o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

CONFIDENTIAL TREATMENT REQUEST UNDER RULE 83

The entity requesting confidential treatment is:
Sage Therapeutics, Inc.
215 First Street
Cambridge, MA 02142
Attn: Anne Marie Cook, Senior Vice President and General Counsel
(617) 299-8380

August 20, 2020

By EDGAR Submission

U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Attn: Christine Allen Torney, Division of Corporation Finance

Re: Sage Therapeutics, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2019
Filed February 27, 2020
File No. 001-36544

Dear Ms. Torney:

Sage Therapeutics, Inc. ("Sage", the "Company", or "we") is transmitting this letter in response to comments received from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission"), contained in the Staff's letter dated July 23, 2020 (the "Comment Letter"), with respect to the Company's Form 10-K for the fiscal year ended December 31, 2019 filed with the Commission on February 27, 2020 (the "Form 10-K"). For your convenience, the Staff's comments are reproduced in bold type below, followed by the Company's responses thereto.

Form 10-K for the Fiscal year Ended December 31, 2019

Notes to Consolidated Financial Statements

Cost of Goods Sold, page F-10

1. **You disclose that certain manufacturing costs associated with product shipments of ZULRESSO were expensed prior to FDA approval and, therefore, were not included in cost of goods sold as of December 31, 2019 and March 31, 2020. Please tell us and provide proposed disclosure to be included in future periodic reports that addresses the following:**

    - **The cost of the inventory build-up prior to your regulatory approval that had been expensed in prior periods as research and development expenses (i.e. zero cost inventories),**

Sage Therapeutics™

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

- **The estimated selling value of zero cost inventory on hand at March 31, 2020 and when you expect, based on your current sales trends, the zero cost inventories to be depleted, and**
- **The shelf life of your inventory and your consideration of whether or not any additional inventory will be determined to be obsolete in future periods.**

We respectfully acknowledge the Staff's comments and provide the following information in response:

ZULRESSO® (brexanolone) CIV injection is manufactured in three stages: 1) bulk active pharmaceutical ingredient ("API") manufacturing, which yields the active ingredient, brexanolone; 2) drug product manufacturing, which yields filled drug product vials containing formulated brexanolone (i.e., ZULRESSO); and 3) labeling and packaging of the filled drug product vials in individual cartons, which yields a ready-to-sell finished good. After the first stage of the manufacturing process is completed, the bulk API has an initial shelf life of 48 months from the date of manufacture. However, the end of the 48 months represents a retest date and not an expiration date. At any point after the initial 48 months passes (e.g., 49 months, 60 months, 70 months, etc.), the API can be retested for stability and, if it passes, the API can be used in the second stage of manufacturing immediately after the retest. Upon completion of the second stage of the manufacturing process, the filled drug product vials containing formulated brexanolone have a shelf life of 48 months from the manufacture date. The labeling and packaging of the vials in the third stage do not change the expiration date of the vials from the original 48 months from the manufacture date. Sage utilizes third-party contract manufacturing organizations to perform each step in this manufacturing process.

- **The cost of the inventory build-up prior to your regulatory approval that had been expensed in prior periods as research and development expenses (i.e. zero cost inventories)**

The total amount expended for the build-up of inventory that was expensed in prior periods as research and development expenses prior to receiving regulatory approval (i.e., zero cost inventory) was approximately $8.9M. This zero cost inventory consists of filled drug product vials, API and raw materials.

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

- **The estimated selling value of zero cost inventory on hand at March 31, 2020 and when you expect, based on your current sales trends, the zero cost inventories to be depleted**

