

October 5, 2021

Via EDGAR and FedEx

Ms. Jeanne Baker  
Mr. Terence O'Brien  
United States Securities and Exchange Commission  
Division of Corporation Finance  
Office of Life Sciences  
100 F Street, NE Washington, DC 20549

**Re: Neurocrine Biosciences, Inc.**

**Form 10-K for the fiscal year ended December 31, 2020, filed February 5, 2021**

**Form 8-K filed August 3, 2021**

**Form 8-K filed February 4, 2021**

**File No. 000-22705**

Ladies and Gentlemen:

This letter is being transmitted by Neurocrine Biosciences, Inc. (the "**Company**") in response to comments received from the staff (the "**Staff**") of the Securities and Exchange Commission (the "**SEC**"), by letter dated September 22, 2021 (the "**Comment Letter**"), with respect to the Company's (i) Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "**10-K**"), (ii) Current Report on Form 8-K filed on August 3, 2021 (the "**August 8-K**") and (iii) Current Report on Form 8-K filed on February 4, 2021 (the "**February 8-K**"). The text of the Staff's comments has been included in this letter in italics for your convenience, and we have numbered the paragraphs below to correspond to the numbering of the Comment Letter.

*Form 10-K for the Fiscal Year Ended December 31, 2020*

*Management's Discussion and Analysis  
Research and Development, page 54*

1. *We have the following comments on your research and development disclosures:*
  - *Please disclose the costs incurred during each period presented for each of your key research and development programs. If you do not track your research and development costs by program, please disclose that fact and explain why you do not maintain and evaluate research and development costs by program;*
  - *Notwithstanding the above bullet, we note that you separately present milestone payments, payroll and benefits, and facilities and other expenses. Given that these costs are separately presented, please explain the nature of the costs you include in the Late, Early and Research and discover stages; and*
  - *Please expand upon your statement that the increase in R&D expense from 2019 to 2020 was primarily the result of increased investment to support advancing your clinical portfolio to provide greater insight into the drivers of this increased investment.*

**Response:** With respect to the first part of Comment #1, the Company is supplementally providing to the Staff under separate cover a summary of the costs incurred during each period presented for each of the Company's key research and development programs.

In addition, the Company respectfully advises the Staff that in recent years, the Company has shifted its business strategy as a result of migrating from a research and development ("**R&D**") only company with only a few clinical development programs to a commercial and R&D enterprise with a substantially different business and financial profile. As a result of this business profile change, the Company's R&D strategy has expanded from out-licensing certain of its internally developed compounds to focusing on continued internal R&D and selectively acquiring rights to programs, primarily mid-to-late stage, development and commercial products to take advantage of its drug development and commercial capabilities. More specifically, since 2017 the Company's clinical development pipeline has expanded from 3 to 12 clinical development programs. To manage its expanded clinical development pipeline and enterprise risk profile, the Company takes a portfolio approach that balances the size of the market opportunities with clear and defined clinical and regulatory paths to approval.

Although the Company tracks its external R&D costs by development program, the Company evaluates such costs by development stage to make operating and business development decisions assessing capital and resource allocation decisions. The Company believes its pipeline is better evaluated by development stage as each stage of development reflects a distinct level of cost and risk profile. For example, early-stage programs carry more risk and require more time until commercialization, while late-stage programs are further along in development but require a more significant level of investment.

A summary of how the Company allocates R&D costs by development stage is described under the response to the second part of Comment #1 below.

With respect to the second part of Comment #1, the Company respectfully advises the Staff that for each of the Company's R&D programs, the Company incurs both external and internal expenses. External development expenses consist of costs in the Late, Early and Research and Discovery development stages and include costs incurred for clinical and non-clinical activities (such as those performed by contract research organizations and collaboration partners), scientific consulting fees, laboratory services, purchases of clinical trial drug product materials and third-party manufacturing development costs. The Company does not allocate milestone expenses to allow for a clearer view of normal, recurring R&D expense trends. Internal R&D expenses consist of payroll and benefits expenses, facilities expense, and other indirect R&D expenses incurred in support of overall R&D activities and as such are not allocated to a specific development stage.

In addition, the Company respectfully advises the Staff that a description of Research and Development Expenses is included in Note 1 to Company's Consolidated Financial Statements. Specifically, the Company directs the Staff's attention to the following disclosure contained on page 73 of the 10-K:

**“Research and Development Expenses.** *R&D expenses consist primarily of salaries, payroll taxes, employee benefits and share-based compensation charges for those individuals involved in ongoing R&D efforts; as well as scientific consulting fees, preclinical and clinical trial costs, R&D facilities costs, laboratory supply costs and depreciation of scientific equipment. All such costs are charged to R&D expense as incurred. These expenses result from our independent R&D efforts, as well as efforts associated with collaborations, in-licenses and third-party funded research arrangements, including event-based milestones.”*

To address the Staff's comment, the Company commits that, to the extent applicable, it will disclose the nature of the costs included in the Late, Early and Research and Discovery development stages in the Management's Discussion and Analysis section in its future 10-Q and 10-K filings with the SEC. To facilitate the Staff's review, attached as Exhibit A to this letter is an example of such modified disclosures based on the 10-K.

