UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2026

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-37378

ATYR PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-3435077**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10240 Sorrento Valley Road, Suite 300, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 731-8389

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ATYR	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 6, 2026, there were 98,087,425 shares of the registrant's common stock, par value $0.001 per share, outstanding.

ATYR PHARMA, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

aTyr Pharma, Inc.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	June 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 16,160	$ 10,743
Available-for-sale investments	41,258	67,944
Other receivables	426	873
Prepaid expenses	518	677
Total current assets	58,362	80,237
Restricted cash	1,495	2,235
Property and equipment, net	4,127	4,263
Operating lease, right-of-use assets	5,353	5,524
Financing lease, right-of-use assets	298	596
Other assets	190	148
Total assets	$ 69,825	$ 93,003
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,242	$ 3,891
Accrued expenses	6,690	9,791
Current portion of operating lease liability	946	836
Current portion of financing lease liability	518	630
Total current liabilities	11,396	15,148
Long-term operating lease liability, net of current portion	9,799	10,308
Long-term financing lease liability, net of current portion	36	259
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 undesignated authorized shares as of June 30, 2026 (unaudited) and December 31, 2025, respectively; no shares issued or outstanding as of June 30, 2026 (unaudited) and December 31, 2025	—	—
Common stock, $0.001 par value per share; 340,000,000 and 170,000,000 authorized shares as of June 30, 2026 (unaudited) and December 31, 2025, respectively; 98,087,425 and 98,031,014 issued and outstanding shares as of June 30, 2026 (unaudited) and December 31, 2025, respectively	98	98
Additional paid-in capital	676,022	673,554
Accumulated other comprehensive loss	(68)	(8)
Accumulated deficit	(627,264)	(606,164)
Total aTyr Pharma, Inc. stockholders' equity	48,788	67,480
Noncontrolling interest in Pangu BioPharma Limited	(194)	(192)
Total stockholders' equity	48,594	67,288
Total liabilities and stockholders' equity	$ 69,825	$ 93,003

See accompanying notes.

aTyr Pharma, Inc.

Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
		(unaudited)		
Operating expenses:				
Research and development	$ 6,748	$ 15,384	14,065	27,198
General and administrative	4,133	4,929	8,252	8,888
Total operating expenses	10,881	20,313	22,317	36,086
Loss from operations	(10,881)	(20,313)	(22,317)	(36,086)
Total other income (expense), net	571	781	1,215	1,673
Consolidated net loss	(10,310)	(19,532)	(21,102)	(34,413)
Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	1	1	2	2
Net loss attributable to aTyr Pharma, Inc.	$ (10,309)	$ (19,531)	$ (21,100)	$ (34,411)
Net loss per share, basic and diluted	$ (0.11)	$ (0.22)	$ (0.22)	$ (0.39)
Shares used in computing net loss per share, basic and diluted	98,069,915	90,120,235	98,056,949	88,312,722

See accompanying notes.

aTyr Pharma, Inc.

Condensed Consolidated Statements of Comprehensive Loss
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
	(unaudited)			
Consolidated net loss	$ (10,310)	$ (19,532)	$ (21,102)	$ (34,413)
Other comprehensive loss:				
Change in unrealized gain (loss) on available-for-sale investments, net of tax	2	(9)	(60)	(35)
Comprehensive loss	(10,308)	(19,541)	$ (21,162)	$ (34,448)
Comprehensive loss attributable to noncontrolling interest in Pangu BioPharma Limited	1	1	2	2
Comprehensive loss attributable to aTyr Pharma, Inc. common stockholders	$ (10,307)	$ (19,540)	$ (21,160)	$ (34,446)

See accompanying notes.

aTyr Pharma, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Six Months Ended June 30, 2026 (unaudited)						
	Common Stock		Additional Paid-In Capital	Other Comprehensive Gain/(Loss)	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance as of December 31, 2025	98,031,104	$ 98	$ 673,554	$ (8)	$ (606,164)	$ (192)	$ 67,288
Issuance of common stock upon release of restricted stock units	20,108	—	—	—	—	—	—
Stock-based compensation	—	—	1,307	—	—	—	1,307
Net unrealized loss on investments, net of tax	—	—	—	(62)	—	—	(62)
Net loss	—	—	—	—	(10,791)	(1)	(10,792)
Balance as of March 31, 2026	98,051,212	98	674,861	(70)	(616,955)	(193)	57,741
Issuance of common stock pursuant to employee stock purchase plan	36,213	—	16	—	—	—	16
Stock-based compensation	—	—	1,145	—	—	—	1,145
Net unrealized gain on investments, net of tax	—	—	—	2	—	—	2
Net loss	—	—	—	—	(10,309)	(1)	(10,310)
Balance as of June 30, 2026	98,087,425	$ 98	$ 676,022	$ (68)	$ (627,264)	$ (194)	$ 48,594

	Six Months Ended June 30, 2025 (unaudited)						
	Common Stock		Additional Paid-In Capital	Other Comprehensive Gain/(Loss)	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance as of December 31, 2024	84,038,922	$ 84	$ 602,021	$ (40)	$ (532,046)	$ (187)	$ 69,832
Issuance of common stock upon release of restricted stock units	21,108	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	900	—	2	—	—	—	2
Issuance of common stock from at-the-market offerings, net of offering costs	4,941,895	5	18,752	—	—	—	18,757
Stock-based compensation	—	—	1,178	—	—	—	1,178
Net unrealized loss on investments, net of tax	—	—	—	(26)	—	—	(26)
Net loss	—	—	—	—	(14,880)	(1)	(14,881)
Balance as of March 31, 2025	89,002,825	89	621,953	(66)	(546,926)	(188)	74,862
Issuance of common stock upon exercise of stock options	7,520	—	17	—	—	—	17
Issuance of common stock pursuant to employee stock purchase plan	31,007	—	79	—	—	—	79
Issuance of common stock from at-the-market offerings, net of offering costs	3,829,830	4	17,930	—	—	—	17,934
Stock-based compensation	—	—	1,305	—	—	—	1,305
Net unrealized loss on investments, net of tax	—	—	—	(9)	—	—	(9)
Net loss	—	—	—	—	(19,531)	(1)	(19,532)
Balance as of June 30, 2025	92,871,182	$ 93	$ 641,284	$ (75)	$ (566,457)	$ (189)	$ 74,656

See accompanying notes.

aTyr Pharma, Inc.

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Six Months Ended June 30,	
	2026	**2025**
	(unaudited)	
Cash flows from operating activities:		
Consolidated net loss	$ (21,102)	$ (34,413)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	330	333
Stock-based compensation	2,452	2,483
Accretion of discount of available-for-sale investment securities	(401)	(981)
Amortization of right-of-use assets	469	437
Gain on financing lease bargain purchase option	(48)	—
Changes in operating assets and liabilities:		
Other receivables	455	1,238
Prepaid expenses and other assets	109	1,445
Accounts payable and accrued expenses	(3,733)	485
Operating lease liability	(399)	(341)
Net cash used in operating activities	(21,868)	(29,314)
Cash flows from investing activities:		
Purchases of property and equipment	(211)	(9)
Purchases of available-for-sale investment securities	(13,846)	(41,260)
Maturities of available-for-sale investment securities	40,873	40,150
Net cash provided by (used in) investing activities	26,816	(1,119)
Cash flows from financing activities:		
Proceeds from issuance of common stock through option exercises	—	19
Proceeds from issuance of common stock through employee stock purchase plan	16	79
Proceeds from issuance of common stock from at-the-market offerings, net of offering costs	—	36,691
Principal paid on finance lease liabilities	(287)	(264)
Net cash (used in) provided by financing activities	(271)	36,525
Net change in cash, cash equivalents and restricted cash	4,677	6,092
Cash, cash equivalents and restricted cash at beginning of period	12,978	14,006
Cash, cash equivalents and restricted cash at the end of period	$ 17,655	$ 20,098
Cash and cash equivalents at the end of period	$ 16,160	$ 17,220
Restricted cash at the end of period	1,495	2,878
Cash, cash equivalents and restricted cash at the end of period	$ 17,655	$ 20,098
Supplemental disclosure of cash flow information:		
Interest paid	$ 30	$ 53
Purchases of property and equipment in accounts payable	$ —	$ 17

See accompanying notes.

aTyr Pharma, Inc.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization, Business, Basis of Presentation and Summary of Significant Accounting Policies

Organization and Business

We were incorporated in the state of Delaware on September 8, 2005. We are a clinical stage biotechnology company leveraging evolutionary intelligence to translate tRNA synthetase biology into new therapies for fibrosis and inflammation. tRNA synthetases are ancient, essential proteins that have evolved novel domains that regulate diverse pathways extracellularly in humans. Our discovery platform is focused on unlocking hidden therapeutic intervention points by uncovering signaling pathways driven by our proprietary library of domains derived from all 20 tRNA synthetases.

