

CERTAIN PORTIONS OF THIS LETTER AS FILED VIA EDGAR HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS. OMITTED INFORMATION HAS BEEN REPLACED IN THIS LETTER AS FILED VIA EDGAR WITH A PLACEHOLDER IDENTIFIED BY THE MARK “[*].”**

January 14, 2021

By EDGAR Submission

U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549
Attn: Division of Corporation Finance, Office of Life Sciences
Ms. Ibolya Ignat and Ms. Mary Mast

**Re: Blueprint Medicines Corporation
 Form 10-K for the Fiscal Year Ended December 31, 2019
 Filed February 13, 2020
 Form 10-Q for the Fiscal Quarter Ended September 30, 2020
 Filed October 29, 2020
 File No. 001-37359**

Dear Mses. Ignat and Mast:

Blueprint Medicines Corporation (“Blueprint Medicines” or the “Company”) 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 December 2, 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 13, 2020 (the “Form 10-K”) and the Company’s Form 10-Q for the fiscal quarter ended September 30, 2020, filed with the Commission on October 29, 2020 (the “Form 10-Q”). For your convenience, the Staff’s comments are reproduced in bold type below, followed by the Company’s responses thereto.

Unless otherwise stated in this letter, the “CStone collaboration” refers to the Company’s collaboration with CStone Pharmaceuticals (“CStone”) pursuant to a collaboration agreement, dated June 1, 2018 (the “CStone collaboration agreement”), and the “Roche pralsetinib collaboration” refers to the Company’s collaboration with Roche (as defined below) pursuant to a collaboration agreement, dated July 13, 2020 (the “Roche 2020 collaboration agreement”). With respect to the Roche pralsetinib collaboration, “Roche” means F. Hoffmann-La Roche Ltd and Genentech, Inc.

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

Notes to the Consolidated Financial Statements

2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements
Revenue Recognition - Research and Development Services, page F-12

1. **You state that payments or reimbursements from and payments to the partner that are the result of a collaborative relationship with the partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction to research and development. We note on page 98 of the 10-K and page 36 of the September 30, 2020 10-Q that you state that research and development activities are central to your business model. Please address the following:**
 - **Tell us why you believe recording the reimbursements as a reduction of research and development for collaborative arrangements is appropriate. In this respect, clarify why you believe that research and development activities are, or are not, part of your ongoing major or central operations/ordinary activities.**

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- **Address the example in ASC 808-10-55-7 through 55-10 and differentiate how your fact pattern for each collaboration agreement, including the Roche July 2020 agreement, differs from the example.**
- **Cite any other applicable guidance you considered in determining your accounting treatment and provide proposed disclosure to clarify your accounting policy, if necessary.**

We respectfully acknowledge the Staff’s comments and provide the information set forth below in response. For your convenience, each bullet of the Staff’s comment is reproduced in bold, italicized type below, followed by the Company’s responses thereto.

Tell us why you believe recording the reimbursements as a reduction of research and development for collaborative arrangements is appropriate. In this respect, clarify why you believe that research and development activities are, or are not, part of your ongoing major or central operations/ordinary activities.

When we perform the analysis for our collaborative arrangements, we consider Accounting Standards Update (“ASU”) 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* (“ASU 2018-18”) to determine which components of each collaborative arrangement should be accounted for under Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers* (“ASC 606”) when the counterparty is a customer for a distinct good or service. We evaluate the components of each collaborative arrangement separately and in the context of the joint operating activities in each arrangement with our collaboration partner. We apply the unit-of-account guidance in ASC 606 (ASC 606-10-15-4 and ASC 606-10-25-19 through 25-22) to determine the distinct components of a collaborative arrangement. We assess the economics and nature of the collaborative arrangement, the nature of the activities, the contractual terms of the collaborative arrangement and the nature of our business operations to determine whether such research and development activities are an output of our ordinary activities in the context of the collaborative arrangement. While research and development activities are a part of the Company’s ongoing operations and ordinary activities, providing research and development activities for those presented as a reduction of research and development expenses is not part of our ordinary activities in the context of those collaborations. For distinct research and development activities, if the counterparty is a customer in the context of the unit-of-account, we account for those activities under ASC 606 as collaboration revenue; if the counterparty is not a customer in the context of the unit-of-account, we account for those research and development activities by analogy to other authoritative accounting literature or, if there is no appropriate analogy, by using a reasonable, rational and consistently applied accounting policy election. We have made an accounting policy election to account for research and development reimbursements received from our collaboration partner that are outside of the scope of ASC 606 as a reduction of research and development expenses to best reflect the economics and nature of the transaction in the context of the unit-of-account.

Address the example in ASC 808-10-55-7 through 55-10 and differentiate how your fact pattern for each collaboration agreement, including the Roche July 2020 agreement, differs from the example.

As of September 30, 2020, the Company had two collaboration agreements that had components within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”): the CStone collaboration and the Roche pralsetinib collaboration. The Company’s detailed analysis is set forth below for each of these collaboration agreements.

CStone Collaboration

The CStone collaboration agreement consists of two material components: (i) the CStone territory-specific license and related activities in the CStone territory, and (ii) the parties’ participation in global development activities of the licensed products in the CStone territory. We accounted for the CStone territory-specific license and related activities in the CStone territory under ASC 606 because CStone is a customer with regard to the component that includes the CStone territory-specific license and related activities in CStone territory. In the global development activities conducted in the CStone territory, we and CStone are jointly developing the licensed products. CStone is obligated to reimburse the Company for any research and development expenses that the

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Company paid on behalf of CStone pursuant to the CStone collaboration agreement and manufacturing costs associated with the Company’s clinical supplies provided to CStone for the global pre-clinical and clinical studies conducted in the CStone territory. The clinical supplies provided to CStone support the overall purpose of executing the global research and development activities, and both parties ultimately share in the risk and reward of these activities. The Company does not view its execution of global development activities as performing services on behalf of CStone, and in the context of the unit-of-account, CStone has not contracted with the Company to obtain goods or services that are an output of the Company’s ordinary activities in exchange for consideration. Therefore, the Company does not have a vendor-customer relationship with CStone with respect to the global development activities conducted in the CStone territory for the purpose of ASC 606, and the Company does not consider reimbursement by CStone of the foregoing costs to be collaboration revenue. Because the development of our drug candidates represents a joint operating activity under the CStone collaboration, wherein both parties meet the requirements of active participation under ASC 808, and both parties are exposed to significant risks and rewards, we concluded that the parties’ participation in the global development of the licensed products in the CStone territory (including the research and development activities and cost-sharing payments related to such activities), are within the scope of ASC 808. When evaluating an appropriate analogy to other accounting guidance or an accounting policy for the research and development activities conducted in the CStone territory, we assessed our relationship with CStone, the economics and nature of those global research and development activities conducted in the CStone territory, and the contractual terms of CStone collaboration agreement. Based on this assessment, we concluded that, in accordance with our policy, accounting for research and development reimbursements received from CStone as a reduction of research and development expenses best reflects the economics and nature of the transaction in the context of the collaboration and unit-of-account.