With respect to the third part of Comment #1, the Company respectfully advises the Staff that the increase in R&D expense from 2019 to 2020 was primarily due to the increased investment to support the Company's research and discovery programs and advancing clinical portfolio, including increased investment in the Company's (i) Phase III programs in congenital adrenal hyperplasia for adults and for pediatric patients, and continued enrollment of the Company's Phase III Huntington Disease trial, and (ii) the Company's early-stage programs, including three in-licensed psychiatry clinical development programs in mid-2020 and advancement of the Company's two in-licensed epilepsy programs which began at the end of 2019. The Company commits that, to the extent applicable, the Company will provide expanded disclosure related to changes in R&D expenses in its future 10-Q and 10-K filings with the SEC.

Form 8-K filed August 3, 2021

Exhibit 99.1, page 1

2. *We note that you have excluded milestone payments received from licenses and collaborations, milestones paid related to licenses and collaborations, non-cash collaboration revenue and acquired in-process research and development to arrive at non-GAAP net income and non-GAAP income per share. We also note that you have excluded milestones paid related to licenses and collaborations to arrive at non-GAAP R&D. Please tell us your consideration of the guidance in Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretations for these adjustments. In this regard, you disclose in your Form 10-K that one of your business strategies is to utilize strategic alliances to enhance your development and commercialization capabilities. You also provide a risk factor which indicates that you depend on your current collaborators for the development and commercialization of several of your products and product candidates and may need to enter into future collaborations to develop and commercialize certain of your product candidates.*

**Response:** The Company acknowledges the Staff's comment and respectfully advises the Staff that the Company has reviewed the Compliance and Disclosure Interpretations on Non-GAAP Measures in responding to Comment #2.

The Company's policy is to supplement its GAAP consolidated financial statements and GAAP financial measures with other financial measures, such as non-GAAP R&D expense, non-GAAP SG&A expense, and non-GAAP net income and net income per share. These measures are referred to as "**Non-GAAP Financial Measures.**"

The Company believes that these Non-GAAP Financial Measures provide additional insight into the normal and recurring economics of the Company's business and reflect how the Company manages its business internally and sets operational goals. The Company acknowledges that Non-GAAP Financial Measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

The Company excludes from non-GAAP net income and non-GAAP income per share milestone payments received from licenses and collaborations, milestones paid related to licenses and collaborations, non-cash collaboration revenue and acquired in-process research and development ("**IPR&D**") expense. The Company excludes from Non-GAAP R&D expense milestones paid related to licenses and collaborations. These exclusions are collectively referred to as "**Non-GAAP Adjustments.**"

The Company believes that these Non-GAAP Adjustments differ from the normal, recurring, cash items necessary to operate its business. Below is a description of the Non-GAAP Adjustments:

- Receipt and payment of milestones are highly variable and unpredictable and obscures overall trends in the Company's normal and recurring R&D efforts and product revenues. To date, milestone revenues and expenses have been based upon the achievement of unpredictable milestones, such as the results of clinical trials and attainment of regulatory review and approval. This precludes reliable prediction of the timing and amount of milestone revenues and expenses. In contrast, normal and recurring R&D expenses relate to the Company's planned scientific endeavors, and such expenses and product revenues are predictable in nature. Exclusion of milestones allows the Company to present meaningful and comparable financial information to investors.
- IPR&D expenses differ from normal, recurring R&D expenses and are distorting in their impact on R&D expense trends. Collaborative and licensing agreements are strategic, and the Company enters into such agreements to enhance its development and commercialization capabilities. Upon entering into such agreements, the Company may incur IPR&D expenses, which consist of upfront payments made to acquire intangible assets in an asset acquisition for use in R&D activities which have no alternative future use on the acquisition date. Because upfront payments are highly negotiated based on numerous factors, including the fair value of the rights conveyed, there is typically no clear or consistent relationship between the amount of the upfront payment and the normal and recurring R&D expenses incurred under the associated collaboration arrangement. Such upfront payments are typically discrete, not tied to measurable events, and made at the onset of a relationship that may last many years.

The magnitude of these transactions is unusual for the Company. For example, IPR&D expenses that the Company adjusted for within its Non-GAAP Financial Measures for the twelve months ended December 31, 2018, 2019 and 2020 were approximately 3%, 44% and 37%, respectively, of the Company's total GAAP R&D expense for such periods. Exclusion of

these IPR&D expenses allows for a clearer view of normal, recurring R&D expense trends, which is relevant and useful to investors.

- Non-cash collaboration revenue is infrequent and distorting in its impact on revenue. Non-cash collaboration revenue for the periods presented in the August 8-K is related to the Company's collaboration with Mitsubishi Tanabe Pharma Corporation ("**MTPC**"). In March 2015, the Company entered into a collaboration and license agreement with MTPC, under which the Company out-licensed the development and commercialization rights for INGREZZA for movement disorders in Japan and other select Asian markets. Under the terms of the agreement, the Company received a \$30.0 million upfront payment, of which \$19.8 million, associated with the delivery of a technology license and existing know-how, was recognized as revenue upon entering the collaboration, and \$10.2 million of revenue was deferred in connection with the Company's continuing performance obligations under the collaboration.