Principles of Consolidation

Our unaudited condensed consolidated financial statements include our accounts and our 98% majority-owned subsidiary in Hong Kong, Pangu BioPharma Limited (Pangu BioPharma). All intercompany transactions and balances are eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP) and follow the requirements of the U.S. Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. In our opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of our financial position and our results of operations and cash flows for periods presented. These statements do not include all disclosures required by U.S. GAAP and should be read in conjunction with our financial statements and accompanying notes for the fiscal year ended December 31, 2025, contained in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 5, 2026. The results of the interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

Liquidity and Financial Condition

We have incurred net losses and negative cash flows from operations since our inception in 2005, including a consolidated net loss of $10.3 million and $21.1 million for the three and six months ended June 30, 2026. As of June 30, 2026, we had an accumulated deficit of $627.3 million. We currently have an "at-the-market" offering program (the Jefferies ATM Offering Program) through an Open Market Sale Agreement℠ with Jefferies LLC (Jefferies). We did not utilize the Jefferies ATM Offering Program during the three and six months ended June 30, 2026.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years at a minimum. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to raise substantial additional capital to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts and the timing and nature of the regulatory approval process for our product candidates. We anticipate that we will seek to fund our operations through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements. However, we may be unable to raise additional capital or enter into such arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such arrangements when needed would have a negative impact on our financial condition and ability to develop our product candidates.

We believe that our existing cash, cash equivalents, restricted cash and available-for-sale investments of $58.9 million as of June 30, 2026 will be sufficient to meet our material cash requirements from known contractual and other obligations for a period of at least one year from the filing date of this Quarterly Report on Form 10-Q.

Restricted Cash

As of June 30, 2026, restricted cash was approximately $1.5 million, which was held as a security deposit in conjunction with our corporate headquarters facility lease and financing leases as discussed further in Note 4 - Commitments and Contingencies.

Allowance of Credit Losses

For available-for-sale investments in an unrealized loss position, we first assess whether we intend to sell, or if it is more likely than not that we will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale investments that do not meet the aforementioned criteria, we evaluate whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, we consider the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive income (loss) on the unaudited condensed consolidated statements of operations and comprehensive loss.

We elected the practical expedient to exclude the applicable accrued interest from both the fair value and amortized costs basis of our available-for-sale investments for purposes of identifying and measuring an impairment. Accrued interest receivable on available-for-sale investments is recorded within other receivables on our unaudited condensed consolidated balance sheets. Our accounting policy is to not measure an allowance for credit loss for accrued interest receivable and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which we consider to be in the period in which we determine the accrued interest will not be collected by us.

Use of Estimates

Our unaudited condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our unaudited condensed consolidated financial statements requires us to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure for these items in our unaudited condensed consolidated financial statements and accompanying notes. The most significant estimates in our unaudited condensed consolidated financial statements relate to clinical trial and research and development expenses. Although these estimates are based on our knowledge of current events and actions we may undertake in the future, actual results may ultimately differ materially from these estimates and assumptions.

Accrued Expenses

Accrued expenses include salaries, wages, benefits costs, consulting fees, legal and research and development costs. We have entered into contractual arrangements related to our clinical studies with clinical research organizations (CROs) and contracted development and manufacturing organizations (CDMOs) and recognize expense based on work completed and efforts expended pursuant to our contractual arrangements. We make estimates of our accrued CRO costs as of each balance sheet date based on facts and circumstances known at the time and include total trial management costs, sites activated, patients enrolled and number of patient visits. We estimate the time period over which services will be performed and the level of effort to be expended in each period. There may be instances in which payments made to our service providers including CROs and CDMOs, will temporarily exceed the level of services provided and result in a prepayment of the expense. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense balance accordingly. Historically, our estimated accrued liabilities have materially approximated actual expenses incurred.

Leases

We determine if an arrangement is a lease at inception. Short-term leases with an initial term of 12 months or less are not recorded on our balance sheet. For long-term leases with an initial term of greater than 12 months, we recognize a right-of-use asset (ROU) and a lease liability based on the present value of future lease payments using an estimated rate of interest that we would pay to borrow equivalent funds on a collateralized basis at the lease commencement date. We determine the lease term at the commencement date by considering whether renewal options and termination options are reasonably assured of exercise. Rent expense for operating leases is recognized on a straight-line basis over the lease term and is included in operating expenses in our unaudited condensed consolidated statements of operations. For financing leases, interest expense and amortization of the ROU is included in operating expenses in our unaudited condensed consolidated statements of operations and variable lease payments are expensed as incurred.

If a lease is modified, the modified contract is evaluated to determine whether it is or contains a lease. If a lease continues to exist, the lease modification is determined to be a separate contract when the modification grants the lessee an additional ROU that is not included in the original lease and the lease payments increase commensurate with the standalone price for the additional ROU. A lease modification that results in a separate contract will be accounted for in the same manner as a new lease. For a modification that is not a separate contract, we reassess the lease classification using the modified terms and conditions and the facts and circumstances as of the effective date of the modification and recognize the amount of the remeasurement of the lease liability for the modified lease as an adjustment to the corresponding ROU asset.

Our ROU assets consist of a non-cancelable operating lease for our corporate headquarters and financing leases for various research and development and information technology equipment.

We do not separate lease and non-lease components for our long-term leases.

Revenue Recognition

We evaluate our agreements under Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* and ASC Topic 808, *Collaborative Arrangements*. We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreement, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

We recognize revenue in one of two ways, over time or at a point in time. We recognize revenue over time when we are executing on our performance obligation over time and our partner receives benefit over time. For example, we recognize revenue over time when we provide research and development services. We recognize revenue at a point in time when we transfer control of a distinct performance obligation to our partner. For example, if a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of warrants for common stock, options and restricted stock units outstanding under our stock option plans and estimated shares to be purchased under our employee stock purchase plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to our net loss position.

Potentially dilutive securities not considered for the calculation of diluted net loss per share are as follows (in common stock equivalents):

	Six Months Ended June 30,	
	2026	**2025**
Common stock options and restricted stock units	13,976,293	9,734,321
Employee stock purchase plan	38,241	46,883
Total	14,014,534	9,781,204

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance. We view our operations and manage our business in one operating segment, which includes all activities related to the discovery and development of our product candidates. Our CODM is our Chief Executive Officer, who reviews and evaluates consolidated research and development expenses, general and administrative expenses, net loss, net cash used in operating activities and our consolidated cash and cash equivalents for purposes of making operating decisions, allocating resources and planning and forecasting future periods.

The table below summarizes the significant expense categories regularly reviewed by our CODM for the three and six months ended June 30, 2026 and 2025.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development expenses:				
Efzofitimod expenses	$ 2,106	$ 12,290	5,641	21,094
Preclinical development and other shared research and development expenses	4,230	2,623	7,585	5,184
Non-cash expenses (depreciation and stock-based compensation)	412	471	839	920
Total research and development expenses	6,748	15,384	14,065	27,198
General and administrative expenses:				
Other general and administrative expenses	3,232	3,928	6,307	6,992
Non-cash expenses (depreciation and stock-based compensation)	901	1,001	1,945	1,896
Total general and administrative expenses	4,133	4,929	8,252	8,888
Other segment items [(1)]	571	781	1,215	1,673
Consolidated net loss	$ (10,310)	$ (19,532)	$ (21,102)	$ (34,413)

(1) Other segment items includes interest income and interest expense.

Recent Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40),* which requires entities to disclose, on an annual and interim basis, disaggregated information about certain income statement expense line items on the face of the income statement. The standard is effective for annual reporting periods beginning after December 15, 2026 and interim periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. We are currently evaluating the impact of the standard on our consolidated financial statements and related disclosure.

2. Fair Value Measurements

The carrying amounts of cash equivalents, prepaid and other assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Investment securities are recorded at fair value.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Financial assets measured at fair value on a recurring basis consist of investment securities. Investment securities are recorded at fair value, defined as the exit price in the principal market in which we would transact, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Level 2 securities are valued using quoted market prices for similar instruments, non-binding market prices that are corroborated by observable market data, or discounted cash flow techniques and include our investments in commercial paper, corporate debt securities and U.S. government agencies

securities. We have no financial liabilities measured at fair value on a recurring basis. None of our non-financial assets and liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

Assets measured at fair value on a recurring basis are as follows (in thousands):

		Fair Value Measurements Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of June 30, 2026				
Assets:				
Current:				
Cash equivalents	$ 14,253	$ 14,253	$ —	$ —
Available-for-sale investments:				
Commercial paper	19,312	—	19,312	—
Corporate debt securities	16,938	—	16,938	—
Municipal bonds	5,008	—	5,008	—
Total available-for-sale investments	41,258	—	41,258	—
Total assets measured at fair value	$ 55,511	$ 14,253	$ 41,258	$ —

		Fair Value Measurements Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2025				
Assets:				
Current:				
Cash equivalents	$ 7,916	$ 7,916	$ —	$ —
Available-for-sale investments:				
Commercial paper	33,626	—	33,626	—
Corporate debt securities	29,281	—	29,281	—
Municipal bonds	5,037	—	5,037	—
Total available-for-sale investments	67,944	—	67,944	—
Total assets measured at fair value	$ 75,860	$ 7,916	$ 67,944	$ —

As of June 30, 2026 and December 31, 2025, available-for-sale investments are detailed as follows (in thousands):

		June 30, 2026			
	Contractual Maturity	Gross Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Available-for-sale investments:					
Commercial paper	Within 1 year	$ 19,319	$ —	$ (7)	$ 19,312
Corporate debt securities	Within 1 year	16,945	—	(7)	16,938
Municipal bonds	Within 1 year	5,012	—	(4)	5,008
		$ 41,276	$ —	$ (18)	$ 41,258

		December 31, 2025			
	Contractual Maturity	Gross Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Available-for-sale investments:					
Commercial paper	Within 1 year	$ 33,602	$ 24	$ —	$ 33,626
Corporate debt securities	Within 1 year	29,269	17	(5)	29,281
Municipal bonds	Within 1 year	5,031	6	—	5,037
		$ 67,902	$ 47	$ (5)	$ 67,944

We evaluate our available-for-sale debt securities for credit losses when the amortized cost basis exceeds fair value. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive loss. When evaluating an investment for impairment, we review factors such as the severity of the impairment, changes in underlying credit ratings, our intent to sell or the likelihood that we would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. We recorded no allowance for credit losses in the unaudited condensed consolidated statements of operations and comprehensive loss during the three and six months ended June 30, 2026.