The payments received from CStone associated with global studies conducted in the CStone territory are analogous to the cost sharing described in the example in ASC 808-10-55-7 through 55-10 below, which are recorded as a reduction of research and development expense:

Pharma has concluded that other authoritative accounting literature does not apply directly to net payments to Biotech, including Topic 606 because Biotech is not a customer. Pharma has concluded that Biotech is not a customer because Biotech has not contracted with Pharma to obtain goods or services that are an output of Pharma’s ordinary activities in exchange for consideration. Pharma also has concluded that there is no other authoritative accounting literature that is appropriate to apply by analogy, and, accordingly, its accounting policy is to evaluate the presentation of amounts due from or owed to other participants associated with multiple activities in a collaborative arrangement based on the nature of each separate activity. As a result, Pharma disaggregates the \$13.75 million net payable to Biotech in accordance with the nature of the individual components of the payable and characterizes the portion of the payable related to 50 percent of the commercialization activities (sales to third parties less associated manufacturing and marketing costs) as cost of sales (\$16.25 million). Pharma characterizes the portion of the net payable related to research and development activities as a reduction of its research and development expenses (\$2.5 million), because performing contract research and development services is not part of its ordinary activities.

Roche Pralsetinib Collaboration

Under the Roche pralsetinib collaboration, the Company granted Roche exclusive rights to develop and commercialize the Company’s drug candidate pralsetinib outside the U.S., excluding the CStone territory (the “Roche territory”), and a co-exclusive license in the U.S. to develop and commercialize pralsetinib (the “Shared Territory”). In the U.S., the Company and Roche are working together to co-commercialize pralsetinib, and the Company and Roche have also agreed to co-develop pralsetinib globally, excluding the CStone territory (the “Territory”).

Pursuant to the collaboration agreement, the Company and Roche have agreed to jointly develop pralsetinib in the Territory to expand the indications for which we have received or plan to seek marketing approval. The Company and Roche will initially share global development costs for pralsetinib at a rate of 45 percent and 55

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percent, respectively, up to a specified amount of aggregate joint development costs, after which the Company’s share of global development costs for pralsetinib will be reduced by a specified percentage. As part of the joint development activities in the Territory, we are responsible for conducting certain studies planned to be performed under the Roche pralsetinib collaboration agreement, and Roche is responsible for conducting the remaining studies. Both parties jointly participate in the joint committees to determine the development plan and oversee the operation of the studies. The Company does not view its execution of joint development activities in the Territory as performing services on Roche’s behalf, and in the context of the unit-of-account, Roche has not contracted with the Company to obtain goods or services that are an output of the Company’s ordinary activities in exchange for consideration. Therefore, the Company does not have a vendor-customer relationship with Roche with respect to the joint development activities in the Territory for the purpose of ASC 606, and the Company does not consider Roche’s reimbursement of research and development activities in connection with joint development activities in the Territory to be collaboration revenue. Because the co-development activities represent a joint operating activity, wherein both parties meet the requirements of active participation under ASC 808, and both parties are exposed to significant risks and rewards, the Company has concluded that the activities associated with the joint development activities for pralsetinib in the Territory are within the scope of ASC 808. When evaluating an appropriate analogy to other accounting guidance or an accounting policy for the joint research and development activities conducted in the Territory, we assessed our relationship with Roche, the economics and nature of those global research and development activities and the contractual terms of the collaboration agreement. Based on this assessment, we concluded that, in accordance with our policy, accounting for research and development reimbursements received from Roche as a reduction of research and development expenses best reflects the economics and nature of the transaction in the context of the unit-of-account.

The net payments received from Roche associated with joint development activities conducted in the Territory are analogous to the cost sharing described in the examples in ASC 808-10-55-7 through 55-14, which are recorded as a reduction of research and development expense. Similarly, the net payments made to Roche associated with joint development activities are accounted for as an increase in research and development expense:

Little Pharma has concluded that other authoritative accounting literature does not apply directly to net payments to Big Pharma, including Topic 606 because Big Pharma is not a customer. Little Pharma has concluded that Big Pharma is not a customer because Big Pharma has not contracted with Little Pharma to obtain goods or services that are an output of Little Pharma’s ordinary activities in exchange for consideration. Little Pharma also has concluded that there is no other authoritative accounting literature that is appropriate to apply by analogy, and, accordingly, its accounting policy is to evaluate the presentation of amounts associated with each separate activity. As a result, Little Pharma disaggregates its \$4.75 million net payable to Big Pharma in accordance with the nature of the individual item and characterizes a portion of the net payable related to 35 percent of the profit related to the sales in the United States as expenses from collaborative arrangement (\$22.75 million) and characterizes the portion of the net payable to Big Pharma for research and development activities as research and development expenses. Little Pharma concludes that the portion of the net payable directly related to profit sharing from Big Pharma’s third-party sales in Europe and Asia is analogous to a royalty and therefore should characterize the \$10.5 million as revenue similar to a royalty. Little Pharma also concludes that any payment from Big Pharma for research and development activities will be characterized as a reduction of its research and development costs (\$7.5 million) because performing contract research and development services is not part of its ordinary activities.

Please refer to the Company’s response to comment #2 below for more background and accounting consideration details related to the Roche pralsetinib collaboration agreement.

Revised Disclosure in Future Periodic Reports

To further enhance the Company’s disclosure related to the accounting policies associated with collaborative arrangements, starting with the Company’s Form 10-K for the fiscal year ended December 31, 2020,

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the Company intends to modify the disclosures in its future periodic reports to be consistent with our historical accounting policy elections as set forth on Appendix A attached to this letter.

