disease.

- **SAGE-324:** In July 2019, Sage announced results from Phase 1 single-ascending dose (SAD) and multiple-ascending dose (MAD) studies of SAGE-324 in healthy volunteers, as well as results from a Phase 1b single dose, open-label study of SAGE-324 in six patients with ET.
    - *SAD and MAD studies:* Results demonstrated a pharmacokinetic (PK) profile suitable for chronic dosing in indications amenable to the GABA PAM mechanism and a long half-life, an attribute well-suited for development in neurological conditions where stable plasma levels are a clinical challenge.

- *SAGE-324 in ET:* Data demonstrated a reduction in tremor from baseline, with a maximum mean reduction in accelerometer upper limb total score of 48 percent. A clear pharmacokinetic/pharmacodynamic relationship was observed in plasma concentration over 24 hours. Sage plans to initiate a Phase 2 clinical study of SAGE-324 in essential tremor in 2H 2019.
- SAGE-324 was generally well tolerated. The most common (>5%) AEs were feeling of relaxation, dizziness, and somnolence.

Neuropsychiatry Franchise:

SAGE-718, a first-in-class NMDA receptor PAM, is in development as a potential therapy for cognitive disorders associated with NMDA receptor dysfunction.

- **SAGE-718:** In July 2019, results from five Phase 1 healthy volunteer studies, including SAD, MAD, and three target engagement biomarker studies demonstrated SAGE-718 was generally well-tolerated in the studies with a long half-life consistent with once-daily dosing. Additional results demonstrated SAGE-718 had effects on electrophysiological, functional neuroimaging, and cognitive measures consistent with CNS activity. Sage plans to evaluate SAGE-718 in Phase 2 clinical development programs in certain neurodegenerative disorders and other conditions where executive function is impaired. Timing for initiation of these studies will be provided in 2H 2019.

Anticipated Upcoming Milestones

- **Top-line Data Readouts:**
  - SAGE-718 Phase 1 cohort data in Huntington's disease (2H 2019)
  - SAGE-217 MDD Phase 3 MOUNTAIN Study (4Q 2019/1Q 2020)
  - SAGE-217 MDD Phase 3 RAINFOREST and SHORELINE Studies (2020)
- **Clinical Trial Initiations:**
  - Phase 2 placebo-controlled study with SAGE-324 in Essential Tremor (2H 2019)
  - Phase 3 REDWOOD (MDD-302) trial with SAGE-217 (3Q 2019)

Financial Results for the Second Quarter of 2019

- **Revenues:** Sage recorded $0.9 million in revenues in the second quarter of 2019, compared to $90.0 million for the same period of 2018. Second quarter revenues in 2019 included $0.5 million of net revenues from sales of ZULRESSO, which consisted entirely of channel stocking in preparation for the U.S. commercial launch and $0.4 million in collaboration revenues from Shionogi & Co., Ltd. related to reimbursement of product expense. All revenues for the second quarter of 2018 were attributable to the $90.0 million upfront payment from Sage's strategic collaboration with Shionogi & Co., Ltd.
- **Cash Position:** Cash, cash equivalents, restricted cash, and marketable securities as of June 30, 2019 were approximately $1.2 billion, compared to $925.1 million at December 31, 2018. The increase was primarily due to proceeds from Sage's follow-on public offering completed in February 2019.

- **R&D Expenses:** Research and development expenses were $89.1 million, including $13.7 million of non-cash stock-based compensation expense, in the second quarter of 2019, compared to $69.0 million, including $12.1 million of non-cash stock-based compensation expense, for the same period of 2018. The increase in R&D expenses year-over-year was primarily due to advancement of the pivotal program for SAGE-217 in depression and continued research efforts across the Company's early-stage clinical and discovery pipeline.
- **SG&A Expenses:** Selling, general and administrative expenses were $88.2 million, including $21.1 million of non-cash stock-based compensation expense, in the second quarter of 2019, compared to $43.2 million, including $16.9 million of non-cash stock-based compensation expense, for the same period of 2018. The increase in SG&A expenses was primarily due to the increase in personnel-related expenses, professional fees to support expanding operations, costs related to the commercial launch of ZULRESSO, and facilities-related costs to support expanding operations.
- **Net Loss:** Net loss was $168.2 million for the second quarter of 2019 compared to a net loss of $17.0 million, for the comparable period of 2018. The difference in net loss was driven by $90 million in revenue related to our Shionogi collaboration that we recorded in the second quarter of 2018.