As of June 30, 2026, all available-for-sale investments had a variety of effective maturity dates of less than one year. As of June 30, 2026, 12 out of 13 available-for-sale investments were in a gross unrealized loss position, all of which have held this status for less than one year.

As of June 30, 2026 and December 31, 2025, accrued interest receivable on available-for-sale investments was $0.4 million for each period.

3. License, Collaboration and Other Agreements

Kyorin Pharmaceutical Co., Ltd.

In January 2020, we entered into a collaboration and license agreement (Kyorin Agreement) with Kyorin Pharmaceutical Co., Ltd. (Kyorin) for the development and commercialization of efzofitimod for the treatment of interstitial lung disease (ILD) in Japan. Under the Kyorin Agreement, Kyorin received an exclusive right to develop and commercialize efzofitimod in Japan for all forms of ILD, and was obligated to fund all research, development, regulatory, marketing and commercialization activities in Japan.

On May 12, 2026, we received notice of termination of the Kyorin Agreement with Kyorin. Kyorin elected to terminate the Kyorin Agreement without cause in accordance with the terms of the Kyorin Agreement, and the termination became effective on July 30, 2026 (the Termination Date). Following the Termination Date, the rights to develop and commercialize efzofitimod in Japan for all forms of ILD have reverted to us. Consequently, we hold the rights to develop and commercialize efzofitimod globally.

4. Commitments and Contingencies

Operating Leases

Corporate Headquarters Facility Lease

In May 2022, we entered into a non-cancelable facility lease that is subject to base lease payments that started at $5.75 per square foot of rentable area per month for the first 12 months of the lease and which escalate 3.0% annually over the term of the lease, and additional charges for common area maintenance and other costs. The term of the lease (the Lease Term) commenced on March 20, 2023 (the Lease Commencement Date) and will continue for 124 months from the Lease Commencement Date. We also have one option to extend the Lease Term for five years. In April 2024, we entered into a lease amendment for additional common area amenities, effective as of June 2023. The amendment increased the total rentable square feet from 23,696 rentable square feet to 24,866 rentable square feet. We provided a $0.7 million security deposit in the form of a letter of credit which is included in restricted cash as of June 30, 2026.

Future minimum payments under the facility lease and a reconciliation to the operating lease liability as of June 30, 2026 were as follows (in thousands):

	Operating Leases
2026	$ 900
2027	1,916
2028	1,975
2029	2,035
2030 and thereafter	7,802
Less: Amount representing interest	(3,883)
Present value of lease payments	10,745
Less: Current portion of operating lease liability	(946)
Long-term operating lease liability, net of current portion	$ 9,799

For each of the three months ended June 30, 2026 and 2025, we recorded an operating lease expense of $0.4 million. For each of the six months ended June 30, 2026 and 2025, we recorded an operating lease expense of $0.8 million. As of June 30, 2026, the weighted-average remaining lease term was 7.1 years and the weighted average discount rate was 8.8%.

Financing Leases

In April 2022, we entered into a master financing lease agreement. Under this master agreement, we entered into various financing lease agreements from July 2022 through November 2023 to lease various research and development and information technology equipment over a 48-month term. Future minimum payments under the financing lease and reconciliation to the financing lease liability as of June 30, 2026 were as follows (in thousands):

	Financing Leases
2026	$ 312
2027	264
Less: Amount representing interest	(22)
Present value of lease payments	554
Less: Current portion of financing lease liability	(518)
Long-term financing lease liability, net of current portion	$ 36

As of June 30, 2026, the weighted-average remaining lease term was 0.8 years and the weighted-average discount rate was 8.4%. As of June 30, 2026, we have a $0.8 million deposit held as collateral for the leased equipment, and this deposit is included in restricted cash.

Litigation

On October 9, 2025 and October 22, 2025, two substantially similar putative securities class action complaints were filed in the U.S. District Court for the Southern District of California, naming aTyr Pharma, Inc. and our Chief Executive Officer, Sanjay Shukla. The complaints assert that we and Mr. Shukla violated Section 10(b) of the Exchange Act of 1934, as amended (the Exchange Act), and SEC Rule 10b-5, by making materially false or misleading statements related to efzofitimod. The complaints also assert that Mr. Shukla violated Section 20(a) of the Exchange Act. Plaintiffs seek class certification, an award of unspecified damages, and award of reasonable costs and expenses, including attorneys' fees and expert fees, and further relief as the court may deem just and proper. On February 9, 2026, the court consolidated the two cases and appointed co-lead plaintiffs to oversee the litigation. On May 1, 2026, co-lead plaintiffs filed an Amended Consolidated Complaint.

The Amended Consolidated Complaint is based on the same underlying allegations as the original complaints, asserts the same claims and seeks the same relief, and adds our Chief Financial Officer, Jill M. Broadfoot, as a defendant. On July 17, 2026, we moved to dismiss the Amended Consolidated Compliant. Under the current schedule, any opposition to a motion to dismiss is due August 28, 2026, with any reply due September 28, 2026.

We make provisions for liabilities when they are both probable that a liability has been incurred and the amount can be reasonably estimated. No such liability has been recorded related to this matter. With regard to legal fees, such as attorney fees related to this matter or any other legal matters, we recognize such costs as incurred.

5. Stockholders' Equity

At the Market Offering Programs

In April 2022, we entered into an Open Market Sale Agreement[SM] with Jefferies implementing the Jefferies ATM Offering Program. In December 2024, we amended the Jefferies ATM Offering Program. Under the Jefferies ATM Offering Program we may offer and sell, from time to time and at our option, up to an aggregate of $215.0 million of shares of our common stock (inclusive of $65.0 million of sales made prior to the amendment) through Jefferies, acting as sales agent. Jefferies is entitled to a fixed commission rate of up to 3.0% of the gross sales proceeds of shares sold under the Jefferies ATM Offering Program. During the year ended December 31, 2025, we sold an aggregate of 13,887,177 shares of common stock at a weighted-average price of $4.94 per share for net proceeds of approximately $66.4 million under the Jefferies ATM Offering Program. We did not utilize the Jefferies ATM Offering Program during the six months ended June 30, 2026.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance was as follows:

	June 30, 2026
Common stock options and restricted stock units	13,976,293
Shares available under the 2015 equity incentive plan	6,164,361
Shares available under the 2022 inducement plan	167,675
Shares available under the employee stock purchase plan	537,999
	20,846,328

The following table summarizes our stock option activity under all equity incentive plans for the six months ended June 30, 2026:

	Number of Outstanding Stock Options		Weighted-Average Exercise Price
Outstanding as of December 31, 2025	9,591,504	$	3.82
Granted	4,274,091	$	0.73
Canceled/forfeited/expired	(296,519)	$	8.00
Outstanding as of June 30, 2026	13,569,076	$	2.75

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Expected term (in years)	5.50	5.50 – 6.00	5.50 – 6.08	5.50 – 6.08
Risk-free interest rate	4.2%	3.9% – 4.1%	3.7% – 4.2%	3.9% – 4.5%
Expected volatility	107.5%	76.9% – 77.5%	105.5% – 107.5%	75.9% – 77.5%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

The following table summarizes our restricted stock unit activity under all equity incentive plans for the six months ended June 30, 2026:

	Number of Outstanding Restricted Stock Units		Weighted-Average Grant Date Fair Value
Balance as of December 31, 2025	20,108	$	5.52
Granted	446,940	$	0.71
Released	(20,108)	$	5.52
Cancelled	(39,723)	$	0.71
Balance as of June 30, 2026	407,217	$	0.71

Stock-based Compensation

The allocation of stock-based compensation for all options and restricted stock units and stock issued pursuant to our employee stock purchase plan is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 264	$ 325	$ 547	$ 629
General and administrative	881	980	1,905	1,854
Total stock-based compensation expense	$ 1,145	$ 1,305	$ 2,452	$ 2,483

6. Subsequent Events

On August 7, 2026, our board of directors approved the implementation of a corporate restructuring and program prioritization plan (the Restructuring Plan) to streamline our operations, and conserve capital prior to the potential initiation of a new Phase 3 study of efzofitimod in pulmonary sarcoidosis (the Planned Phase 3 Study). In connection with the Restructuring Plan, we committed to a reduction in our total workforce by approximately 60% to 20 full-time employees. We began notifying affected employees on August 7, 2026. We estimate that we will record charges of approximately $4.2 million for employee severance, employee health benefit obligations and other related termination benefits. Severance payments are expected to be paid in full between August 2026 and September 2027. The charges that we expect to incur in connection with, or as a result of, the Restructuring Plan, are subject to a number of assumptions, and actual results may differ materially. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the Restructuring Plan.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and accompanying notes included in this Quarterly Report on Form 10-Q (Quarterly Report), our audited consolidated financial statements and accompanying notes thereto for the fiscal year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission (SEC), on March 5, 2026 (2025 Annual Report).