Form 10-Q for the Nine Months Ended September 30, 2020

Notes to the Consolidated Financial Statements

10. Collaboration and License Agreements, page 15

2. You state on page 15 that on July 13, 2020 you entered into a collaboration agreement with Roche pursuant to which you granted Roche an exclusive right to develop and commercialize pralsetinib worldwide, excluding the CStone territory, and a co-exclusive license in the U.S. to develop and commercialize pralsetinib. You state on page 16 that the agreement contains four material components. Please address the following:
- **Tell us how you applied ASU 2018-18 to determine that part of the agreement should not be accounted for under ASC 606. In this respect, tell us why the collaborative partner is not considered a customer within the unit of account under ASU 2018-18 that would be required to be accounted for under ASC 606.**
 - **For the portion of the agreement you believe is outside ASC 606, clarify what authoritative literature you are using or what methodology you are using to account for the non-ASC 606 portion. Refer to ASC 808-10-45-3.**
 - **Explain why the entire \$695.7 million was allocated to the components accounted for under ASC 606 and why some of the amount was not required to be allocated to the other material components of the agreement.**
 - **Please clarify the nature of the transition date discussed on page 17, why that date determines if you are the principal for the product sales, and if at that point, reimbursements will also be recorded as revenue. Clarify how the fact pattern compares to Example 3 in ASC 808-10-55-11 through 55-14 and provide any authoritative support.**

We respectfully acknowledge the Staff’s comments and provide the information set forth below in response. For your convenience, each bullet of the Staff’s comment is reproduced in bold, italicized type below, followed by the Company’s responses thereto.

1. ***Tell us how you applied ASU 2018-18 to determine that part of the agreement should not be accounted for under ASC 606. In this respect, tell us why the collaborative partner is not considered a customer within the unit of account under ASU 2018-18 that would be required to be accounted for under ASC 606.***

The Company considered ASC 808-10-15-5B, ASC 606-10-15-03, ASC 606-10-25-19 through 25-22 to determine whether Roche is considered a collaborative partner or customer for all material distinct promised goods or services of the Roche pralsetinib collaboration agreement.

The Roche pralsetinib collaboration agreement consisted of four material components: (i) licenses granted to Roche to develop and commercialize pralsetinib worldwide, excluding the CStone territory (the “pralsetinib licenses”); (ii) the Roche territory-specific commercialization activities for pralsetinib, including manufacturing activities for the Roche territory; (iii) the parties’ joint development activities for pralsetinib worldwide, excluding the CStone territory; and (iv) the parties’ joint commercialization activities for pralsetinib in the U.S.

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License Grants

Under the Roche pralsetinib collaboration agreement, the Company granted Roche licenses to develop and commercialize pralsetinib in the Roche territory and the Shared Territory. In making the determination as to whether the licenses of intellectual property under the Roche pralsetinib collaboration agreement are distinct, specifically whether the licenses are capable of being distinct, we assessed whether Roche could benefit from the licenses on its own or together with other resources that are readily available to Roche. For the duration of the license period, the chemical composition of the active pharmaceutical ingredient, pralsetinib, is unable to be unilaterally changed and the functionality of the intellectual property that was delivered upon execution of the collaboration agreement is not expected to change. Upon execution of the collaboration agreement, Roche obtained the right to jointly develop pralsetinib with the Company in the Territory, including conducting clinical studies and, subject to regulatory approval, commercializing pralsetinib. In addition, these licenses granted to Roche include an exclusive license to develop, manufacture and commercialize pralsetinib in the Roche territory, and Roche became responsible for all future development of pralsetinib for any Roche territory-specific clinical trials outside the U.S. and for commercializing pralsetinib in the Roche territory, as well as any risks associated with those activities. Upon receipt of the licenses, which included all the clinical and manufacture data as submitted to the U.S Food and Drug Administration (“FDA”) and the European Medicines Agency (“EMA”), Roche obtained all the know-how of pralsetinib and had the ability to benefit from each license with resources readily available to it. Roche is a mature, fully-integrated pharmaceutical company that has the knowledge and expertise for global drug development, manufacturing and commercialization. We believe Roche could fully benefit from the licenses and intellectual property that it obtained control of upon executing the collaboration agreement.

As part of the collaboration agreement, the Company agreed to manufacture and supply to Roche pralsetinib for development and commercialization purposes for activities conducted in the Roche territory for up to 24 months following the execution of the collaboration agreement. The Company does not own or operate, and currently does not have any plans to own or operate, any manufacturing facilities anywhere in the world, and therefore, the Company currently sources all of raw material supply as well as the manufacturing of clinical and commercial supplies of pralsetinib through third party contract manufacturing organizations (“CMOs”). The resources required for manufacture of the drug are readily available in the marketplace and the manufacturing process used to produce the drug does not require unique or specialized technology. The formulation of the active pharmaceutical ingredient and drug product is outlined in the patents for pralsetinib and could be reproduced by either Roche or third-party CMOs with the licenses granted. In addition, details related to the manufacture of pralsetinib are documented in the manufacturing data, as submitted to the FDA and EMA, which were made available to Roche upon execution of the collaboration agreement.

The licenses granted to Roche include the right to manufacture pralsetinib for use in the Roche territory, and Roche is obligated to take control over the manufacturing of pralsetinib for the Roche territory within 24 months of the execution of the collaboration agreement. During the transition period, Roche will purchase pralsetinib from the Company for clinical and, if approved, commercial use in the Roche territory. Because the process used to manufacture pralsetinib does not require unique or specialized technology and can be reproduced by Roche or third-party CMOs who could then supply pralsetinib to Roche, we concluded that the criterion in ASC 606-10-25-19(a) was met for the licenses to be distinct. These facts closely align with those outlined in ASC 606-10-55-371, in which the license was determined to be distinct.

The Company also assessed whether the licenses were separately identifiable from the other promises in the Roche pralsetinib collaboration agreement pursuant to ASC 606-10-25-19(b). Neither the licenses nor the supply of pralsetinib is significantly modified or customized by the other, and the Company is not providing a significant service of integrating those items into a combined output. The licenses and the supply of pralsetinib are not interdependent or interrelated, as the Company was able to fulfill its promise to transfer control over the license to Roche independent of fulfilling the Company’s promise to subsequently supply pralsetinib. Importantly, the subsequent supply of pralsetinib did not modify or customize the initial licenses that were conveyed. In addition, the supply of pralsetinib represented a distinct good that is sold separately with separate pricing and conditions consistent with the terms outlined in the Roche pralsetinib collaboration agreement.