Financial Guidance

- Based on its current operating plan, Sage anticipates that its balance of cash, cash equivalents, restricted cash, and marketable securities will be at least $950 million at the end of 2019.
- Sage expects that its operating expenses will increase year-over-year in 2019 to support continued pipeline advancement and commercialization of ZULRESSO in PPD.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 a.m. EDT to discuss its second quarter 2019 financial results and recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will be available on Sage's website approximately two hours after the completion of the event and will be archived for up to 30 days.

About Sage Therapeutics

Sage Therapeutics is a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain. We are pursuing new pathways with the goal of improving brain health and our depression, neurology and neuropsychiatry franchise programs aim to change how brain disorders are thought about and treated. Our mission is to make medicines that matter so people can get better, sooner. For more information, please visit www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation: our views and expectations regarding our commercial launch of ZULRESSO, including the potential timing of availability of sites capable of administering ZULRESSO, the potential timing of revenue momentum and the potential for reimbursement of ZULRESSO; our development plans, goals and strategy and the potential timing and results of our development efforts; our belief in the potential of our product candidates in various indications; the potential profile and benefit of our product candidates; the goals, opportunity and potential for our business; and our expectations regarding our

cash position at year-end and increases in operating expense. These statements constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: we may encounter issues or other challenges in commercializing ZULRESSO, including issues related to market acceptance by healthcare providers, healthcare settings and women with PPD, issues related to the willingness of sites to administer ZULRESSO, issues related to reimbursement, issues related to the requirements of the REMS, and challenges associated with execution of our sales and patient support activities, which in each case could limit the potential of ZULRESSO and the timing and amount of future revenues; results achieved with use of ZULRESSO in the treatment of PPD in commercial use may be different than observed in clinical trials, and may vary among patients; the number of women with PPD or the unmet need for additional treatment options may be significantly smaller than we expect; we may encounter unexpected safety or tolerability issues with ZULRESSO or any of our product candidates; we may not be successful in our development of any of our current or future product candidates in any indication we are currently pursuing or may in the future pursue; success in earlier stage clinical trials or nonclinical studies may not be repeated or observed in ongoing or future studies of any of our product candidates; ongoing and future clinical or nonclinical results may generate results that are different than we expect or may not support further development or be sufficient to gain regulatory approval of our product candidates; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; the FDA may decide that the development program for any of our product candidates, even if positive, is not sufficient for a new drug application filing or approval; decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further development; we may experience slower than expected initiation or enrollment in ongoing or future clinical trials; we may encounter unexpected safety or tolerability issues with our product candidates; the internal and external costs required for our ongoing and planned research and development efforts, and to build our organization in connection with such activities, and the resulting expense increases and use of cash, may be higher than expected which may cause us to change or curtail some of our plans; and we may encounter technical and other unexpected hurdles in the development of our product candidates; as well as those risks more fully discussed in the section entitled “Risk Factors” in our most recent quarterly report filed with the Securities and Exchange Commission (SEC), and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. In addition, any forward-looking statements represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Product revenue, net	$ 519	$ —	$ 519	$ —
Collaboration revenue	354	90,000	819	90,000
Total revenue	873	90,000	1,338	90,000
Operating costs and expenses:				
Cost of goods sold	44	—	44	—
Research and development	89,059	68,980	175,457	118,250
Selling, general and administrative	88,227	43,167	172,146	72,016
Total operating costs and expenses	177,330	112,147	347,647	190,266
Loss from operations	(176,457)	(22,147)	(346,309)	(100,266)
Interest income, net	8,220	5,137	14,662	8,666
Other income, net	16	32	20	24
Net loss	$ (168,221)	$ (16,978)	$ (331,627)	$ (91,576)
Net loss per share - basic and diluted	$ (3.28)	$ (0.36)	$ (6.65)	$ (2.02)
Weighted average shares outstanding - basic and diluted	51,257,640	46,541,716	49,882,377	45,439,666

Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(Unaudited)

	June 30, 2019	December 31, 2018
Cash, cash equivalents, restricted cash and investments	$ 1,238,916	$ 925,143
Total assets	$ 1,315,547	$ 952,705
Total liabilities	$ 112,672	$ 89,734
Total stockholders' equity	$ 1,202,875	$ 862,971

About ZULRESSO™ (brexanolone) injection CIV

ZULRESSO, the first medicine specifically approved by the U.S. Food and Drug Administration (FDA) for the treatment of postpartum depression (PDD) in adults, is a positive allosteric modulator of both synaptic and extrasynaptic GABAA receptors. Allosteric modulation of neurotransmitter receptor activity results in varying degrees of desired activity rather than complete activation or inhibition of the receptor.

What is ZULRESSO?

ZULRESSO™ (brexanolone) CIV is a prescription medicine used in adults to treat a certain type of depression called Postpartum Depression.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZULRESSO?

ZULRESSO can cause serious side effects, including:

- **Excessive sedation and sudden loss of consciousness.** ZULRESSO may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Your healthcare provider should check you for symptoms of excessive sleepiness every 2 hours while you are awake.
  - During your ZULRESSO infusion, tell your healthcare provider right away if you feel like you cannot stay awake during the time you are normally awake or if you feel like you are going to pass out. Your healthcare provider may lower your dose or stop the infusion until symptoms go away.
  - You must have a caregiver or family member with you to help care for your child(ren) during your ZULRESSO infusion.
- Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, ZULRESSO is only available through a restricted program called the ZULRESSO REMS.

Before receiving ZULRESSO, tell your healthcare provider about all your medical conditions, including if you:

- drink alcohol
- have kidney problems
- are pregnant or think you may be pregnant. It is not known if ZULRESSO will harm your unborn baby.
  - There is a pregnancy registry for females who are exposed to ZULRESSO during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ZULRESSO and their baby. If you become pregnant during treatment with ZULRESSO, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/
- are breastfeeding or plan to breastfeed. ZULRESSO passes into breast milk. Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby while receiving ZULRESSO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZULRESSO and some medicines may interact with each other and cause serious side effects.

Especially tell your healthcare provider if you take other antidepressants, opioids, or Central Nervous System (CNS) depressants (such as benzodiazepines).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if other medicines can be taken with ZULRESSO.

How will I receive ZULRESSO?

ZULRESSO is given to you by continuous intravenous (IV) infusion into your vein. The infusion will last for a total of 60 hours (2.5 days).

What should I avoid while receiving ZULRESSO?

- ZULRESSO may make you feel dizzy and sleepy. Do not drive a car or do other dangerous activities after your ZULRESSO infusion until your feeling of sleepiness has completely gone away. See "**What is the most important information I should know about ZULRESSO?**"
- Do not drink alcohol while receiving ZULRESSO.

What are the possible side effects of ZULRESSO?

ZULRESSO can cause serious side effects, including:

- See "**What is the most important information I should know about ZULRESSO?**"
- **Increased risk of suicidal thoughts or actions.** ZULRESSO and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
- Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Tell your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- Attempts to commit suicide, thoughts about suicide or dying, new or worse depression, other unusual changes in behavior or mood

The most common side effects of ZULRESSO include:

- Sleepiness, dry mouth, passing out, flushing of the skin or face.

These are not all the side effects of ZULRESSO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see **Full Prescribing Information including Boxed Warning** and **Medication Guide** for ZULRESSO™ and discuss any questions you may have with your healthcare provider.

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