This Quarterly Report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Such forward looking statements, which represent our intent, belief or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions. Factors that could cause or contribute to differences in results include, but are not limited to those set forth under "Risk Factors" under Part II, Item 1A, and elsewhere in this Quarterly Report. Except as required by law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report or to reflect actual outcomes.

Overview

We are a clinical stage biotechnology company leveraging evolutionary intelligence to translate tRNA synthetase biology into new therapies for fibrosis and inflammation. tRNA synthetases are ancient, essential proteins that have evolved novel domains that regulate diverse pathways extracellularly in humans. Our discovery platform is focused on unlocking hidden therapeutic intervention points by uncovering signaling pathways driven by our proprietary library of domains derived from all 20 tRNA synthetases.

Efzofitimod

Our lead therapeutic candidate is efzofitimod, a novel biologic immunomodulator in clinical development for the treatment of interstitial lung disease (ILD), a group of immune-mediated disorders that can cause inflammation and fibrosis, or scarring, of the lungs. Efzofitimod is a tRNA synthetase derived therapy that selectively modulates activated myeloid cells through neuropilin-2 (NRP2) to resolve aberrant inflammation without immune suppression and potentially prevent the progression of fibrosis.

In September 2025, we announced top-line data from a global Phase 3 randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis (the EFZO-FIT study). The EFZO-FIT study was a 52-week study in 268 patients with pulmonary sarcoidosis consisting of three parallel cohorts randomized equally to either 3.0 mg/kg or 5.0 mg/kg of efzofitimod or placebo dosed intravenously once every four weeks for a total of 12 doses, with a 4-week safety follow-up. The study design incorporated a protocol guided steroid taper in the first 12 weeks of the study, followed by continued taper or rescue until week 48. The study did not meet its primary endpoint of change from baseline in mean daily oral corticosteroid (OCS)

dose at week 48. The change from baseline in mean daily OCS dose reduced to an average of 2.79 mg for 5.0 mg/kg efzofitimod vs 3.52 mg for placebo (p=0.3313). The study's statistical analysis plan was designed on a hierarchical assessment basis, as such since the primary endpoint was not met, all subsequent statistical testing is reported as nominal findings. The study demonstrated a clinically meaningful improvement in the King's Sarcoidosis Questionnaire (KSQ)-Lung score at week 48 for 5.0 mg/kg efzofitimod compared to placebo (p=0.0479), with a responder analysis of patients who achieved complete steroid withdrawal at week 48 with an improved KSQ-Lung score also showing improvement in patients treated with 5.0 mg/kg efzofitimod compared to placebo (p=0.0196). Lung function as measured by forced vital capacity (FVC) at week 48 was maintained in all groups. Efzofitimod was generally well-tolerated at both the 3.0 mg/kg and 5.0 mg/kg doses, consistent with previously observed safety profile in all trials conducted to date. At the European Respiratory Society (ERS) Congress in late September 2025, we announced additional findings from the EFZO-FIT study, including analyses of additional pre-specified outcomes that demonstrated clinical improvements in mean change from baseline in the Fatigue Assessment (FAS) Total Score (p=0.0226) and KSQ-General Health score (p=0.0197) in patients treated with 5.0 mg/kg efzofitimod versus placebo. Treatment with efzofitimod was also associated with a trend toward a greater proportion of patients achieving steroid-free status for at least six months. Based on the trial findings, which we believe indicate drug activity for efzofitimod as evidenced by improvements across multiple clinically relevant efficacy endpoints, we held a Type C meeting with the FDA in mid-April 2026 to review the results of the EFZO-FIT study and determine the path forward for efzofitimod in pulmonary sarcoidosis. In May 2026, we received the official meeting minutes from the FDA.

Based on feedback from the FDA, we plan to continue the development of efzofitimod in pulmonary sarcoidosis in a new Phase 3 study in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease utilizing FVC as the primary endpoint of the study and the KSQ-Lung score as the key secondary endpoint (the Planned Phase 3 Study). We chose these endpoints based on the FDA's indication that FVC and KSQ-Lung are direct measures of how patients suffering from pulmonary sarcoidosis function and feel, and we concluded FVC to be a more appropriate primary endpoint at this time pending further content validation work for KSQ-Lung as recommended by the FDA. We determined the patient population for the Planned Phase 3 Study, those with restrictive lung disease, based on data from the EFZO-FIT study which included 44 patients with restrictive lung disease (defined as FVC percent predicted ≤ 80%) and showed a difference of 124 ml in change from baseline in FVC between restrictive patients treated with 5.0 mg/kg efzofitimod and placebo.

As part of our discussion with the FDA regarding the benefit risk profile for efzofitimod, we plan to increase the frequency of dosing of 5.0 mg/kg efzofitimod or placebo from once every four weeks in past trials to once every three weeks in the Planned Phase 3 Study. We are choosing the dosing regimen based on the FDA's acknowledgment of its reasonableness from a clinical pharmacology perspective, subject to inclusion of adequate safety monitoring and risk mitigation procedures. We plan to include additional risk mitigation strategies, enhanced safety surveillance for the potential development of anti-synthetase syndrome and a data safety monitoring committee.

The Planned Phase 3 Study is expected to be a global, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of efzofitimod in patients with moderate to severe pulmonary sarcoidosis. The Planned Phase 3 Study is a 54-week study and will consist of two parallel cohorts randomized equally to either 5.0 mg/kg efzofitimod or placebo dosed intravenously once every 3 weeks for a total of 17 doses. The Planned Phase 3 Study is intended to enroll up to approximately 372 patients with symptomatic pulmonary sarcoidosis with restrictive lung disease who are receiving a stable dose of ≤ 5.0 mg daily oral corticosteroid and/or a background immunosuppressant. All background treatment will remain stable throughout the duration of the Planned Phase 3 Study. The primary endpoint of the Planned Phase 3 Study will be change from baseline in FVC at week 48 and the key secondary endpoint will be change from baseline in the KSQ-Lung score at week 48.

Our Phase 2 proof-of-concept clinical trial of efzofitimod (the EFZO-CONNECT study) is a randomized, double-blind placebo-controlled proof-of-concept study to evaluate the efficacy, safety and tolerability of efzofitimod in patients with SSc-ILD. This is a 28-week study with three parallel cohorts randomized 2:2:1 to either 270 mg or 450 mg of efzofitimod or placebo dosed intravenously monthly for a total of six doses. The study intended to enroll up to 25 patients at multiple centers in the United States. The objective of the study is to evaluate the efficacy of multiple doses of IV efzofitimod on pulmonary, cutaneous (limited or diffuse) and systemic manifestations in patients with SSc-ILD. The primary endpoint is reduction in FVC. Secondary endpoints include certain measures regarding safety and tolerability. In July 2024, we amended the study to add an open-label extension (OLE) to patients. Patients who complete the study and wish to receive ongoing treatment with efzofitimod are eligible to participate in the 24-week OLE. In June 2025, we announced interim data from the study showing three out of four efzofitimod-treated diffuse SSc-ILD patients showed clinically important improvement based on the modified Rodnan Skin Score (mRSS) assessment at 12 weeks and that efzofitimod was generally well-tolerated at all doses. We have completed enrollment of the study with 23 patients. Topline data are anticipated in the first quarter of 2027.

Discovery Platform

Using efzofitimod as a model, we have developed a process to advance novel tRNA synthetase domains from a concept to therapeutic candidate. This process leverages our early discovery work as well as current scientific understanding of tRNA synthetase

evolution, protein structure, gene splicing and tissue-specific regulation to identify potentially active protein domains. Screening approaches are employed to identify target cells and extracellular receptors for these tRNA synthetase-derived proteins. These cellular systems can then be used in mechanism-of-action studies to elucidate the role these proteins play in cellular responses and their potential therapeutic utility. We are working to identify new tRNA synthetase based drug candidates through our internal discovery efforts and external collaboration efforts.

tRNA Synthetase Candidates

Utilizing our novel approach, we have identified target receptors for domains of certain additional tRNA synthetases, gaining insights into their potential biological activity in immunology and fibrosis. These fragments form the basis of our additional pipeline candidates. We plan to further elucidate the therapeutic potential of these candidates through mechanistic investigations, including *in vitro* and *in vivo* preclinical studies.

ATYR0101

ATYR0101 is a fusion protein derived from a domain of aspartyl-tRNA synthetase (DARS) that is engineered with a human Fc region to extend its serum half-life. The molecule possesses a unique mechanism of action focused on the selective elimination of activated myofibroblasts, which are the primary cellular drivers of pathological extracellular matrix (ECM) deposition in fibrotic diseases. ATYR0101 specifically targets Latent TGF-β Binding Protein-1 (LTBP-1) within the ECM, binding to a region that encompasses the fibrillin-1 binding domain at the C-terminus. LTBP-1 serves a dual role in matrix architecture by organizing structural proteins and modulating the signaling of Transforming Growth Factor-beta (TGF-β) through a complex mechanosensory apparatus. Early data suggest ATYR0101 exerts its antifibrotic effects by inducing apoptosis of myofibroblasts in a TGFβ dependent manner. We believe ATYR0101 may have broad therapeutic applications in multiple fibrotic diseases, such as pulmonary fibrosis, SSc, liver fibrosis and kidney fibrosis. We have initiated IND-enabling activities for ATYR0101.