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Therefore, as a result of the combination of the following, we concluded that the licenses were distinct from the supply of pralsetinib, and that the licenses have standalone value as Roche could benefit from the license upon contract inception: (1) the manufacturing technology not being unique and specialized and being readily able to be reproduced by Roche or third party CMOs with licenses granted; (2) the collaboration agreement conveying the license rights to manufacture pralsetinib; (3) Roche having the ability to assume control of the manufacturing rights at its sole discretion within the 24 months transition period; and (4) that neither the license grants nor supply of pralsetinib are significantly modified or customized by the other.

We had previously granted licenses to CStone and other third parties in exchange for cash consideration. Therefore, we determined that providing licenses of intellectual property is part of our ordinary activities, and we had a vendor-customer relationship with Roche for the license grants component.

Roche Territory-Specific Commercialization Activities

For the Roche territory-specific commercialization activities, we licensed to Roche the rights to develop, manufacture and commercialize pralsetinib in the Roche territory, as described above. Roche is responsible for commercializing pralsetinib throughout the Roche territory at its sole cost and expense, including responsibility for promoting, marketing and distributing pralsetinib in the Roche territory, and Roche has final decision-making authority with respect to the development and commercialization in the Roche territory. The Company is eligible to receive milestone payments, royalties on sales of licensed products outside the U.S. and the reimbursement by Roche of specified expenses incurred by the Company with respect to the Roche territory, including reimbursement of manufacturing costs for both commercial and clinical supplies, which represented a customer option at the inception of the arrangement and were evaluated and determined not to be a separate material right. Our participation in the joint committees established under the Roche pralsetinib collaboration agreement is a means to protect our interests in the collaboration. The Company and Roche do not jointly share the risk and rewards of the activities conducted in the Roche territory, and we determined that we have a vendor-customer relationship with Roche for activities conducted exclusively for the Roche territory.

Joint Development Activities

Pursuant to the collaboration agreement, the Company and Roche have agreed to jointly develop pralsetinib in the Territory to expand the indications for which we have received or plan to seek marketing approval. The Company and Roche will initially share global development costs for pralsetinib at a rate of 45 percent and 55 percent, respectively, up to a specified amount of aggregate joint development costs, after which the Company's share of global development costs for pralsetinib will be reduced by a specified percentage. As part of the joint development activities, we are responsible for conducting certain studies planned to be performed under the Roche pralsetinib collaboration agreement, and Roche is responsible for conducting the remaining studies. Both parties jointly participate in the joint committees to determine the development plan and oversee the operation of the studies. The Company does not view its execution of joint development activities in the Territory as performing services on Roche's behalf, and in the context of the unit-of-account, Roche has not contracted with the Company to obtain goods or services that are an output of the Company's ordinary activities in exchange for consideration. Therefore, the Company does not have a vendor-customer relationship with Roche with respect to the joint development activities in the Territory for the purpose of ASC 606. Because the development of pralsetinib represents a joint operating activity, wherein both parties meet the requirements of active participation under ASC 808, and both parties are exposed to significant risks and rewards of the economics of the development activities, we concluded that the activities associated with the joint development activities for pralsetinib in the Territory are within the scope of ASC 808.

Joint Commercialization Activities

Pursuant to the collaboration agreement, in the Shared Territory, the Company and Roche have agreed to work together to co-commercialize pralsetinib and equally share profits and losses for the co-commercialization activities. Both parties jointly participate in the joint committees to oversee and manage the medical affairs and

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commercial activities with respect to the co-commercialization activities of pralsetinib in the Shared Territory. The Company does not view its execution of co-commercialization activities in the Shared Territory as performing services on Roche’s behalf, and in the context of the unit-of-account, Roche has not contracted with the Company to obtain goods or services that are an output of the Company’s ordinary activities in exchange for consideration. Therefore, the Company does not have a vendor-customer relationship with Roche with respect to the co-commercialization activities in the Shared Territory for the purpose of ASC 606. Because the co-commercialization of pralsetinib represents a joint operating activity, wherein both parties meet the requirements of active participation under ASC 808, and both parties are exposed to significant risks and rewards of the economics of the activities, we concluded that the activities associated with the co-commercialization activities for pralsetinib in the Shared Territory are within the scope of ASC 808.

- 2. For the portion of the agreement you believe is outside ASC 606, clarify what authoritative literature you are using or what methodology you are using to account for the non-ASC 606 portion. Refer to ASC 808-10-45-3.***

We considered ASC 808-10-45-3 and ASC 808-10-55-3 through 55-14 to determine the appropriate methodology to account for the joint development activities and co-commercialization activities as outlined in the response above.

In the joint global development activities in the Territory, the Company and Roche reimburse each other’s share of specified development costs incurred by the parties. We have concluded that other authoritative accounting literature does not apply directly to these net receivables or payables to or from Roche, either directly or by analogy, including ASC 606, because Roche is not a customer for the components outside of ASC 606 as discussed above. When evaluating an appropriate analogy to other accounting guidance or an accounting policy for the joint research and development activities conducted in the Territory, we assessed our relationship with Roche, economics and nature of those global research and development activities conducted in the Territory and the contractual terms of the collaboration agreement. Based on this assessment, we concluded that, in accordance with our policy, accounting for research and development reimbursements received from Roche as a reduction of research and development expenses and net payments made to Roche associated with joint development activities as an increase in research and development expense best reflects the economics and nature of the transaction in the context of the unit-of-account. This presentation is analogous to the cost sharing described in the examples in ASC 808-10-55-7 through 55-14, which is accounted for as a reduction of research and development expense in the period incurred.

For the co-commercialization activities in the Shared Territory, the Company and Roche share equally the costs of co-commercialization activities incurred by each party. We have concluded that other authoritative accounting literature does not apply directly to these net receivables or payables to or from Roche, either directly or by analogy, including ASC 606, because Roche is not a customer for the components outside of ASC 606 as discussed above. When evaluating an appropriate analogy to other accounting guidance or an accounting policy for the joint commercialization activities conducted in the Shared Territory, we assessed our relationship with Roche, the economics and nature of the co-commercialization activities conducted in the Shared Territory, and the contractual terms of the collaboration agreement. Based on this assessment, we made an accounting policy election to account for amounts due from or owed to Roche based on nature of each separate activity. Please refer to response #4 below for details of the income statement classification associated with the co-commercialization activities in the Shared Territory.