Rule 83 Confidential Treatment Request by Sage Therapeutics, Inc.
Request #1

At March 31, 2020, we had [**] filled drug product vials on hand with an estimated gross selling value at the current wholesale acquisition cost ("WAC") of approximately $[**]M. From FDA approval on March 19, 2019 through March 31, 2020, we sold [**] vials of ZULRESSO. Based on current sales trends and forecasts, we anticipate that approximately [**]% of these filled drug product vials currently on hand will expire prior to sale and become non-salable within the next [**] years. As such, we do not believe the estimated selling value of zero cost inventory is a meaningful figure to disclose and do not include it in the proposed disclosure below. Sage also holds significant quantities of API and raw material in inventory that we classify as work in process, which are not included in the estimated gross selling value figure above, as both the API and raw material require a significant amount of further processing to be transformed into a sellable good. Sage had enough inventory of API and raw material on hand at June 30, 2020 to meet customer sales demand for the foreseeable future, and we are well positioned with our contract manufacturing organizations to further process this material and produce additional sellable product, as needed. As mentioned in the background above, our API can be retested and, if it passes, used in manufacturing after its initial shelf life ends. Therefore, based on our past experience with API tested after the initial 48-month period, we do not expect to deplete our zero cost inventory of API or raw material or deem them obsolete for an extended period of time. In addition, if our zero cost inventories were depleted or disposed of, and we began selling ZULRESSO made from materials manufactured or purchased after FDA approval, we would not expect our cost of goods sold as a percentage of net product revenue to change materially. We estimate that, in such event, it would remain in the mid-single digit percentage range as the manufacturing cost for ZULRESSO itself (i.e., excluding royalties and amortization of intangible assets) is less than [**] percent of total net product revenue.

Sage Therapeutics, Inc. respectfully requests that the information contained in the response be treated as confidential information and that the Commission provide timely notice to Anne Marie Cook, Senior Vice President and General Counsel, Sage Therapeutics, Inc., 215 First Street, Cambridge, MA 02142, (617) 299-8380, before it permits any disclosure of the bracketed information in Request #1.

- **The shelf life of your inventory and your consideration of whether or not any additional inventory will be determined to be obsolete in future periods**

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

The shelf life of our inventory is discussed above. All of the costs to manufacture API and drug product inventories as of March 31, 2020 had been expensed, therefore there will be no charges for obsolescence in future periods. As mentioned above, our API can be retested and our filled drug product vials that reach expiry over the next three years will be disposed of with no associated charge to expense.

We intend to modify our disclosures in our future periodic reports, starting with our Form 10-Q for the period ending September 30, 2020. The proposed disclosure would be the same for both the three and nine months ended September 30, 2020. The tracked changes below are based on our Form 10-Q for the period ended June 30, 2020 as follows:

MD&A – Critical Accounting Policies and Significant Judgments and Estimates

Cost of goods sold

~~During~~Cost of goods sold was [$xx.x] and [$xx.x] for the [three or nine] months ended ~~June~~September 30, 2020 and 2019, ~~cost of goods sold of $0.1 million and $44,000,~~ respectively, ~~was related to royalties on net sales of ZULRESSO payable~~and is made up of a low-single digit royalty cost on net product revenue to CyDex ~~Pharmaceuticals, Inc., or CyDex,~~ and The Regents of the University of California ~~under license agreements (see Note 5, Leases, Commitments and Contingencies in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report), labeling and packaging costs incurred after FDA approval for ZULRESSO,~~, the amortization of ~~intangibles related to~~intangible assets associated with ZULRESSO and ~~certain~~ third-party manufacturing and distribution costs associated with labeling, packaging, and shipping of ZULRESSO. Prior to receiving initial FDA approval for ZULRESSO on March 19, 2019, we manufactured ZULRESSO inventory to be sold upon commercialization and recorded ~~all costs incurred~~approximately [$xx.x] million related to this inventory build-up as research and development expense. As a result, the manufacturing costs related to the ZULRESSO inventory build-up incurred before FDA approval were already expensed in a prior period and are therefore excluded from the cost of goods sold for the [three or nine] months ended ~~June~~September 30, 2020 ~~and 2019~~. We ~~expect~~estimate our cost of goods sold ~~for ZULRESSO to increase~~ as a percentage of net ~~sales in future periods as we produce and then sell inventory that reflects the full cost~~product revenue will remain in the mid-single digit percentage range for the foreseeable future. We expect to utilize zero cost inventory with respect to ZULRESSO for an extended period of ~~manufacturing~~time.

