Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, DC 20549
Attn: Mary Mast and Daniel Gordon

Re: Applied Therapeutics, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2022
Filed March 23, 2023
Form 10-Q for the Nine Months Ended September 30, 2023
Filed November 9, 2023
File number 001-38898

Ladies and Gentlemen:

On behalf of Applied Therapeutics, Inc. (the "Company", "we," and "our"), set forth below is the Company's response to the comment letter dated December 7, 2023 provided by the staff of the Office of Life Sciences of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") to the Company regarding the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "Form 10-K"), filed on March 23, 2023 and the Company's Quarterly Report on From 10-Q for the nine months ended September 30, 2023, filed on November 9, 2023.

For the Staff's convenience, we have repeated the comment in full.

Form 10-Q for the Nine Months Ended September 30, 2023
Notes to the Financial Statements 15. Revenue License Agreement with Advanz Pharma, page 30

1. **You disclose on page F-32 of the 10-K that under the agreement with ADVANZ PHARMA you remain responsible for development of the Licensed Product, and must conduct such development in the Territory. You state that you retain sole responsibility for the conduct of all clinical trials (subject to cost sharing with ADVANZ PHARMA), unless the company provides ADVANZ PHARMA prior consent to conduct certain studies following marketing authorization, or ADVANZ PHARMA exercises certain step-in rights. The company is also responsible for the manufacture and supply of the Licensed Product to ADVANZ PHARMA. You state on page 31 of the 10-Q that you identified two performance obligations, the exclusive license to commercialize the Licensed Product, that was satisfied on the date of the execution of the ADVANZ Agreement when control of the license was transferred, and the obligation to manufacture and supply ADVANZ with the Product. Please address the following:**

- **Tell us why you have not identified the development of the Licensed Product and performance of the clinical trials as a performance obligation.**

The Company respectfully acknowledges the Staff's comment and has reviewed its position in light of the Staff's comment. In future filings, the Company will revise its accounting analysis of the arrangement with ADVANZ PHARMA ("ADVANZ") and related revenue recognition, as detailed below. In particular, the Company has concluded that additional promises exist within the ADVANZ License and Development Agreement (the "Agreement" or the "Contract").

The Company considered ASC 606-10-25-14 through 25-22 in evaluating the promises in the Contract. The Company identified the following promises to ADVANZ (the "Customer"): (1) delivery of the exclusive license to commercialize the Licensed Product; (2) commitment to provide research and development of the product pre- and post-marketing authorization; (3) participation in the pricing and market access committee ("PMAC"); (4) the commitment to manufacture and supply ADVANZ with the product at its cost; and (5) granting ADVANZ a right of negotiation and "most-favored nation" rights with respect to acquiring the European commercialization rights for any additional indications.

The Company concluded the following with respect to each identified promise:

(1) Delivery of the exclusive license to commercialize the Licensed Product – as discussed below, the Company has concluded that the license is distinct from the other promises and is considered a performance obligation.
(2) Commitment to provide research and development of the product pre- and post-marketing authorization – as discussed below, the Company has concluded that this promise is distinct from the other promises in the Contract and is considered a performance obligation.
(3) Participation in the PMAC – The Company has considered that while both parties are required to participate in the PMAC, this participation is considered to be informative in nature and the time and value of the promise is not material to the Company or the Agreement, quantitatively or qualitatively. As a result, consistent with the guidance in ASC 606-10-25-16A, the Company did not assess this promise as a performance obligation.
(4) The commitment to manufacture and supply ADVANZ with product at its cost – Under the terms of the agreement, the Company is obligated to manufacture and supply ADVANZ for any optional purchases of product by ADVANZ post marketing authorization. While the purchases by ADVANZ are optional, the Company concluded that the pricing (at cost) represented a material right, consistent with the guidance in ASC 606-10-55-42.
(5) The right of negotiation and "most-favored nation" rights with respect to acquiring the European commercialization rights for any additional indications is purely an option provided to the Customer which allows it to submit a pricing proposal that the Company may or may not accept. As such, it does not represent a right to acquire a license at a discount to the standalone selling price. The Company will account for this option if and when it is exercised as a separate contract. The Company concluded that this is a marketing offer and not a performance obligation.