- 3. Explain why the entire \$695.7 million was allocated to the components accounted for under ASC 606 and why some of the amount was not required to be allocated to the other material components of the agreement.***

We allocated the entire \$695.7 million to the components accounted for under ASC 606 but not ASC 808 based on the nature of the Roche pralsetinib collaboration agreement and the development phase of pralsetinib at the time of execution of the collaboration agreement. With respect to the development phase of pralsetinib, prior to the execution date of the collaboration agreement:

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- The Company completed the submission of a rolling new drug application (“NDA”) with the FDA for pralsetinib for the treatment of patients with RET fusion-positive non-small cell lung cancer (“NSCLC”) in the first quarter of 2020, and the Company completed the submission of an NDA for pralsetinib for the treatment of patients with advanced or metastatic RET mutant medullary thyroid cancer and RET fusion-positive thyroid cancers in the second quarter of 2020.
- On September 4, 2020, the FDA approved pralsetinib for the treatment of adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA approved test, and on December 1, 2020, the FDA approved pralsetinib for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant MTC who require systemic therapy or with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
- In the second quarter of 2020, the Company completed the submission to the EMA of a marketing authorization application for pralsetinib for RET fusion-positive NSCLC.

The joint development activities with Roche include the development of pralsetinib for additional indications and for indications for which we have not yet received marketing approval. The Company and Roche will share development costs for pralsetinib at a rate of 45 percent for the Company and 55 percent for Roche up to a specified amount of aggregate joint development costs, after which the Company’s share of development costs for pralsetinib will be reduced by a specified percentage. In the Shared Territory, the Company and Roche have agreed to work together to co-commercialize pralsetinib and equally share profits and losses for the co-commercialization activities.

The purpose of the entire \$695.7 million paid by Roche is to obtain license grants to the intellectual property related to pralsetinib and the right to participate in any future economics that pralsetinib could generate in the Roche Territory and the Shared Territory, but not to pre-fund any future development or commercialization activities. Cost incurred for future development activities in the Territory or commercialization activities in the Shared Territory will be shared based on the percentage as outlined in the Roche pralsetinib collaboration agreement. Upon execution of the collaboration agreement, Roche received the license grants for the intellectual property rights and the right to participate in any future economics that pralsetinib could generate. As a result, the entire \$695.7 million was allocated to components accounted for under ASC 606.

As discussed above, there are two components accounted for under ASC 606, the pralsetinib licenses and the Roche territory-specific commercialization activities for pralsetinib, including manufacturing activities in the Roche territory. For the pralsetinib licenses component, we identified one performance obligation, which is to transfer the licenses as outlined in the collaboration agreement to Roche. The licenses, including all the relevant know-how and data, were transferred to Roche upon the execution of the collaboration agreement. For the Roche territory-specific activities component, the Company determined that, for the purpose of ASC 606, the clinical and commercial supply of pralsetinib to Roche represents a customer option at the inception of the arrangement, but not a performance obligation. Roche is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company and the expected pricing was not issued at a significant and incremental discount. The potential supply of pralsetinib does not provide Roche with a material right in accordance with ASC 606-10-55-41 through 45. Therefore, the entire transaction price of \$695.7 million was only allocated to the licenses transferred.

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- 4. Please clarify the nature of the transition date discussed on page 17, why that date determines if you are the principal for the product sales, and if at that point, reimbursements will also be recorded as revenue. Clarify how the fact pattern compares to Example 3 in ASC 808-10-55-11 through 55-14 and provide any authoritative support.**

Pursuant to the Roche pralsetinib collaboration agreement, the transition date for booking of sales for pralsetinib in the Shared Territory is anticipated to be [***] (the “Transition Date”). Prior to the Transition Date, [***]. Following the Transition Date, [***].

ASC 606-10-55-36 provides guidance in determining whether an entity is a principal or an agent with respect to the satisfaction of a performance obligation. An entity is the principal if it controls the goods or services before they are transferred to the customer and if it controls the good or service prior to transferring control to the customer qualifies to recognize revenue on a gross basis. The definition of control per ASC 606-10-25 is the power to direct the use of and the ability to obtain substantially all of the benefits from the good or service. In addition, ASC 606-10-55-39 provides three indicators in determining whether an entity controls a good before it is transferred to a customer.

We determined that the Company is the principal of product sales for pralsetinib in the Shared Territory prior to the Transition Date based on assessment of the three indicators. The first indicator is that the Company is the party responsible for fulfilling the promise to provide pralsetinib to customers because the Company is (i) the party to contracts with wholesalers and specialty pharmacies, (ii) the direct contact to resolve any operations issues with the customers, (iii) the party to contracts with government agencies for government programs and to submit government pricing reports and (iv) the party to establish credit limits for new customers and approve credit overrides. The second indicator is inventory risk, and the Company is the party to contract with CMOs and oversee the manufacturing process and resolve any operation and quality issues. In addition, the Company is the party to contract with third-party logistic providers to manage the distribution, warehousing and fulfillment of pralsetinib. The final indicator is discretion to establish prices. Prior to the Transition Date, [***]. Based upon the above factors, the Company controls pralsetinib prior to it being transferred to the customers. As a result, the Company is the principal in the transaction, qualifying for gross accounting treatment.

Following the Transition Date, Roche will be solely responsible for all activities related to booking of sales (including contracting with wholesalers and specialty pharmacies), pricing and distribution for pralsetinib in the Shared Territory and will control the products before they are transferred to the customers. Therefore, Roche will become the principal for product sales of pralsetinib to customers in the Shared Territory following the Transition Date. The Company will recognize its portion of shared profits (losses) as revenues (expenses) from the collaboration arrangement in the Company’s consolidated statements of operations in accordance with the examples in ASC 808-10-55-7 through 55-14, which the portion of the net receivables (payables) related to the profit sharing recorded as revenues (expenses) from collaborative arrangement:

As a result, Little Pharma disaggregates its \$4.75 million net payable to Big Pharma in accordance with the nature of the individual item and characterizes a portion of the net payable related to 35 percent of the profit related to the sales in the United States as expenses from collaborative arrangement (\$22.75 million) and characterizes the portion of the net payable to Big Pharma for research and development activities as research and development expenses. Little Pharma concludes that the portion of the net payable directly related to profit sharing from Big Pharma’s third-party sales in Europe and Asia is analogous to a royalty and therefore should characterize the \$10.5 million as revenue similar to a royalty.