6. Collaboration Agreement, page F-26

2. **With regards to your strategic collaboration agreement with Shionogi, please provide the following information so we may further evaluate your accounting. Tell us how you concluded:**

   - **The license is distinct and has standalone value under ASC 606-10-25-19 through 25-22, specifically addressing ASC 606-10-25-19a. In this regard, include in your response if the supply of API is available from entities other than you. Refer also to ASC 606-10-55-368 through 55-374, Example 56.**

Sage Therapeutics™
o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

- **The supply of API is an option and not a performance obligation. Refer to ASC 606-10-25-14 through 25-22, specifically 21c, and ASC 606-10-55-41 through 55-45 and 55-54 through 55-58.**

We respectfully acknowledge the Staff's comments and provide the following information in response:

Background

In June 2018, we entered into a collaboration and license agreement (the "Agreement") with Shionogi & Co., Ltd ("Shionogi"). Pursuant to the Agreement, Shionogi has sole responsibility for the ongoing development of the drug candidate SAGE-217 and, if approved for marketing, the commercialization of the drug product, in each case within the Shionogi territories, which consist of Japan, South Korea, and Taiwan, together known as the "Shionogi Territory", including all costs associated with the pursuit of such efforts. The license rights granted to Shionogi are comprehensive and include a license of intellectual property ("IP") for the development, manufacturing, and commercialization of SAGE-217 in the Shionogi Territory, which was delivered upon signing of the Agreement in June 2018. Shionogi has the right to sublicense the license rights provided. Although SAGE-217 was in Phase 2 clinical trials in the United States at the time the Agreement was executed, it was necessary for Shionogi to conduct its own Phase 1 and 2 clinical trials in the Shionogi Territory.

- **The license is distinct and has standalone value under ASC 606-10-25-19 through 25-22, specifically addressing ASC 606-10-25-19a. In this regard, include in your response if the supply of API is available from entities other than you. Refer also to ASC 606-10-55-368 through 55-374, Example 56.**

Capable of Being Distinct and Standalone Value

In making the determination as to whether the license of IP to Shionogi under the Agreement is distinct, specifically whether the license is capable of being distinct, we assessed whether Shionogi could benefit from the license on its own or together with other resources that are readily available to Shionogi. During the clinical trials and for the duration of the license period, the composition of SAGE-217 is unable to be unilaterally changed and the functionality of the IP that was delivered upon contract execution is not expected to change. Upon execution of the Agreement, Shionogi became responsible for all future development of SAGE-217 in the Shionogi Territory, including conducting clinical trials and ultimately commercializing SAGE-217 in the Shionogi Territory, as well as any risks associated with those activities. The licenses

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

granted to Shionogi for the Shionogi Territory include an exclusive license to develop, manufacture and commercialize SAGE-217 in the Shionogi Territory. Shionogi is a mature fully integrated pharmaceutical company that has the knowledge and expertise for drug development, manufacturing and commercialization in the Shionogi Territory and, therefore, we believe could fully benefit from the license and IP that it obtained control of upon executing the Agreement. In addition, Shionogi has the ability to benefit from the IP by executing its right to sublicense the IP.

In connection with the Agreement, Sage entered into a clinical supply agreement with Shionogi on October 26, 2018 (the "Clinical Supply Agreement"), pursuant to which Sage has agreed to supply Shionogi with SAGE-217 API and SAGE-217 drug product for development purposes. We neither own nor operate, and currently have no plans to own or operate, any manufacturing facilities, and therefore currently source all of our clinical material supply through third party contract manufacturing organizations ("CMOs"). We have established relationships with CMOs under which the CMOs manufacture clinical and nonclinical supplies of the API or drug product for SAGE-217. Although the API and the drug product are patentably distinct, the manufacturing process to produce such API and drug product is not unique or specialized. There are other companies that could manufacture the API, including Shionogi. Currently, Sage does not have a patented process for manufacturing the API. The manufacturing of the API is a multi-step process consistent with other small molecule development, meaning that from a synthetic perspective, the API can be manufactured using common production techniques. The process is reproducible by any third party capable of executing standard chemical synthetic techniques. The materials required for manufacture are readily available in the marketplace.