The Company confirms that it will provide expanded disclosure of all performance obligations related to the Agreement in its future annual and quarter reports filed pursuant to under the Securities Exchange Act of 1934, as amended, beginning with the Company's upcoming filing on Form 10-K for the year ended December 31, 2023. See Appendix A for expanded disclosure.

- **Clarify to us if you believe the license is distinct from the other performance obligations and provide your accounting basis for your conclusion.**

In accordance with ASC 606-10-25-19, the Company first assessed whether the Customer could benefit from the license either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct). Upon the delivery of the license, the Customer had the ability to benefit from the intellectual property ("IP") by executing its right to sublicense the IP. The Customer also has the ability and resources to complete the development itself or with the assistance of a contract research organization, without changing the licensed IP given that all of the requisite knowledge and information had been conveyed to the Customer as part of the license transfer. Further, the Customer, and certain third-party providers, have the requisite knowledge, experience and capabilities to perform the associated manufacturing and commercialization activities. As a result, the license is considered to have stand-alone value and the Customer could derive full utility from the delivered license. The promise to deliver the license was capable of being distinct, satisfying the criterion set forth in ASC 606-10-25-19(a).

After concluding that the license was capable of being distinct, the Company assessed whether the license was distinct in the context of the contract in accordance with ASC 606-10-25-19(b). In assessing whether the Company's promises to transfer the license and the other promises are separately identifiable, the Company considered the factors in ASC 606-10-25-21. The Company concluded that the license and the other promises in the contract, including the commitment to perform research and development of the product, are not inputs to a combined item in the Contract. The Customer could separately purchase the license without significantly affecting its ability to benefit from the license (i.e., the Customer could sub-license). Neither the license nor the other promises in the Contract are significantly modified or customized by the other since the product is in a Phase 3 trial and the underlying IP is not expected to be modified. In addition, entity is not providing a significant service of integrating those items into a combined output. Further, the license and the other promises are not highly interdependent or highly interrelated because the Company was able to fulfill its promise to transfer the license independent of fulfilling its other promises in the Contract. Therefore, the Company concluded that the performance obligation to deliver the license was distinct in the context of the Contract, satisfying the criterion set forth in ASC 606-10-25-19(b) .

- **Tell us why you have not allocated some of the upfront payment to the manufacture and supply of the License Product as well as the obligation to develop the Licensed Product and perform the clinical trials**.

In our revised analysis, we allocated the total transaction price to the following performance obligations on a relative standalone selling price basis and determined whether the transaction price allocated to each performance obligation should be recognized at a point in time or over time:

Performance Obligation	Allocated Transaction Price (in millions) at Contract Inception	Recognition
Delivery of the exclusive license to commercialize the Licensed Product	$9.3	Point in time – upon delivery
Commitment to provide research and development of the Licensed Product pre- and post-marketing authorization	1.3	Over time - The Company recognizes revenue related to research and development services performed using an input method based on costs incurred relative to total costs expected to be incurred as this measure of progress best depicts our performance in transferring control to the Customer.
Commitment to manufacture and supply Advanz with the product – material right	0.1	The Company will recognize revenue when the future supply is transferred or when the option expires
Total	$10.7	

With respect to the 2023 annual financial statements, the Company will record a deferral of revenue of approximately $667,000 at December 31, 2023, related to the performance obligations not yet satisfied as of year-end 2023. We evaluated the materiality of the error from a quantitative and qualitative perspectives with respect to the Company's 2023 quarterly financial statements and concluded that the error was not material to any period.

The Company confirms that it will provide expanded disclosure related to the Agreement in its future annual and quarter reports filed pursuant to the Securities Exchange Act of 1934, as amended, beginning with the Company's upcoming filing on Form 10-K for the year ended December 31, 2023. See Appendix A for expanded disclosure.