When determining the appropriate financial statement presentation for the profit (loss) sharing of the commercialization activities in the Shared Territory prior to the Transition Date, we considered examples in ASC 808-10-55-7 through 55-14. Similar to principals in the examples, the Company is the principal for product sales of pralsetinib with third parties and presents 100% of such product sales, cost of sales and marketing expenses that are incurred by the Company in its income statements. We concluded that other authoritative accounting literature does not apply directly to these net receivables from Roche, either directly or by analogy, including ASC 606 because

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Roche is not a customer for the components outside of ASC 606 as discussed above. We recorded the net receivable from Roche in accordance with the nature of the individual components of the receivable and characterized the portion of the receivable related to 50% of the commercialization activities (sales to third parties less associated manufacturing and marketing costs) as a reduction of our selling, general and administrative (“SG&A”) expenses because it is similar to a reimbursement of SG&A expenses from Roche.

Revised Disclosure in Future Periodic Reports

To further enhance the Company’s disclosure related to the accounting treatment for the Roche pralsetinib collaboration agreement, starting with the Company’s Form 10-K for the fiscal year ended December 31, 2020, the Company intends to modify the disclosures in its future periodic reports as set forth on Appendix B attached to this letter.

Management’s Discussion and Analysis

Financial Operations Overview

Cost of Sales, page 34

3. **You state on page 10 that until the date at which regulatory approval has been received or is otherwise considered probable, you record all costs as research and development expenses. You disclose on page 34 that cost of sales for newly launched products will not be significant until the initial pre-launch inventory is depleted, and additional inventory is manufactured. You also state that the gross margin was enhanced by amounts previously expensed as research and development expense in prior year. Please provide proposed disclosure to include in future filings to address the following:**
- **the amount of estimated revenues represented by inventory on hand at September 30, 2020 for which manufacturing costs were expensed in prior periods as research and development expenses (i.e. "zero cost inventories"),**
 - **when you expect to finish selling the zero cost inventories,**
 - **the extent to which inventory capitalized may be required to be classified as noncurrent, and**
 - **what you estimate your gross margin percentage will be after the zero cost inventories are sold.**

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

- **the amount of estimated revenues represented by inventory on hand at September 30, 2020 for which manufacturing costs were expensed in prior periods as research and development**

At September 30, 2020, the Company had inventory on hand for AYVAKIT™ (avapritinib) and GAVRETO™ (pralsetinib) consisting of filled drug product bottles and unbottled tablets, which based on current sales trends and forecasts for our approved indications, the Company currently anticipates will be sold over a period of approximately two to three years. The assumptions for AYVAKIT could be impacted by the potential approval of the Company’s recent supplemental new drug application for the treatment of advanced systemic mastocytosis, which was submitted to the FDA in December 2020. In addition, the assumptions for GAVRETO will be impacted upon transition of activities under the Roche pralsetinib collaboration agreement. Upon the transition of activities under the collaboration agreement, Roche will be the principal for product sales of pralsetinib to customers in the Shared Territory and therefore, the Company will no longer record cost of sales directly for this product. In addition, upon approval outside the U.S., Roche will be the principal for product sales of pralsetinib to customers in the Roche Territory and will also record the associated cost of sales. As a result of the uncertainty around the foregoing assumptions, the Company does not believe the estimated revenues represented by inventory on hand is a meaningful figure to disclose and did not include it in the revised disclosure noted below.

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The Company also holds significant quantities of raw materials and API in inventory that it classifies as work in process, which are not included in the estimated selling period above, as both the raw materials and API require a significant amount of further processing to be transformed into finished goods. The Company had enough inventory of raw materials and API on hand at September 30, 2020 to meet customer sales demand for the foreseeable future, and the Company believes it is well-positioned with existing third party CMOs to further process this material and produce additional finished goods, as needed. The API for both products has an initial shelf life of 36 months from the date of manufacture. The API can be retested after the initial 36-month period and, if it passes retesting, used in the next stage of manufacturing. Therefore, based on the Company’s past experience with API tested after the initial 36 month period, we do not expect to deplete our zero cost inventory of raw materials or API or deem them obsolete for an extended period of time.

- **when you expect to finish selling the zero cost inventories**

At September 30, 2020, the Company had inventory on hand for AYVAKIT and GAVRETO consisting of filled drug product bottles and unbottled tablets, which based on current sales trends and forecasts for our approved indications, the Company currently anticipates will be sold over a period of approximately two to three years. As discussed above, based on the uncertainty around the Company’s assumptions, the Company does not believe the expected date for which it expects to finish selling the zero cost inventories is a meaningful figure to disclose and did not include it in the revised disclosure noted below.

- **the extent to which inventory capitalized may be required to be classified as noncurrent**

The Company believes that approximately 30% of its inventory balance at September 30, 2020 should be classified as non-current based on the current demand assumptions. The Company believes this amount is not material to its financial statements as it represents less than 1% of the Company’s total assets at September 30, 2020. In future filings, the Company plans to classify these balances as non-current.

- **what you estimate your gross margin percentage will be after the zero cost inventories are sold**

The Company estimates that once zero cost inventories are fully sold, the manufacturing costs for AYVAKIT will be less than [***]% of total net product revenue. As discussed above, following the Transition Date under the Roche pralsetinib collaboration agreement, Roche will be the principal for product sales of GAVRETO to customers in the Shared Territory, and effective upon signing of the collaboration agreement, Roche was the principal for product sales of GAVRETO to customers in the Roche territory.

Revised Disclosure in Future Periodic Reports

To address the foregoing comment, starting with the Company’s Form 10-K for the fiscal year ended December 31, 2020, the Company intends to modify its disclosures in future periodic reports as set forth on Appendix C attached to this letter.

* * *

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Due to the commercially sensitive nature of information contained in this letter, this submission is accompanied by the Company’s request for confidential treatment for selected portions of this letter. The Company has filed a separate letter with the Office of Freedom of Information and Privacy Act Operations in connection with the confidential treatment request, pursuant to Rule 83 of the Commission’s Rules on Information and Requests, 17 C.F.R. § 200.83. For the Staff’s reference, we have enclosed a copy of the Company’s letter to the Office of Freedom of Information and Privacy Act Operations as well as a copy of this correspondence, marked to show the portions redacted from the version filed via EDGAR and for which the Company is requesting confidential treatment.