The formulation of the API is outlined in the patent for SAGE-217 and could be reproduced by either Shionogi or other contract manufacturers. Further, details related to the manufacture of API are documented in production batch records, which are available to Shionogi. The license granted to Shionogi includes the right to manufacture SAGE-217 for use in the Shionogi Territory. Although the Agreement provides that Shionogi shall purchase API from Sage, Shionogi has the ability to take control over the manufacturing of the API from Sage in the event of a continuing material supply breach, as well as in the situation where Sage cannot meet certain cost reduction proposals. Because the manufacturing process used to produce the API is not unique or specialized and can be reproduced by Shionogi or other CMOs who could then supply API, we concluded that the criterion in paragraph 606-10-25-19(a) was met for the license. These facts closely align with those outlined in ASC 606-10-55-371, in which the license was determined to be distinct.

Distinct in the Context of the Contract

We also assessed whether the license was separately identifiable from the other promises in the Agreement pursuant to ASC 606-10-25-19(b). Neither the license, on the one hand, nor supply of certain clinical materials or the supply of API, on the other hand, is significantly modified or customized by the other, and we are not providing a significant service of integrating those items into a combined output. We were able to fulfill our promise to transfer control over

Sage Therapeutics™
o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

the license to Shionogi independent of fulfilling our promise to subsequently supply certain clinical materials and API (i.e., the license and the API are not interdependent or interrelated) . Importantly, the subsequent supply of clinical materials and API did not modify or customize the initial license that was conveyed. In addition, the supply of clinical material and API represented a distinct good that is sold separately under the terms of the Clinical Supply Agreement with separate pricing and conditions consistent with the terms outlined in the Agreement.

In summary

Therefore, as a result of the combination of (1) the manufacturing not being unique and specialized and being readily able to be reproduced by third party CMOs or Shionogi (thus meeting the criteria in ASC 606-10-25-19a), (2) the Agreement conveying the license rights to manufacture SAGE-217, (3) Shionogi having the ability to assume control of the manufacturing rights in the event Sage is unable to manufacture it or is not able or willing to implement certain cost reduction proposals, and (4) that neither the license nor manufacturing of certain clinical material or API is modified or customized by the other, we concluded that the license was distinct from both the supply of clinical material and the supply of API, and that the license has standalone value as Shionogi could benefit from the license upon contract inception.

- **The supply of API is an option and not a performance obligation. Refer to ASC 606-10-25-14 through 25-22, specifically 21c, and ASC 606-10-55-41 through 55-45 and 55-54 through 55-58.**

In assessing our performance obligations under ASC 606-10-25-14 through 25-22, we determined that the supply of clinical material to Shionogi, which by nature includes the supply of API, represents a performance obligation, while the supply of API for commercial purposes is an option under ASC 606.

We have concluded that the supply of API for commercial use is not considered a performance obligation and instead represents an “at the money” customer option under ASC 606 at the inception of the arrangement (i.e., equivalent to sharing a price listing with a customer). Any potential agreement to supply commercial API is subject to future negotiations between the Company and Shionogi. Shionogi will not need to evaluate its requirements for commercial supply until after several years of development. Given that Shionogi would be required to run multiple clinical trials in the Shionogi Territory, perform other development work with respect to the drug candidate, and apply for and obtain regulatory approval in order to commercialize SAGE-217 in the Shionogi Territory, all of which would have to occur in order to require supply of API for commercial use, the supply of API for commercial purposes is considered a separate purchasing decision and therefore not a performance obligation at the outset of the Agreement.

We also evaluated and concluded that the potential supply of API in the commercial period was a customer option under ASC 606 that does not provide the customer with a material

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

right in accordance with ASC 606-10-55-41 through 45. This is because the expected price for the commercial supply was included in the Agreement and considered to be standalone selling price and comparable to what other CMOs would charge to acquire comparable goods.

The factors that management considered in determining that the future supply of commercial API would be considered an option that did not provide a material right (i.e., not a performance obligation) under ASC 606 are as follows:

- The Clinical Supply Agreement was entered into between the Company and Shionogi in October 2018 and was limited to supply of drug product and API solely during the clinical period (i.e., for clinical research purposes). This was contemplated as part of the Agreement entered in June 2018, which outlined key terms for supply and provided an estimated timeline for entering into the supply agreement. A separate supply agreement to provide API for commercial use, which will be subject to negotiation between the Company and Shionogi, will need to be executed in the future.
- Due to the significant research and development risk and uncertainty associated with SAGE-217 in the Shionogi Territory given its stage of development (beginning of Phase 1 clinical trials) upon execution of the Agreement, the delivery of any supply of API for commercial use is dependent on Shionogi's efforts to research and develop the drug candidate, conduct successful clinical trials and obtain the necessary regulatory approvals in the Shionogi Territory, all of which are uncertain and will take several years to complete.
- Prior to entering into a supply agreement for commercial supply of API with Shionogi, we will need to enter into one or more long-term supply agreements with our CMOs. We do not currently have any long-term agreements in place for commercial supply of API for SAGE-217 as it is dependent on the ongoing development and, ultimately, approval of the drug, which is uncertain at this time given the challenges of drug development.
- The pricing included in the Agreement for the future commercial supply of API represented the standalone selling price of the API as it was considered comparable to what other CMOs would charge. Any supply agreement for commercial supply of API is subject to negotiation, but it is expected that the final price will be calculated based on the terms outlined in the Agreement.
- There were no fixed or minimum quantities prescribed under the Agreement for the supply of API for commercial use.
- Under the Agreement, Shionogi has the ability to assume control over the manufacturing of API in the event of a continuing material supply breach by Sage, or

Sage Therapeutics™
o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

in the event Sage does not implement certain cost reduction proposals. If Shionogi were to assume the manufacturing of the API, it could use a CMO or potentially manufacture the API itself, as we believe it has the requisite knowledge and expertise.

- Lastly, the supply of API for commercial use does not affect the license rights that were conveyed upon entering the Agreement in June 2018. Therefore, under ASC 606-10-25-21c, the license and the API are not highly interdependent or interrelated. We believe that the conveyance of the license rights in June 2018 is separate and distinct from the supply of the clinical material and API and therefore we believe they are fulfilling separate promises to Shionogi.

To clarify that the supply of API for commercial use was considered an option under ASC 606, we plan on revising the disclosure to be included in future periodic reports, starting with our Form 10-Q for the period ending September 30, 2020. The tracked changes below are based on our Form 10-Q for the period ended June 30, 2020 as follows:

6. Collaboration Agreement

Effective June 12, 2018, the Company entered into a strategic collaboration with Shionogi for the clinical development and commercialization of zuranolone for the treatment of major depressive disorder ("MDD") and other potential indications in Japan, Taiwan and South Korea. On October 26, 2018, the Company entered into a supply agreement with Shionogi for zuranolone clinical material.

Under the terms of the collaboration agreement, Shionogi will be responsible for all clinical development, regulatory filings and commercialization of zuranolone for MDD, and potentially other indications, in Japan, Taiwan and South Korea. Shionogi was required to make an upfront payment to the Company of $90.0 million, and the Company will be eligible to receive additional payments of up to $485.0 million if certain regulatory and commercial milestones are achieved by Shionogi. The potential future milestone payments include up to $70.0 million for the achievement of specified regulatory milestones, up to $30.0 million for the achievement of specified commercialization milestones, and up to $385.0 million for the achievement of specified net sales milestones. The Company is eligible to receive tiered royalties on sales of zuranolone in Japan, Taiwan and South Korea, if development efforts are successful, with tiers averaging in the low to mid-twenty percent range, subject to other terms of the agreement. Shionogi has also granted to the Company certain rights to co-promote zuranolone in Japan. The Company maintains exclusive rights to develop and commercialize zuranolone outside of Japan, Taiwan and South Korea. The upfront cash payment and any payments for milestones and royalties are non-refundable and non-creditable. Due to the uncertainty of pharmaceutical development and the high historical failure rates generally associated with drug development, the Company may not receive any milestone payments or any royalty payments from Shionogi.

Sage Therapeutics™

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

The Company concluded that Shionogi meets the definition to be accounted for as a customer because the Company is delivering intellectual property and know-how rights for the zuranolone program in support of territories in which the parties are not jointly sharing the risks and rewards. In addition, the Company determined that the Shionogi collaboration met the requirements to be accounted for as a contract, including that it was probable that the Company will collect the consideration to which the Company was entitled in exchange for the goods or services that will be delivered to Shionogi.