- **Clarify to us, and in future filings, how you account for the cost-sharing with ADVANZ PHARMA and tell us the basis for your accounting treatment.**

Thank you for your comment. As described above, the Company has concluded that the promise to provide research and development of the product pre- and post-marketing authorization represents a performance obligation that is recognized over time. Any consideration received under the cost-sharing arrangement represents variable consideration and is subject to the constraint guidance in ASC 606-10-32-11 and ASC 606-10-32-12. The Company estimated the amount of the variable consideration using the expected value method in accordance with ASC 606-10-32-8 at contract inception and will update its estimate at the end of each of the reporting period (including our assessment of whether the estimate of variable consideration is constrained) in accordance with ASC 606-10-32-14.

Appendix A

Revised Footnote Disclosure

Accounting Policy Footnote:

Under ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASC 606, as amended by ASU 2016-08, 2016-10, 2016-12 and 2016-20, the Company recognizes revenue in an amount that reflects the consideration to which it expects to be entitled in exchange for the transfer of promised goods or services to customers. To determine revenue recognition for contracts with customers that are within the scope of ASC 606, the Company performs the following steps: (1) identifies the contract with the customer, (2) identifies the performance obligations in the contract, (3) determines the transaction price, (4) allocates the transaction price to the performance obligations in the contract, and (5) recognizes revenue when (or as) the entity satisfies a performance obligation.

The Company has entered into an agreement to license its intellectual property, or IP, related to Galactosemia and SORD to develop, manufacture and/or commercialize drug products with Mercury Pharma Group Limited, trading as Advanz Pharma Holdings, ("Advanz Pharma"). The agreement contains multiple performance obligations, including licenses of IP, research and development services, and the manufacturing and supply material right. Payments to the Company under this agreement may include nonrefundable fees, payments for research activities, payments based upon the achievement of certain milestones and royalties on any resulting net product sales.

The Company identifies agreements as contracts that create enforceable rights and obligations when the agreement is approved by the parties, the Company can identify the rights of the parties and the payment terms, the contract has commercial substance and it is probable that the Company will collect substantially all of the consideration to which it will be entitled in exchange for the goods and services that will be transferred to the customer. The counterparty is considered to be a customer when it has contracted with the Company to obtain goods and services that are the output of the Company's ordinary activities (i.e., development of pharmaceutical products) in exchange for consideration.

A performance obligation is a promise to transfer distinct goods or services to a customer. Performance obligations that are both capable of being distinct and distinct within the context of the contract are considered to be separate performance obligations. Performance obligations are capable of being distinct if the counterparty is able to benefit from the good or service on its own or together with other resources that are readily available to it. Performance obligations are distinct within the context of the contract when each performance obligation is separately identifiable. In assessing whether the Company's promises to transfer goods or services to the customer are separately identifiable, the Company considers factors in ASC 606, including whether the Company uses the goods or services as inputs to produce or deliver a combined output or outputs specified by the customer, whether one or more of the goods or services significantly modify or customize one of the other goods or services in the contract, and whether the goods or services are highly interdependent or highly interrelated. If a promised good or service is not distinct, it is combined with other promised goods or services until the Company identifies a bundle of goods or services that is distinct, which is accounted for as a single performance obligation. The determination of whether promised goods or services in a contract are distinct may require significant judgment.

The transaction price is the amount of consideration that the Company expects to be entitled to in exchange for transferring promised goods or services to the customer based on the contract terms at inception of a contract. The Company estimates an amount of variable consideration, if any, by using either the expected value or the most likely amount method depending on which method the Company expects to better predict the amount of consideration to which it will be entitled, and only to the extent that it is probable that that a significant reversal in the amount of cumulative revenue recognized will not occur in the future when the uncertainty is resolved. The determination of whether it is probable that a significant reversal of revenue will occur in the future depends on the likelihood and magnitude of the reversal. Factors that could increase the likelihood or magnitude of a reversal of revenue include (a) the susceptibility of the amount of consideration to factors outside the entity's influence, such as the outcome of clinical trials, the timing of initiation of clinical trials by the counterparty and the approval of drug product candidates by regulatory agencies, (b) situations in which the uncertainty is not expected to be resolved for a long period of time, and (c) level of the Company's predictive experience in the field with similar types of contracts. At the end of each reporting period, the Company will update the estimated transaction price. When the estimated transaction price is updated, the Company allocates the updated consideration to the separate performance obligations in the same manner as described below.