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 contact the undersigned (MLandsittel@blueprintmedicines.com or 617-714-6676), Christopher Frankenfield, Vice President, Corporate Legal Affairs of Blueprint Medicines (cfrankenfield@blueprintmedicines.com or 617-714-6712), or Ariel Hurley, Vice President, Finance and Controller, and Chief Accounting Officer of Blueprint Medicines (AHurley@blueprintmedicines.com or 617-714-6695).

Sincerely,

/s/ Michael Landsittel

Michael Landsittel

Chief Financial Officer

cc: Tracey McCain, Executive Vice President & Chief Legal Officer, *Blueprint Medicines Corporation*
Ariel Hurley, Vice President, Finance and Controller, and Chief Accounting Officer, *Blueprint Medicines Corporation*
Christopher Frankenfield, Vice President, Corporate Legal Affairs, *Blueprint Medicines Corporation*
Danielle Lauzon, *Goodwin Procter LLP*

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Appendix A

The modified disclosures referenced in the Company’s response are set forth below in tracked changes and are based on the Company’s Form 10-K for the period ended December 31, 2019:

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently. The Company evaluates the income statement classification for presentation of amounts due from or owed to other participants associated with multiple activities in a collaboration arrangement based on the nature of each separate activity, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenues as such amounts are incurred by the collaboration partner. Where amounts owed to a collaboration partner exceed the Company’s collaboration revenues in each quarterly period, such amounts are classified as research and development expense. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

* * * * *

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Appendix B

The modified disclosures referenced in the Company’s response are set forth below in tracked changes and are based on the Company’s Form 10-Q for the period ended September 30, 2020:

Roche – Pralsetinib Collaboration

On July 13, 2020, the Company entered into a collaboration agreement (the Roche pralsetinib collaboration agreement) with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively, Roche), pursuant to which the Company granted Roche exclusive rights to develop and commercialize the Company’s drug candidate pralsetinib worldwide, excluding the CStone territory (as defined below), and a co-exclusive license in the U.S. to develop and commercialize pralsetinib. In addition, Roche has the right to opt in to a next-generation RET compound co-developed by the Company and Roche.

Under the Roche pralsetinib collaboration agreement, the Company received an upfront cash payment of \$675.0 million in the third quarter of 2020. In addition, the Company is eligible to receive up to \$927.0 million in contingent payments, including specified development, regulatory and sales-based milestones for pralsetinib and any licensed product containing a next-generation RET compound. During the three months ended September 30, 2020, as a result of initial U.S. marketing approval for GAVRETO, the Company achieved \$40.0 million in specified regulatory and commercialization milestones.

In the U.S., the Company and Roche will work together to co-commercialize pralsetinib and will equally share responsibilities, profits and losses. In addition, the Company is eligible to receive tiered royalties ranging from high-teens to mid-twenties on annual net sales of pralsetinib outside the U.S., excluding Greater China (the Roche territory). The Company and Roche have also agreed to co-develop pralsetinib globally in RET-altered solid tumors, including non-small cell lung cancer, medullary thyroid carcinoma and other thyroid cancers, as well as other solid tumors. The Company and Roche will share global development costs for pralsetinib at a rate of 45 percent for the Company and 55 percent for Roche up to a specified amount of aggregate joint development costs, after which the Company’s share of global development costs for pralsetinib will be reduced by a specified percentage. The Company and Roche will also share specified global development costs for any next-generation RET compound co-developed under the collaboration in a similar manner.

Unless earlier terminated in accordance with its terms, the Roche pralsetinib collaboration agreement will expire on a licensed product-by-licensed product basis (i) in the U.S. upon the expiration of the gross profit sharing term for such licensed product and (ii) outside the U.S. on a country-by-country basis at the end of the applicable royalty term for such licensed product. Roche may terminate the agreement in its entirety or on a licensed product-by-licensed product or country-by-country basis subject to certain notice periods. Either party may terminate the Roche pralsetinib collaboration agreement for the other party’s uncured material breach or insolvency. Subject to the terms of the Roche pralsetinib collaboration agreement, effective upon termination of the agreement, the Company is entitled to retain specified licenses to be able to continue to exploit the licensed products.

In connection with the Roche collaboration agreement, on July 13, 2020, the Company also entered into a stock purchase agreement with Roche Holdings, Inc. (Roche Holdings) pursuant to which the Company issued and sold an aggregate of 1,035,519 of shares of common stock to Roche Holdings at a purchase price of \$96.57 per share and received \$100.0 million in the third quarter of 2020. The closing for a minority portion of the equity investment occurred following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions.

The Company considered the ASC 606 criteria for combining contracts and determined that the Roche pralsetinib collaboration agreement and stock purchase agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The Company accounted for the common stock issued to Roche Holdings based on the fair market value of the common stock on the dates of issuance. The fair market value of the common stock issued to Roche Holdings was \$79.3 million, based on the closing price of

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the Company's common stock on the dates of issuance, resulting in a \$20.7 million premium. The Company determined that the premium paid by Roche Holdings for the common stock should be attributed to the transaction price of the Roche pralsetinib collaboration agreement.

The Company determined that the Roche pralsetinib collaboration agreement contained four material components: (i) licenses granted to Roche to develop and commercialize pralsetinib worldwide, excluding the CStone territory (pralsetinib license); (ii) the Roche territory-specific commercialization activities for pralsetinib, including manufacturing Roche territory activities; (iii) the parties' joint development activities for pralsetinib worldwide, excluding the CStone territory; and (iv) the parties' joint commercialization activities for pralsetinib in the U.S. The Company considered the guidance in ASC 606 to determine which of the components of the Roche pralsetinib collaboration agreement are performance obligations with a customer and concluded that the pralsetinib license and the Roche territory activities are within the scope of ASC 606 because the Company is not exposed to significant risks and rewards, and Roche is a customer with regard to those components.