Corporate Restructuring and Program Prioritization

On August 7, 2026, our board of directors approved the implementation of a corporate restructuring and program prioritization plan (the Restructuring Plan) to streamline our operations, and conserve capital prior to the potential initiation of the Planned Phase 3 Study. We submitted a protocol to our existing investigational new drug (IND) application for the Planned Phase 3 Study to the FDA in June 2026, and we await comments from the FDA on the protocol by the end of August 2026. To conduct the Planned Phase 3 Study, in addition to implementing the Restructuring Plan, we will need to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements.

In connection with the Restructuring Plan, we committed to a reduction in our total workforce by approximately 60% to 20 full-time employees, and we estimate that the Restructuring Plan will reduce annualized operating expenses by approximately $13 million, beginning in the fourth quarter of 2026. We began notifying affected employees on August 7, 2026 and expect the Restructuring Plan to be substantially completed in the second half of 2026. We estimate that we will record charges of approximately $4.2 million for employee severance, employee health benefit obligations and other related termination benefits. Severance payments are expected to be paid in full between August 2026 and September 2027, and we expect to incur the charges in the third quarter of 2026. The charges that we expect to incur in connection with, or as a result of, the Restructuring Plan, are subject to a number of assumptions, and actual results may differ materially. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the Restructuring Plan.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception. As of June 30, 2026, we had an accumulated deficit of $627.3 million, and we expect to continue to incur net losses for the foreseeable future. As of June 30, 2026, we had cash, cash equivalents, restricted cash and available-for-sale investments of $58.9 million. We believe that our current cash, cash equivalents, restricted cash and available-for-sale investments, will be sufficient to meet our material cash requirements from known contractual and other obligations for a period of at least one year from the date of this Quarterly Report. In addition to the factors discussed under “Material Cash Requirements,” our ability to fund our longer-term operating needs, including the completion of the Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis, will depend on our ability to raise additional funding through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements, and other factors, including those discussed in Part II, Item 1A. “Risk Factors—Risks related to our financial condition and need for additional capital—We will need to raise additional capital or enter into strategic partnering relationships to fund our operations.”

Sources of Cash

From our inception through June 30, 2026, we have financed our operations primarily through the sale of equity securities and convertible debt, venture debt, term loans and through license and collaboration agreement revenues. In recent years, we have relied primarily on our “at-the-market” offering program (the Jefferies ATM Offering Program) implemented through our Open Market Sale

Agreement℠ with Jefferies LLC (Jefferies) for financing our activities. Given ongoing volatility in capital markets generally, the price of our common stock has fluctuated materially since the start of 2025 and, since the announcement of top-line data from the EFZO-FIT study particularly, we have experienced a material decline in our stock price. If markets remain volatile or our stock price continues to remain depressed, this may negatively affect our ability to generate cash from financing activities in future periods, including negatively affecting our ability to generate sufficient funds through our Jefferies ATM Offering Program.

At-the-Market Offering Programs

In April 2022, we entered into an Open Market Sale Agreement℠ with Jefferies implementing the Jefferies ATM Offering Program. In December 2024, we amended the Jefferies ATM Offering Program. Under the Jefferies ATM Offering Program, we may offer and sell, from time to time and at our option, up to an aggregate of $215.0 million of shares of our common stock (inclusive of $65.0 million of sales made prior to the amendment) through Jefferies, acting as sales agent. Jefferies is entitled to a fixed commission rate of up to 3.0% of the gross sales proceeds of shares sold under the Jefferies ATM Offering Program. During the year ended December 31, 2025, we sold an aggregate of 13,887,177 shares of common stock at a weighted-average price of $4.94 per share for net proceeds of approximately $66.4 million under the Jefferies ATM Offering Program. We did not utilize the Jefferies ATM Offering Program during the six months ended June 30, 2026.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	Six Months Ended June 30,	
	2026	**2025**
Net cash provided by (used in):		
Operating activities	$ (21,868)	$ (29,314)
Investing activities	26,816	(1,119)
Financing activities	(271)	36,525
Net change in cash, cash equivalents and restricted cash	$ 4,677	$ 6,092

Operating activities. Net cash used in operating activities for the six months ended June 30, 2026 and 2025 was $21.9 million and $29.3 million, respectively. The net cash used during the six months ended June 30, 2026 was primarily attributable to discovery costs for our preclinical product candidates and for efzofitimod development, which includes certain close-out costs relating to the EFZO-FIT study as well as ongoing costs for the EFZO-CONNECT study. The net cash used during the six months ended June 30, 2025 was primarily for efzofitimod development, including pre-commercialization activities and manufacturing costs incurred prior to the announcement of top-line data from the EFZO-FIT study. We expect cash used in operating activities will fluctuate and be dependent upon our ability to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements to enable us to conduct the Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis.

Investing activities. Net cash provided by (used in) investing activities for the six months ended June 30, 2026 and 2025 was $26.8 million and $(1.1) million, respectively. The fluctuation in net cash provided by or used in investing activities resulted primarily from the timing differences in investment purchases, sales and maturities, and the fluctuation of our portfolio mix between cash equivalents and investment holdings. The average term to maturity in our investment portfolio is less than one year.

Financing activities. Net cash (used in) provided by financing activities for the six months ended June 30, 2026 and 2025 was $(0.3) million and $36.5 million, respectively. Net cash used in financing activities for the six months ended June 30, 2026 primarily consisted of principal payments on our financing lease agreement. Net cash provided by financing activities for the six months ended June 30, 2025 primarily consisted of $36.7 million in proceeds from the issuance of common stock through the Jefferies ATM Offering Program, net of offering costs.

Material Cash Requirements

To date, we have not generated any revenues from product sales. Our expenses may increase in connection with the potential advancement of efzofitimod in clinical development, manufacturing, and regulatory activities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We currently have minimal sales and marketing capabilities and would need to expand our organization to support these activities. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements are difficult to forecast and will depend on many factors. Refer to Part II, Item 1A, "Risk Factors - Risks related to our financial condition and need for additional capital—We will need to raise additional capital or enter into strategic partnering relationships to fund our operations." for a discussion of these factors.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements. To the extent we raise additional capital through the sale of equity, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our other technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. The incurrence of additional indebtedness would increase our fixed payment obligations and may require us to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We may be unable to raise additional funds on acceptable terms or at all. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional funds, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

As of June 30, 2026, our material cash requirements from known contractual and other obligations consisted primarily of (i) an operating lease for our corporate headquarters and laboratory space, and (ii) our master financing lease agreement for various research and development and informational technology equipment.

Corporate Headquarters Facility Lease

In May 2022, we entered into a non-cancelable facility lease that is subject to base lease payments that started at $5.75 per square foot of rentable area per month for the first 12 months of the lease and which escalate 3.0% annually over the term of the lease, and additional charges for common area maintenance and other costs. The term of the lease (the Lease Term) commenced on March 20, 2023 (the Lease Commencement Date) and will continue for 124 months from the Lease Commencement Date. We also have one option to extend the Lease Term for five years. In April 2024, we entered into a lease amendment for additional common area amenities, effective as of June 2023. The amendment increased the total rentable square feet from 23,696 rentable square feet to 24,866 rentable square feet. We provided a $0.7 million security deposit in the form of a letter of credit which is included in restricted cash as of June 30, 2026.

Financing Lease

In April 2022, we entered into a master financing lease agreement. Under this master agreement, we entered into various financing lease agreements from July 2022 through November 2023 to lease various research and development and information technology equipment over a 48-month term. Financing lease liabilities total $0.6 million as of June 30, 2026. Additionally, as of June 30, 2026, we have $0.8 million in cash collateral for the financing lease, and this amount is included in restricted cash.

We did not have any off-balance sheet arrangements as of June 30, 2026.

Financial Operations Overview

Organization and Business; Principles of Consolidation

We conduct substantially all of our activities through aTyr Pharma, Inc., a Delaware corporation, at our facility in San Diego, California. aTyr Pharma, Inc. was incorporated in the State of Delaware in September 2005. The unaudited condensed consolidated financial statements in this Quarterly Report include our accounts and our 98% majority-owned subsidiary in Hong Kong, Pangu BioPharma, as of June 30, 2026. All intercompany transactions and balances are eliminated in consolidation.

Research and Development Expenses

To date, our research and development expenses have been related primarily to the development of, and clinical trials for, our product candidates, and to research efforts targeting the potential therapeutic application of other tRNA synthetase-based immunomodulators. These expenses consist primarily of:

- salaries and employee-related expenses, including stock-based compensation and benefits for personnel in research and product development functions;
- costs associated with conducting our preclinical, development and regulatory activities, including fees paid to third-party professional consultants, service providers and our scientific, therapeutic and clinical advisory board;

- costs to acquire, develop and manufacture preclinical study and clinical trial materials and to support biologics license application (BLA) filing activities with contracted development and manufacturing organizations (CDMOs);
- costs to support our pre-commercialization efforts;
- costs incurred under clinical trial agreements with CROs and investigative sites;
- costs for laboratory supplies; and
- allocated facilities, depreciation and other allocable expenses.