In determining the appropriate amount of revenue to be recognized under Topic 606, the Company performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measured the transaction price, including the constraint on variable consideration; (iv) allocated the transaction price to the performance obligations; and (v) recognized revenue when (or as) the Company satisfied each performance obligation.

The Company determined that the performance obligations in the contract included the license to zuranolone and the supply of certain materials during the clinical development phase, which includes the supply of active pharmaceutical ingredient ("API"). The performance obligation related to the license to zuranolone was determined to be distinct from other performance obligations and therefore was a ~~standalone~~separate performance obligation for which control was transferred upon signing. The obligation to provide certain clinical materials, including API for use during the development period, was determined to be a separate performance obligation. ~~The~~ Given that Shionogi is not obligated to purchase any minimum amount or quantities of commercial API, the supply of API to Shionogi for commercial use was determined to be an option for Shionogi ~~to purchase~~, rather than a ~~firm~~performance obligation~~, because no minimum amount or quantities are specified and therefore,~~ of the Company at contract inception and will be accounted for if and when exercised. The Company also determined that there was no separate material right in connection with the supply of API for commercial use as the expected pricing was not ~~considered~~at a ~~performance obligation within the main agreement~~discount. Given this fact pattern, the Company has concluded the agreement has two performance obligations.

Under the clinical supply agreement, the Company will manufacture and supply to Shionogi (i) clinical quantities of API reasonably required by Shionogi for the development of licensed products in the Shionogi territory under the collaboration and license agreement and (ii) quantities of drug product reasonably required for use by Shionogi in Phase 1 studies of zuranolone in the Shionogi territory under the collaboration and license agreement, in the quantities agreed to by the parties. Collaboration revenue from the clinical supply agreement, which excludes the $90.0 million upfront payment, pertains to the clinical material sold under the terms of the clinical supply agreement. The Company records the costs related to the clinical supply agreement in research and development expense on its condensed consolidated statements of operations and comprehensive loss.

Sage Therapeutics™

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

The Company completed the evaluation of the standalone selling prices of each of the performance obligations and determined that the standalone selling price of the license performance obligation was $90.0 million. The Company recognized the transaction price allocated to the license performance obligation of $90.0 million as revenue during the quarter upon delivery of the license to Shionogi and resulting ability of Shionogi to use and benefit from the license, which was in the three months ended June 30, 2018. The remaining transaction price related to the performance obligation for the supply of certain clinical material is not significant. The potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. The Company will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

3. Please tell us where you have filed the collaboration agreement with Shionogi. If this agreement was not filed, tell us how you determined the collaboration agreement not to be material given that you have not generated any revenues prior to the revenue recognized under this agreement.

We have not filed the Agreement as we have determined that it has not been, and is not, required to be filed pursuant to the requirements of Item 601(b)(10) of Regulation S-K. Under Item 601(b)(10)(ii), contracts that ordinarily accompany the kind of business conducted by a registrant will be deemed to have been made in the ordinary course and need not be filed unless such contracts fall into one of the categories listed in Item 601(b)(10)(ii)(A)-(D). Thus, we first considered whether the Agreement is of a type that ordinarily accompanies the kind of business conducted by our Company. Based on the significant experience of our management team in biopharmaceutical companies, we believe that region-specific, limited license and collaboration agreements ordinarily accompany the business of companies such as ours in the biopharmaceutical industry. In fact, these sorts of agreements are part of our strategy, as outlined in our Form 10-K, where we list key elements of our strategy, including our plan to "[c]ontinue to explore other opportunities to establish agreements or alliances with pharmaceutical company collaborators or distributors for our product candidates where we believe the partnering opportunity will add significant value to our efforts, including through capabilities, infrastructure, speed or financial contributions." It is common for biopharmaceutical companies to enter into these region-specific, limited license and collaboration agreements so that pharmaceutical companies can put new product candidates in their pipelines and biotech companies can access the resources needed for later-stage development, clinical trials, manufacturing, and distribution, in particular where certain expertise may be required for particular regional markets and regulatory regimes. Additionally, these license and collaboration agreements allow companies to focus on their most advanced programs internally while still progressing earlier stage programs.