At inception of a contract, the Company allocates the transaction price to the distinct performance obligations based upon their relative standalone selling prices. Standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. The best evidence of standalone selling price is an observable price of a good or service when sold separately by an entity in similar circumstances to similar customers. Since the Company typically does not have such evidence, it estimates standalone selling price so that the amount that is allocated to each performance obligation equals the amount that the Company expects to receive for transferring the promised goods or services. The methods that the Company uses to make such estimates include (1) the adjusted market assessment approach, under which the Company forecasts and analyzes Galactosemia and SORD sales in the appropriate market, the phase of clinical development as well as considering recent similar license arrangements within the same phase of clinical development, therapeutic area, type of agreement, etc. and (2) the expected cost of satisfying the performance obligations plus a margin, or the expected cost plus a margin approach.

The Company recognizes revenue when, or as, it satisfies a performance obligation by transferring a promised good or service to a customer and the customer obtains control of the good or service. Revenue related to the grant of a license of functional IP that is distinct from the other promised goods or services in the contract and therefore represents a performance obligation is recognized at the point in time that the Company has the right to payment for the license, the customer has legal title to the license and can direct the use of the license (for example, to grant sublicenses) to benefit from its right to use the intellectual property, the customer has the significant risks and rewards of ownership of the license and the customer has accepted the asset (license) by signing the license agreement.

Recognition of revenue related to research and development services that are a distinct performance obligation is deferred at inception of a contract and is recognized as services are performed to satisfy the performance obligation based on the costs incurred as a percentage of the estimated total costs to be incurred to satisfy the performance obligation. The Agreement requires that Advanz Pharma receive regular updates and data on any research and development services as the services are performed. In accordance with ASC 606-10-25-27, the Company determined that Advanz Pharma simultaneously benefits from the research and development services that are satisfied over time. The Company believes this method most faithfully depicts its performance in transferring the promised services while research and development services are ongoing.

Milestone payments are considered to be variable consideration and are not included in the transaction price at inception of the contract if it is uncertain that the milestone will be achieved. Rather, when it becomes probable that the milestone will be achieved and, therefore, there will not be a significant reversal of revenue in future periods, the respective amount to be earned is included in the transaction price, allocated to the distinct performance obligations based on their relative standalone selling price and recognized as revenue, as described above. Sales based milestones and sales-based royalty payments related to a license of IP are recognized as revenue when the respective sales occur.

Revenue Recognition Footnote:

On January 3, 2023, the Company entered into an Exclusive License and Supply Agreement (the “Advanz Agreement”) with Advanz Pharma . Pursuant to the Advanz Agreement, the Company granted Advanz Pharma the exclusive right and license to commercialize drug products containing AT-007 (also known as govorestat), our proprietary Aldose Reductase Inhibitor (ARI) (the “Licensed Product”), for use in treatment of Sorbitol Dehydrogenase Deficiency (“SORD”) and Galactosemia (each a “Licensed Indication”) in the European Economic Area, Switzerland and the United Kingdom (the “Territory”). The Agreement provides that Applied will perform research and development services prior to and subsequent to marketing authorization and manufacture and supply product for Advanz Pharma. The Company also granted Advanz Pharma a right of negotiation and “most-favored nation” rights with respect to acquiring the European commercialization rights for any additional indications for which the Licensed Product may be developed in the future (or any other products we may develop solely to the extent used for the Licensed Indications).