Product candidates in later stages of clinical development, such as efzofitimod, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We primarily outsource our clinical trial administration to CROs, and we outsource our manufacturing of clinical trial materials to CDMOs. These outsourced expenses are typically substantially higher than the expenses we incur on candidates in earlier stages of development. As such, we separately track and report on the majority of our research and development expenses associated with the advancement of efzofitimod. For our candidates in preclinical development, the nature of the research and development expenses incurred to advance these candidates is primarily internal personnel, laboratory supply expenses and IND-enabling activities. We do not fully track or allocate these internal expenses between preclinical product candidates because the expenses can often be shared between candidates. We also incur other shared expenses to support our research and development efforts such as facilities expenses, and these expenses are not allocated to efzofitimod or our preclinical product candidates. Additionally, non-cash research and development expenses such as depreciation and stock-based compensation are not tracked or allocated between product candidates and are shared among all product candidates.

We anticipate that our research and development expenses will fluctuate and be dependent upon our ability to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements to enable us to conduct the Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our programs, we are unable to estimate with any certainty the costs we will incur or the timelines we will require in the continued development of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast which programs or product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, pre-commercialization, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include accounting, legal services, expenses associated with applying for and maintaining patents, cost of insurance, cost of various consultants, occupancy costs, information systems costs and depreciation.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the unaudited condensed consolidated financial statements, as well as the reported expenses during the reporting periods. We monitor and analyze these items for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience and on various other factors we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

We discuss our accounting policies and assumptions that involve a higher degree of judgment and complexity within Note 2 to our audited consolidated financial statements in our 2025 Annual Report. There have been no material changes to our critical accounting policies and estimates as disclosed in our 2025 Annual Report.

Results of Operations

Comparison of the Three Months Ended June 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended June 30, 2026 and 2025 (in thousands):

	Three Months Ended June 30,		Increase / (Decrease)
	2026	2025	
Research and development expenses:			
Efzofitimod expenses	$ 2,106	$ 12,290	$ (10,184)
Preclinical development and other shared research and development expenses	4,230	2,623	1,607
Non-cash expenses (depreciation and stock-based compensation)	412	471	(59)
Total research and development expenses	6,748	15,384	(8,636)
General and administrative expenses:			
Other general and administrative expenses	3,232	3,928	(696)
Non-cash expenses (depreciation and stock-based compensation)	901	1,001	(100)
Total general and administrative expenses	4,133	4,929	(796)
Other income (expense), net	571	781	(210)

Research and development expenses. Research and development expenses were $6.7 million and $15.4 million for the three months ended June 30, 2026 and 2025, respectively. The decrease of $8.6 million was primarily driven by a reduction in efzofitimod expenses for the EFZO-FIT study since it was completed in September 2025 as well as decreased manufacturing costs due to the timing of certain manufacturing activities being completed. Preclinical development and other shared research and development expenses increased by $1.6 million, and was primarily attributable to increased discovery costs for our preclinical product candidates, including IND-enabling activities for our ATYR0101 preclinical candidate. Non-cash expenses were consistent as compared to the prior year period. We anticipate that our research and development expenses will fluctuate and be dependent upon our ability to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements to enable us to conduct the Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis.

General and administrative expenses. General and administrative expenses were $4.1 million and $4.9 million for the three months ended June 30, 2026 and 2025, respectively. The decrease of $0.8 million was attributable to pre-commercialization expenses incurred during the same period in the prior year ahead of the announcement of top-line data from the EFZO-FIT study. Non-cash expenses decreased by $0.1 million primarily due to decreased non-cash stock-based compensation expenses. We anticipate that our general and administrative expenses will decrease in the near term in conjunction with the implementation of our Restructuring Plan.

Other income (expense), net. Other income (expense), net was $0.6 million and $0.8 million for the three months ended June 30, 2026 and 2025, respectively. The change was primarily a result of lower interest rates and lower interest earned on lower cash balances as compared to the same period in the prior year.

Comparison of the Six Months Ended June 30, 2026 and 2025

The following table summarizes our results of operations for the six months ended June 30, 2026 and 2025 (in thousands):

	Six Months Ended June 30,		Increase /
	2026	2025	(Decrease)
Research and development expenses:			
Efzofitimod expenses	5,641	21,094	(15,453)
Preclinical development and other shared research and development expenses	7,585	5,184	2,401
Non-cash expenses (depreciation and stock-based compensation)	839	920	(81)
Total research and development expenses	14,065	27,198	(13,133)
General and administrative expenses:			
Other general and administrative expenses	6,307	6,992	(685)
Non-cash expenses (depreciation and stock-based compensation)	1,945	1,896	49
Total general and administrative expenses	8,252	8,888	(636)
Other income (expense), net	1,215	1,673	(458)

Research and development expenses. Research and development expenses were $14.1 million and $27.2 million for the six months ended June 30, 2026 and 2025, respectively. The decrease of $13.1 million was primarily driven by a reduction in efzofitimod expenses for the EFZO-FIT study since it was completed in September 2025 as well as decreased manufacturing costs due to the timing of certain manufacturing activities being completed. Preclinical development and other shared research and development expenses increased by $2.4 million, and was primarily attributable to increased discovery costs for our preclinical product candidates, including IND-enabling activities for our ATYR0101 preclinical candidate. Non-cash expenses were consistent as compared to the prior year period. We anticipate that our research and development expenses will fluctuate and be dependent upon our ability to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements to enable us to conduct the Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis.

General and administrative expenses. General and administrative expenses were $8.3 million and $8.9 million for the six months ended June 30, 2026 and 2025, respectively. The decrease of $0.6 million was attributable to pre-commercialization expenses incurred during the same period in the prior year ahead of the announcement of top-line data from the EFZO-FIT study. Non-cash expenses were consistent as compared to prior year period. We anticipate that our general and administrative expenses will decrease in the near term in conjunction with the implementation of our Restructuring Plan.

Other income (expense), net. Other income (expense), net was $1.2 million and $1.7 million for the six months ended June 30, 2026 and 2025, respectively. The change was primarily a result of lower interest rates and lower interest earned on lower cash balances as compared to the same period in the prior year.

Recent Accounting Pronouncements

For discussion of recently issued accounting pronouncements, refer to Part I, Item 1, Notes to Condensed Consolidated Financial Statements (Unaudited) – Note 1 – Recent Accounting Pronouncements of this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we are required to file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, of the effectiveness of the

design and operation of our disclosure controls and procedures as of the end of the quarter covered by this Quarterly Report. Based on this evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the quarter covered by this Quarterly Report.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, of any changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our evaluation did not identify any changes in our internal control over financial reporting that occurred during the quarter covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On October 9, 2025 and October 22, 2025, two substantially similar putative securities class action complaints were filed in the U.S. District Court for the Southern District of California, naming aTyr Pharma, Inc. and our Chief Executive Officer, Sanjay Shukla. The complaints assert that we and Mr. Shukla violated Section 10(b) of the Exchange Act and SEC Rule 10b-5, by making materially false or misleading statements related to efzofitimod. The complaints also assert that Mr. Shukla violated Section 20(a) of the Exchange Act. Plaintiffs seek class certification, an award of unspecified damages, and award of reasonable costs and expenses, including attorneys' fees and expert fees, and further relief as the court may deem just and proper. On February 9, 2026, the court consolidated the two cases and appointed co-lead plaintiffs to oversee the litigation. On May 1, 2026, co-lead plaintiffs filed an Amended Consolidated Complaint. The Amended Consolidated Complaint is based on the same underlying allegations as the original complaints, asserts the same claims and seeks the same relief, and adds our Chief Financial Officer, Jill M. Broadfoot, as a defendant. On July 17, 2026, we moved to dismiss the Amended Consolidated Complaint. Under the current schedule, any opposition to a motion to dismiss is due August 28, 2026, with any reply due September 28, 2026. We believe we have meritorious defenses and intend to vigorously defend the Company in this matter.

Item 1A. Risk Factors

Risks Factors Summary

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factors summary, and other risks that we face, can be found following this summary and should be carefully considered, together with other information in this Quarterly Report and our other filings with the SEC before making investment decisions regarding our securities.

Investing in our securities involves substantial risk. The risks described under the heading "Risk Factors" immediately following this summary may cause us to not realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the more significant risks we face include the following:

- We will need to raise additional capital or enter into strategic partnering relationships to fund our operations;
- We are a biotechnology company and have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future;
- There is no established U.S. Food and Drug Administration (FDA) regulatory pathway for approval of a drug in pulmonary sarcoidosis. Our new Phase 3 study for efzofitimod in pulmonary sarcoidosis (Planned Phase 3 Study) may not be sufficient to support FDA approval and the FDA may require additional clinical trials which would materially and adversely harm our business;
- We may encounter substantial delays and other challenges in our ongoing or planned clinical trials or we may fail to demonstrate safety and efficacy, such as our failure to meet the primary endpoint in the EFZO-FIT study, to the satisfaction of applicable regulatory authorities;
- If we are unable to successfully complete or otherwise advance clinical development, obtain regulatory or marketing approval for, or successfully commercialize our therapeutic product candidates, including efzofitimod, or experience significant delays in doing so, our business will be materially harmed;

- We may face contracted development and manufacturing organization (CDMO) manufacturing stoppages and other CDMO challenges associated with the clinical or commercial manufacture of our product candidates or regulatory activities required for a biologics license application (BLA) submission;
- Our current product candidates and any other product candidates that we may develop from our discovery platform represent novel therapeutic approaches, which may cause significant delays or may not result in any commercially viable drugs;
- Our therapeutic product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any;
- We have depended and may again in the future depend on collaborations with third parties for the development and commercialization of certain of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates;
- If we are unable to obtain, maintain or protect intellectual property rights related to our product candidates, or if the scope of such intellectual property protection is not sufficiently broad, we may not be able to compete effectively in our markets;
- Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel;
- Unfavorable macroeconomic conditions could adversely affect our business, financial condition or results of operations; and
- The market price of our common stock historically has been highly volatile and is likely to continue to be volatile, and you could lose all or part of your investment.

Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report and in our other public filings with the SEC. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. You should consider all of the risk factors described in our other public filings when evaluating our business. The risk factors set forth below that are marked with an asterisk (*) contain changes to the similarly titled risk factors included in, or did not appear as separate risk factors in, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2025 (Annual Report), which was filed with the SEC on March 5, 2026.

Risks related to our financial condition and need for additional capital

We will need to raise additional capital or enter into strategic partnering relationships to fund our operations.*

The development of therapeutic product candidates is expensive, and we expect our research and development expenses to fluctuate. As of June 30, 2026, our cash, cash equivalents, restricted cash and available-for-sale investments were approximately $58.9 million. We believe that our current cash, cash equivalents, restricted cash and available-for-sale investments, will be sufficient to meet our material cash requirements for known contractual and other obligations for a period of at least one year from the date of this Quarterly Report. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements. Our future funding requirements are difficult to forecast and will depend on many factors, including but not limited to:

- We held a Type C meeting with the FDA in mid-April 2026 to review the results of the EFZO-FIT study and determine the path forward for efzofitimod in pulmonary sarcoidosis. We submitted a protocol under our investigational new drug (IND) application to the FDA in June 2026 and we await comments from the FDA on the protocol by the end of August 2026. We plan to continue the development of efzofitimod in pulmonary sarcoidosis in our Planned Phase 3 Study. The Planned Phase 3 Study and any potential need for additional clinical studies for efzofitimod in pulmonary sarcoidosis will be costly and will require us to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements to conduct such studies;
- the type, number, scope progress, expansions, results, costs and timing of, our clinical trials and preclinical studies for our product candidates or other potential product candidates or indications which we are pursuing or may choose to pursue in the future, including changes in our CROs or CDMOs;
- the costs, timing and outcome of regulatory review of our product candidates;
- potential delays of our planned clinical trials of efzofitimod;

- cost increases related to the manufacturing of preclinical study and clinical trial materials, including cost increases related to technology transfers to additional CDMOs and any delays in the manufacturing of study drug;
- cost increases as a result of global geopolitical tension, armed conflicts, potential future health pandemics, liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets, tariffs and trade tensions, higher interest rates and financial and credit market fluctuations, volatility in the capital markets, labor shortages, economic slowdowns, recessions or market corrections, inflation and monetary supply shifts and tightening of credit markets;
- the number and characteristics of product candidates that we pursue;
- the scope, progress, results and costs of preclinical development, and clinical trials for other product candidates;
- our ability to enter into new collaboration and licensing arrangements and the timing of any payments we may receive under such arrangements;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval.

In any event, we will require additional capital to complete additional clinical trials, to obtain regulatory approval for, and to commercialize, our product candidates, such as efzofitimod.

Raising funds in the current and future economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates, or we may be unable to expand our operations, maintain our current organization and employee base or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. For example, in August 2026, our board of directors approved the implementation of a corporate restructuring and program prioritization plan (the Restructuring Plan) to streamline our operations and conserve capital prior to the potential initiation of the Planned Phase 3 Study. In connection with the Restructuring Plan, we committed to a reduction in our total workforce by approximately 60% to 20 full-time employees.

The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would cause dilution to all of our stockholders. The incurrence of indebtedness would result in fixed payment obligations and may require us to agree to certain restrictive covenants, such as limitations on our ability to incur debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. As a result of global geopolitical and macroeconomic conditions, liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets, tariffs and trade tensions, the recent and potential future shutdowns of the federal government and the resulting effects on its regulatory agencies, higher interest rates and financial and credit market fluctuations, volatility in the capital markets, the global credit and financial markets have experienced volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, volatility in unemployment rates, inflation, higher interest rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. In addition, any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

We are a biotechnology company and have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.*

We are a biotechnology company, and we have not yet generated any revenues from product sales. We have incurred net losses in each year since our inception in 2005, including consolidated net losses of $21.1 million for the six months ended June 30, 2026. As of June 30, 2026, we had an accumulated deficit of $627.3 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through the sale of equity securities and convertible debt and through venture debt, term loans and license and collaboration agreement revenues. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements. We will not generate any revenue from product sales unless and until we

successfully complete development and obtain regulatory approval for a product candidate. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend, in part, upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates in those markets.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will fluctuate in connection with our ongoing activities as we: continue our research and preclinical and clinical development of efzofitimod or any other product candidates that we may develop; obtain clinical trial materials and further develop the manufacturing process for our product candidates; seek regulatory approvals for our product candidates that successfully complete clinical trials; ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; seek to identify and validate additional product candidates; maintain, protect and expand our intellectual property portfolio; acquire or in-license other product candidates and technologies; attract and retain skilled personnel; and create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

Our revenues, expenses and income or losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We have never generated any revenue from product sales and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our product candidates. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research, preclinical development and clinical development of our product candidates, potentially with a strategic partner;
- seeking and obtaining regulatory approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates and establishing supply and manufacturing relationships with third parties;
- launching and commercializing product candidates for which we obtain regulatory approval, either by collaborating with a partner or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting and expanding our intellectual property portfolio;
- obtaining market acceptance of our product candidates as viable treatment options for our target indications;
- identifying and validating new therapeutic product candidates;
- attracting, hiring and retaining qualified personnel; and
- negotiating favorable terms in any licensing, collaboration or other arrangements into which we may enter.

Even if one of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Risks related to the discovery, development and regulation of our product candidates

There is no established FDA regulatory pathway for approval of a drug in pulmonary sarcoidosis. Our Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis may not be sufficient to support FDA approval and the FDA may require additional clinical trials which would materially and adversely harm our business.*

The only FDA-approved therapies for the treatment of sarcoidosis are glucocorticoids which were approved by the FDA in the 1950s, prior to current regulatory standards. As such, the most appropriate efficacy endpoints to demonstrate clinically meaningful treatment effects have not been established. Accordingly, the FDA has not endorsed a specific primary endpoint nor a specific means for measurement of steroid reduction. In 2022, we initiated the EFZO-FIT study, where we selected steroid reduction as the primary endpoint and measured steroid reduction in multiple ways in an effort to support an approval. In 2025, we announced top-line results from the EFZO-FIT study, including that the study did not meet its primary endpoint of steroid reduction.

Although the study did not meet its primary endpoint, we believe the improvements seen across multiple clinically relevant efficacy endpoints indicate drug activity for efzofitimod. Based on these trial findings, we held a Type C meeting with the FDA in April 2026 to review the results of the EFZO-FIT study and determine the path forward for efzofitimod in pulmonary sarcoidosis. Based on feedback from the FDA, we plan to continue the development of efzofitimod in pulmonary sarcoidosis in the Planned Phase 3 Study in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease utilizing FVC as the primary endpoint of the Planned Phase 3 Study and the KSQ-Lung score as the key secondary endpoint. We chose these endpoints based on the FDA's indication that FVC and KSQ-Lung are direct measures of how patients suffering from pulmonary sarcoidosis function and feel, and we concluded FVC to be a more appropriate primary endpoint at this time pending further content validation work for KSQ-Lung as recommended by the FDA. Additionally, as part of our discussion with the FDA regarding the benefit risk profile for efzofitimod, we plan to increase the frequency of dosing of 5.0 mg/kg efzofitimod or placebo from once every four weeks in past trials to once every three weeks in the Planned Phase 3 Study. The Planned Phase 3 Study and any potential need for any additional clinical trials for efzofitimod in pulmonary sarcoidosis, will require a significant amount of additional time and resources to support approval. In addition, it will require us to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements to conduct such studies.

The FDA views the EFZO-FIT study as a failed study due to the fact that the study did not meet its primary endpoint and indicated that results from the EFZO-FIT study will not be useful in establishing effectiveness for efzofitimod in pulmonary sarcoidosis. The FDA highlighted the risk of proceeding with a larger study in a more limited patient population with a higher unstudied dose and expressed concerns regarding patient safety, which may not be mitigated in part or at all by our planned risk mitigation strategies, enhanced safety surveillance for the potential development of anti-synthetase syndrome and data safety monitoring committee. The results of our Planned Phase 3 Study may not ultimately support FDA approval, which would adversely affect our business, prospects, financial condition and results of operations.

In general, the FDA has substantial discretion in the approval process and may refuse to accept our application or decide that our data are insufficient for approval and require additional preclinical, clinical or other trials, which would be costly and significantly delay the potential for regulatory approval. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of efzofitimod based on the completed clinical trials.