As the Agreement is of a type that ordinarily accompanies the kind of business we and other biopharmaceutical companies conduct, we reviewed the requirements of each subsection of

Sage Therapeutics™

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

Item 601(b)(10)(ii) and concluded that the Agreement does not fall within the categories set forth in subsections (A) through (D). Subsections (A), (C), and (D) are generally inapplicable. Item 601(b)(10)(ii)(B) requires contracts made in the ordinary course of business to be filed if a registrant's business is substantially dependent upon them. We have not been, and are not, substantially dependent upon the Agreement. As a result, we do not believe the Agreement is required to be filed.

We have not been, and are not, substantially dependent upon the Agreement due to its scope, operational impact, and financial effect. The Agreement does not involve ZULRESSO, our commercial product; rather, the Agreement covers only SAGE-217, one of several product candidates we are currently developing, and does not constitute a license of the major part of our products and services. We expect to pursue similar agreements with SAGE-217 in other territories and with our other product candidates. As discussed above, the Agreement is limited in geographic scope to activities in the Shionogi Territory. Given that the Agreement is limited to Japan, Taiwan and South Korea, if the Agreement were terminated, we do not anticipate that there would be a material impact to us, our business or our results of operations. In the event of such a termination, we also believe that it is likely we would be able to find another licensee for the Shionogi Territory, were we to seek one. Further, the Agreement includes limited financial obligations from the Company, we do not owe any amounts under the Agreement to Shionogi, and we are not obligated to undertake any research and development efforts with respect to the Shionogi Territory or on behalf of Shionogi.

We also have not been, and are not, substantially dependent upon funding from our collaboration with Shionogi. We received a $90 million upfront payment in connection with entering into the Agreement in 2018. We have not received any additional revenues under the Agreement since that time and have received only immaterial revenues under the Clinical Supply Agreement. Moreover, the $90 million upfront payment represented less than 10% of the $1.1 billion of cash and cash equivalents and marketable securities on our balance sheet when we entered into the Agreement. In addition, at the time we entered into the Agreement, we expected—and did ultimately receive in March 2019—marketing approval for our first commercial product, ZULRESSO.

We do not expect to receive material revenues from Shionogi under the Agreement in the foreseeable future and, having become a commercial stage company, we expect revenues from sales in the United States of ZULRESSO and of our other product candidates, if successfully developed and approved in the United States—and, in particular, revenues from sales in the United States of SAGE-217, if we are successful in our development efforts—to drive our revenue in the future. There is no committed funding payable to us under the Agreement. Any future amounts that may be payable to us thereunder such as milestone payments and royalties are subject to substantial clinical, regulatory, and commercial uncertainty. Specifically, regulatory milestones are based on various regulatory approvals in Japan, where SAGE-217 has recently begun Phase 2 clinical development. Sales milestones and royalties are also based only on commercial activity in the Shionogi Territory. Even if we received payment in full for the successful achievement of all potential milestones under the Agreement, such aggregate amount would be less than our cash and cash equivalents and marketable securities as of June 30, 2020.

Sage Therapeutics™

o (617) 299.8380 f (617) 299.8379
215 First Street, Cambridge, MA 02142
www.sagerx.com

We recognize that a particular agreement may not be material upon execution but may become material as its significance may increase or our business may change over time. As such, we will continue to review the materiality of all of the agreements we have entered into, including the Agreement, on a periodic basis in conjunction with the preparation of our periodic reports.

* * * * *

If you or any other member of the Staff have any questions with regard to the foregoing responses, would like to discuss any of the matters covered in this letter, or otherwise require additional information, please telephone the undersigned or Anne Marie Cook, Senior Vice President and General Counsel of Sage, at (617) 299-8380.

Sincerely,

/s/ Kimi Iguchi

Kimi Iguchi
Chief Financial Officer

cc: Sasha Parikh, Division of Corporation Finance
Anne Marie Cook, Senior Vice President, General Counsel, Sage Therapeutics, Inc.
Jennifer Fitzpatrick, Vice President, Corporate Counsel, Sage Therapeutics, Inc.
Stuart Falber, Wilmer Cutler Pickering Hale and Dorr LLP
Rosemary Reilly, Wilmer Cutler Pickering Hale and Dorr LLP
Office of Freedom of Information and Privacy Act Operations