Advanz Pharma is required to use commercially reasonable efforts to launch and commercialize the Licensed Products in the major markets in the Territory in each Licensed Indication following, and subject to, receipt of marketing authorization therein. Under the Advanz Agreement, Advanz Pharma agreed to pay the Company (i) an upfront payment of EUR $10 million (approximately USD $10.7 million), and certain development milestone payments upon clinical trial completion and receipt of marketing authorization in the territory, as well as certain commercial milestone payments, totaling EUR $134 million (approximately USD $142.2 million) in the aggregate, and (ii) royalties of 20% of net sales of the Licensed Product. Such royalty rate will be payable on a country-by-country basis until the later of (i) the expiration of the licensed patents covering the composition of matter of AT-007, or (ii) 10 years after the European Medicines Agency’s grant of marketing authorization for the Licensed Product. The royalties are subject to certain deductions, including certain secondary finishing costs, certain step-in establishment costs and a portion of fees for any potential third-party patent licenses if applicable in the future. Following the initial term of the license, as described above, the royalty rate will be reduced to 10% and shall continue in perpetuity unless the Advanz Agreement is terminated in various circumstances in accordance with its terms. In addition, the Company is entitled to receive cost sharing consideration for post-marketing authorization studies, if applicable.

In accordance with the Company's ASC 606 assessment, Advanz Pharma is considered to be a customer. The Company identified three performance obligations, the exclusive license to commercialize the Licensed Product, the obligations to provide research and development for pre and post-marketing authorization and the obligation to manufacture and supply Advanz Pharma with the Product, at cost (a material right). The Company determined that the upfront payment of EUR $10 million (approximately USD $10.7 million) is the estimated transaction price at contract inception. The performance-based milestone payments, sales-based milestone payments, sales-based royalties, and post-marketing authorization study cost sharing are each determined to be variable consideration that are fully constrained due to the uncertainty of achievement.

At inception of the Advanz Agreement, the Company determined the estimate of standalone selling price for the license performance obligation by using the adjusted market assessment approach. Under this method, the Company forecasted and analyzed Galactosemia and SORD in the European market, the probability of marketing authorization approval as well as considered recent similar license arrangements within the same phase of clinical development, therapeutic area, type of agreement, forecasted sales for the contract period, probability of success and a market discount rate. To estimate the standalone selling price of the research and development services, the Company forecasted its expected costs of satisfying that performance obligation and added an appropriate margin for that service. To estimate the standalone selling price for the manufacturing supply agreement material right, the Company utilized an adjusted market assessment approach. The Company analyzed the discount Advanz Pharma is expected to obtain by estimating the material right the customer is receiving for the future purchase of manufacturing and supply services. This estimation utilized the estimated number of patients to be treated per year in the Territory; the estimated volume of bottles per patient required per year; typical margin; probability of success; and discounted at market rate.

The Company allocated the total transaction price to each performance obligation on a relative standalone selling price basis and determined whether revenue should be recognized at a point in time or over time. The Company allocated $9.3 million to the license performance obligation; $1.3 million to the research and development performance obligation and $0.1 million to the manufacturing and supply material right.

Revenue should be recognized when, or as, an entity satisfies a performance obligation by transferring a promised good or service to a customer, i.e., when the customer obtains control of the good or service. The license granted to Advanz Pharma is being accounted for as a distinct performance obligation. The Advanz Pharma license relates to functional IP for which revenue is recognized at a point in time – in the case of this license agreement, the point in time is at inception of the contract because the customer obtained control of the license and was able to use and benefit from its right to use the intellectual property at that point. The Company recognized the transaction price allocated to the license obligation of $9.3 million as license revenue on its statements of operations for the twelve months ended December 31, 2023.

The research and development services performance obligation under the Advanz Agreement represents a separate performance obligation. The research and development services were provided to Advanz Pharma by the Company from inception of the agreement in January 2023 and will continue through completion of post marketing authorization approval studies. Revenue related to the research and development services performance obligation was recognized as services were performed based on the costs incurred through December 31, 2023, as a percentage of the estimated total costs to be incurred for this performance obligation. The Company recognized $670,000 of revenue during twelve months ended December 31, 2023, and had deferred revenue of $547,000 related to the research and development performance obligation at December 31, 2023. The Company expects to recognize this deferred revenue over the next three years.

The manufacturing supply agreement material right performance obligation provided to Advanz Pharma by the Company resulted in an allocation of the transaction price and a resulting deferred revenue as of contract inception and December 31, 2023, of approximately $120,000. Revenue associated with this performance obligation will be recognized when Advanz Pharma buys supply from the Company after regulatory approval or upon expiration of the material right.