Since entering into the collaboration with MTPC in March 2015, the Company has shifted its business strategy from out-licensing certain of its internally developed compounds to focus on selectively acquiring rights to programs at all stages of development and commercial products to take advantage of its drug development and commercial capabilities. Given the non-cash nature of the amounts involved and the Company's shift in business strategy, the Company believes adjusting for these amounts provides a more accurate measure of the Company's financial performance from direct business operations.

The Company does not believe the Non-GAAP Adjustments reflect normal, recurring revenues and expenses, as applicable, of its business or that such adjustments cause the presentation of its Non-GAAP Financial Measures to be misleading.

Form 8-K filed February 4, 2021

Exhibit 99.1

Full Year 2021 Expense Guidance, page 3

3. *We note that your Combined GAAP R&D and SG&A expenses do not include any potential milestones or in-process research and development costs associated with current collaborations or future business development activities. Given that these costs should not be excluded from your GAAP measure, please address the appropriateness of this presentation. Refer Item 10(e)(1)(B) and tell us how you intend to revise your disclosures.*

**Response:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it excludes such potential costs due to their uncertainty as the Company cannot ascertain the probability of achieving certain future milestones or acquiring certain future rights through asset acquisitions by way of upfront payments.

The completion of significant future collaboration and licensing arrangements and the associated upfront payments and milestones are highly variable and unpredictable. In addition, milestones associated with the Company's significant collaboration and licensing arrangements are often dependent on future clinical development progress of a program and/or subject to the achievement of regulatory review and approval. Accordingly, the probability of achievement

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cannot be readily determined prior to the achievement of such milestone event. These factors, among others, preclude reliable prediction of timing and amounts. Once significant collaboration and licensing arrangements have been completed or the associated milestones are probable of achievement or have been achieved, IPR&D expenses and milestones are included in the Company's Combined R&D and SG&A expense guidance.

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The Company further acknowledges that it is responsible for the accuracy and adequacy of its disclosures, notwithstanding any review, comments, action or absence of action by the Staff.

Please contact me at (858) 617-7642 with any questions or further comments regarding the Company's responses to the Staff's comments. Sincerely,

/s/ Matthew Abernethy

Matthew Abernethy  
Chief Financial Officer

cc: Darin Lippoldt, Chief Legal Officer  
Jason L. Kent, Cooley LLP

## Exhibit A

### *Research and Development, or R&D.*

We support our drug discovery and development efforts through the commitment of significant resources to discovery, R&D programs, and business development opportunities. We categorize R&D program-related expenses by development stage based upon the program status when the expense is incurred. Therefore, the same program could be reflected in different development stages in the same reporting period. R&D activities for several of our programs are part of our collaborative and other relationships. For each of our R&D programs, we incur both external and internal expenses. External development expenses consist of costs in the Late, Early and Research and Discovery development stages and include costs incurred for clinical and non-clinical activities (such as those performed by contract research organizations and collaboration partners), scientific consulting fees, laboratory services, purchases of clinical trial drug product materials and third-party manufacturing development costs. We do not allocate milestone expenses to allow for a clearer view of normal, recurring R&D expense trends. Internal R&D expenses consist of payroll and benefits expenses, facilities expense, and other indirect R&D expenses incurred in support of overall R&D activities and as such are not allocated to a specific development stage.

R&D expense categories consist of the following:

*Late Stage.* Consist of external costs incurred for product candidates in Phase II registrational studies and onwards.

*Early Stage.* Consist of external costs incurred for product candidates post-investigational new drug application through Phase II non-registrational studies.

*Research and Discovery.* Consist of external costs incurred pre-investigational new drug application.

*Milestone Expenses.* Consist of development and/or regulatory milestone expenses incurred in connection with our collaborative and other arrangements.

*Payroll and Benefits.* Consist of costs incurred for salaries and wages, payroll taxes, benefits and share-based compensation associated with employees involved in R&D activities. Share-based compensation may fluctuate from period to period based on factors that are not within our control, such as our stock price on the dates share-based grants are issued.

*Facilities and Other.* Consist of indirect costs incurred for the benefit of multiple programs, including management costs, depreciation, information technology and facility-based expenses.

The following table presents R&D expense by category:

<i>(in millions)</i>	<b>Year Ended December 31,</b>		
	<b>2020</b>	<b>2019</b>	<b>2018</b>
Late stage	\$ 55.1	\$ 43.7	\$ 14.2
Early stage	30.2	25.3	41.7
Research and discovery	43.3	24.6	17.0
Milestone payments	20.0	10.0	10.0
Payroll and benefits	95.4	71.3	62.0
Facilities and other	31.0	25.1	10.9
Total R&D expense	<u>\$ 275.0</u>	<u>\$ 200.0</u>	<u>\$ 155.8</u>