The Company evaluated the Roche pralsetinib license under ASC 606 and concluded that the pralsetinib license is a functional intellectual property license and is a distinct performance obligation. ~~The transaction price for the pralsetinib license was determined to be \$695.7 million, which consisted of the upfront cash payment of \$675.0 million and the \$20.7 million premium on the sale of common stock to Roche Holdings. The Company determined that Roche benefited from the pralsetinib license at the time of grant, and therefore the related performance obligation is satisfied at a point in time. During the three months ended September 30, 2020, as a result of initial U.S. marketing approval for GAVRETO, the Company achieved \$40.0 million in specified regulatory and commercialization milestones and added the \$40.0 million to the estimated transaction price of the Roche pralsetinib agreement. The other potential milestone payments that the Company is eligible to receive under the Roche pralsetinib agreement have been excluded from the transaction price, as all the remaining milestone amounts were fully constrained based on the probability of achievement. The Company will reevaluate 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, the Company will adjust its estimate of the transaction price, and any addition to the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal.~~

The Company evaluated the Roche territory activities under ASC 606 and identified one material promise associated with manufacturing activities related to development and commercial supply of pralsetinib in the Roche territory for a period up to 24 months. Given that Roche is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company, the Company concluded that, for the purpose of ASC 606, the provision of manufacturing activities related to development and commercial supply of pralsetinib in Roche territory was an option but not a performance obligation of the Company at the inception of the Roche collaboration agreement and will be accounted for if and when exercised, for the purpose of ASC 606. The Company also concluded that there is no separate material right in connection with the development and commercial supply of pralsetinib, as the expected pricing was not issued at a significant and incremental discount, and do not provide Roche with any material rights. Therefore, the manufacturing activities were excluded as performance obligations at the outset of the arrangement. Additionally, the Company is entitled to sales milestones and royalties from Roche upon future sales of pralsetinib in the Roche territory, and revenue will be recognized when the related sales occur. Costs that are incurred associated with the Roche territory activities are reimbursable from Roche and will be recognized as collaboration revenue.

For purposes of ASC 606, the transaction price of the Roche collaboration agreement as of the outset of the arrangement was determined to be \$695.7 million, which consisted of the upfront cash payment of \$675.0 million and the \$20.7 million premium on the sale of common stock to Roche Holdings, which was allocated to the performance obligation related to the pralsetinib licenses. During the three months ended September 30, 2020, as a result of initial U.S. marketing approval for GAVRETO, the Company achieved \$40.0 million in specified regulatory and commercialization milestones and added the \$40.0 million to the estimated transaction price of the Roche pralsetinib agreement. The other potential milestone payments that the Company is eligible to receive under the Roche pralsetinib agreement have been excluded from the transaction price, as all the remaining milestone

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amounts were fully constrained based on the probability of achievement. The Company will reevaluate 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, the Company will adjust its estimate of the transaction price, and any addition to the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal.

The following table summarizes revenue recognized under the Roche pralsetinib collaboration during the ~~three and nine months years~~ ended ~~September 30~~ December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,	
	2020	2019
Upfront license revenue	\$ —	\$ XX,XXX
License milestone revenue	\$ —	\$ XX,XXX
Services related to Roche territory-specific activities	\$ —	\$ XX,XXX
Total Roche pralsetinib collaboration revenue	<u>\$ —</u>	<u>\$ XX,XXX</u>

For the parties’ participation in global development for pralsetinib and the U.S. commercialization activities for GAVRETO, the Company concluded that those activities and cost-sharing payments related to such activities are within the scope of ASC 808, as both parties are active participants in the development, manufacturing and commercialization activities and are exposed to significant risks and rewards of those activities under the Roche pralsetinib collaboration agreement. Payments to or reimbursements from Roche related to the global development activities will be accounted for as an increase to or reduction of research and development expenses. Prior to the ~~transition date as defined in the Roche pralsetinib collaboration agreement~~ to Roche of specified responsibilities associated with product sales to customers, pricing and distribution matters in the U.S., the Company is the principal for product sales to customers in the U.S. and will recognize revenues on sales to third parties in product revenue, net in its consolidated statements of operations. After such transition, Roche ~~will be~~ take over the responsibilities associated with product sales to customers, pricing and distribution matters for GAVRETO in the U.S. and become the principal for product sales to customers in the U.S., and the Company will recognize its portion of the commercial profits and losses sharing as revenue (expenses) from the collaboration arrangement in its consolidated statements of operations.

During the three and nine months ended September 30, 2020, the Company recorded a \$5.3 million reduction in selling, general and administrative expenses in connection with the commercialization of GAVRETO in the U.S. and a \$9.7 million reduction in research and development expenses in connection with global development activities for pralsetinib.

The following table summarizes the contract assets associated with the Roche pralsetinib collaboration as of ~~September 30~~ December 31, 2020 and ~~December 31~~, 2019 (in thousands):

	December 31, 2020	December 31, 2019
Accounts receivable, net	\$ XX,XXX	\$ —
Unbilled accounts receivable	\$ XX,XXX	\$ —

* * * * *

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Appendix C

The modified disclosures referenced in the Company’s response are set forth below in tracked changes and are based on the Company’s Form 10-Q for the period ended September 30, 2020:

MD&A – Results of Operations

Cost of Product Sales

Cost of product sales was ~~\$X.X0.1~~ million for the year ~~three months~~ ended ~~December 31, September 30,~~ 2020 and was related to manufacturing costs associated with our products sales. ~~Costs associated with the manufacture of our products prior to FDA approval were expensed and, therefore, are not included in cost of sales during the current period. Prior to receiving FDA approval for AYVAKIT and GAVRETO in January 2020 and September 2020, respectively, we manufactured inventory to be sold upon commercialization and recorded approximately \$XX.X million related to this inventory as research and development expense. As a result, the manufacturing costs related to the inventory build-up incurred before FDA approval were expensed in a prior period and are therefore excluded from the cost of goods sold for the year ended December 31, 2020. We estimate our cost of goods sold as a percentage of net product revenue will continue to be positively impacted as we sell through certain inventory that was previously expensed prior to FDA approval. We expect to utilize zero cost inventory for an extended period of time.~~

Notes to Consolidated Financial Statements

Inventory

Capitalized inventory consists of the following at December 31, 2020 and December 31, 2019 (in thousands):

	December 31, 2020		December 31, 2019	
Raw Materials	\$	X,XXX	\$	—
Work in process		X,XXX		—
Finished goods		X,XXX		—
Total	\$	X,XXX	\$	—

Balance sheet classification

	December 31, 2020		December 31, 2019	
Inventory	\$	X,XXX	\$	—
Other assets		X,XXX		—
Total	\$	X,XXX	\$	—

Long-term inventory, which primarily consists of work in process, is included in other assets in our consolidated balance sheets.

* * * * *

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