We may encounter substantial delays and other challenges in our ongoing or planned clinical trials or we may fail to demonstrate safety and efficacy, such as our failure to meet the primary endpoint in the EFZO-FIT study, to the satisfaction of applicable regulatory authorities.*

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive, time-consuming, often delayed and uncertain as to outcome. We cannot guarantee that our ongoing clinical trials, including our Phase 2 study in systemic sclerosis (SSc, also known as scleroderma) associated-interstitial lung disease (ILD) (SSc-ILD) (the EFZO-CONNECT study), or planned clinical trials, including our Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis, will be initiated or conducted as planned or completed on schedule, if at all. We cannot assure you that our product candidates will not be subject to new clinical holds or significant delay in the future. For example, we may experience delays in site initiation and patient enrollment, failures to comply with study protocols, delays in the manufacture of study drug for clinical testing and other difficulties in starting or completing our clinical trials. Any inability to initiate or complete clinical trials of our product candidates in the United States, as a result of clinical holds or otherwise, would delay our clinical development plans, may require us to incur additional clinical development costs and could impair our ability to obtain U.S. regulatory approval for such product candidates.

A failure of one or more clinical trials can occur at any stage of testing, and our clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include, but are not limited to:

- our inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of human clinical trials, including clinical trials of certain dosages;
- delays in reaching consensus with regulatory agencies on trial design, and prioritization of outcome measurements that would best support the evaluation of efzofitimod's efficacy;
- delays in reaching agreement on acceptable terms with prospective clinical contract research organizations (CROs) and clinical trial sites, including any delays resulting from changes in CROs;
- delays in obtaining required institutional review board or Ethics Committee approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials, or delays that may result if the number of patients required for a clinical trial is larger than we anticipate;

- imposition of a clinical hold by regulatory agencies, which may occur at any time before or during a clinical trial, including after our submission of data to these agencies or an inspection of our clinical trial operations or trial sites;
- failure by our CROs, investigators, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the good clinical practices (GCPs) of the U.S. Food and Drug Administration (FDA) or applicable regulatory requirements in other countries;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- disagreements with regulators regarding our interpretation of data from preclinical studies or clinical trials;
- occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any delay in or inability to successfully complete preclinical and clinical development (including any delays resulting from any changes in a CRO) could result in additional costs to us and impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates (including our technology transfer to another contracted development and manufacturing organization (CDMO) for bulk drug substance and production capacity changes for efzofitimod), we will need to conduct additional comparability studies to bridge our modified product candidates to earlier versions, and the data generated from these comparability studies will need to be reviewed and accepted by the FDA or other regulatory authorities.

If the results of our clinical trials are, or are perceived to be, negative or inconclusive, or if there are safety concerns or adverse events associated with our product candidates, we may be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements; be delayed in obtaining marketing approval for our product candidates, if at all; obtain approval for indications or patient populations that are not as broad as intended or desired; obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; be subject to changes in the way the product is manufactured or administered; have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy; be subject to litigation, including as described in this report under the caption “Legal Proceedings”; or experience damage to our reputation. For example, in September 2025, we announced that we did not meet the primary endpoint in the EFZO-FIT study. We held a Type C meeting with the FDA in mid-April 2026 to review the results of the EFZO-FIT study and determine the path forward for efzofitimod in pulmonary sarcoidosis. In May 2026, we received the official meeting minutes from the FDA. Based on feedback from the FDA, we plan to continue the development of efzofitimod in pulmonary sarcoidosis in the Planned Phase 3 Study in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease. The Planned Phase 3 Study and any potential need for any additional clinical trials for efzofitimod in pulmonary sarcoidosis, will require a significant amount of additional time and resources to support approval. In addition, it will require us to obtain additional capital through equity offerings or partnering to conduct such studies.

To date, the safety and efficacy of efzofitimod has only been studied in a limited number of humans. Accordingly, efzofitimod and any future product candidates could potentially cause unexpected adverse events. In addition, the inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to the natural progression of the disease. Further, if patients drop out of our ongoing or future clinical trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, or if our clinical trials are otherwise disrupted due to global geopolitical tension, armed conflicts, potential future health pandemics or other adverse macroeconomic and geopolitical events, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program. In addition, the COVID-19 pandemic previously impacted clinical trials broadly, including our completed efzofitimod Phase 1b/2a trial in patients with pulmonary sarcoidosis, where many sites stopped enrollment and patients chose not to enroll or continue participating in the trial due to the impact of COVID-19. While we completed the clinical trial, the availability of results from the Phase 1b/2a clinical trial was delayed until September 2021.

If we are unable to successfully complete or otherwise advance clinical development, obtain regulatory or marketing approval for, or successfully commercialize our therapeutic product candidates, including efzofitimod, or experience significant delays in doing so, our business will be materially harmed.*

To date, we have expended significant time, resources and effort on the discovery and development of product candidates related to the extracellular proteins derived from the histidyl tRNA synthetase (HARS) family, including conducting preclinical studies and clinical trials. We have not yet successfully completed any evaluation of our product candidates in human clinical trials designed to demonstrate efficacy to the satisfaction of the FDA, including the EFZO-FIT study, which we announced in September 2025 did not meet its primary endpoint. Before we can market or sell our therapeutic candidates in the United States or foreign jurisdictions, we will need to commence and complete additional clinical trials and larger, pivotal trials, manage clinical and manufacturing activities, obtain

necessary regulatory approvals from the FDA in the United States and from similar regulatory authorities in other jurisdictions, obtain adequate clinical and commercial manufacturing supplies, build commercial capabilities, which may include entering into a marketing collaboration with a third party, and in some jurisdictions, obtain reimbursement authorization, among other things. We cannot assure you that we will be able to successfully complete the necessary clinical trials, obtain regulatory approvals, secure an adequate commercial supply for, or otherwise successfully commercialize our therapeutic candidates. If we do not receive regulatory approvals for our product candidates, and even if we do obtain regulatory approvals, we may never generate significant revenues, if any, from commercial sales. If we fail to successfully commercialize our therapeutic candidates, we may be unable to generate sufficient revenues to sustain and grow our company, and our business, prospects, financial condition and results of operations will be adversely affected.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our clinical studies, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies, such as our disclosure of an interim analysis of our Phase 2 EFZO-CONNECT study of efzofitimod in SSc-ILD in June 2025. Disclosure of interim data from our clinical studies is subject to the same risks as the disclosure of preliminary or top-line data.

In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of a particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We have encountered and may continue to encounter delays and difficulties enrolling patients in our clinical trials for a variety of reasons, including the limited number of patients who have the diseases for which certain of our product candidates are being studied, which could delay or halt the clinical development of our product candidates.*

Identifying and qualifying patients to participate in clinical trials for our product candidates is critical to our success. Certain of the conditions for which we may elect to evaluate our product candidates may be rare diseases with limited patient pools from which to draw for clinical trials.

We may be unable to identify and enroll a sufficient number of patients with the disease in question and who meet the eligibility criteria for, and are willing to participate in, our clinical trials. For example, we are currently planning to continue development of efzotifimod in pulmonary sarcoidosis in the Planned Phase 3 Study in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease. While estimates of pulmonary sarcoidosis prevalence vary, we estimate that pulmonary sarcoidosis affects an estimated 160,000 patients in the United States, with approximately 90,000 suffering from moderate to severe disease. Of that population, however, we estimate that approximately 38,000 experience restrictive lung disease such that our targeted patient population for our Planned Phase 3 Study is significantly smaller. The eligibility criteria for any of our clinical trials may further limit the pool of available participants in our trials. We may be unable to identify and enroll a sufficient number of patients with the disease in question and who meet the eligibility criteria for, and are willing to participate in, the clinical trials. Once enrolled, patients may decide or be required to discontinue from the clinical trial due to inconvenience, burden of trial requirements, adverse events associated with efzofitimod, limitations required by trial protocols or other reasons.

Our ability to identify, recruit, enroll and maintain a sufficient number of patients, or those with required or desired characteristics to achieve diversity in our clinical trials in a timely manner may also be affected by other factors, including, but not limited to:

- proximity and availability of clinical trial sites for patients;
- severity of the disease under investigation;
- design of the study protocol and the burdens to patients of compliance with our study protocol;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials for the patient populations and indications under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We plan to seek initial marketing approval in the United States. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including, but not limited to:

- difficulty in establishing or managing relationships with or changes in CROs and physicians;
- different requirements and standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of biotechnology products and treatment.

Additionally, if patients are unwilling to participate in our clinical trials because of negative publicity from adverse events in our clinical trials or in the biotechnology or protein therapeutics industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development or termination of our clinical trials altogether. If we have difficulty enrolling and maintaining a sufficient number of patients to conduct our clinical trials as planned for any reason, we may need to delay, limit or terminate clinical trials, any of which would have an adverse effect on our business, prospects, financial condition and results of operations.

Furthermore, clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to obtain orphan exclusivity and successfully commercialize our product candidates and may have an adverse effect on our business, financial condition and results of operations.

We have previously conducted and we or our third-party collaborators may conduct additional clinical trials of efzofitimod outside of the United States. The FDA, however, may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.*

In June 2018, we completed a Phase 1 clinical trial of efzofitimod in healthy subjects in Australia. This randomized, double-blind, placebo-controlled study investigated the safety, tolerability, immunogenicity, and pharmacokinetics (PK) of intravenous efzofitimod in 36 healthy volunteers. In addition, we or our third-party collaborators may choose to conduct additional clinical trials for efzofitimod in countries outside the United States, subject to applicable regulatory approval. For example, Kyorin, conducted and funded an efzofitimod Phase 1 clinical trial in 32 healthy Japanese male volunteers and conducted and funded the Japan portion of the EFZO-FIT study. We conducted the EFZO-FIT study with a total of 268 subjects in centers in the United States, Europe, Brazil, and Japan. We plan to conduct our Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis globally as well.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data is generally subject to certain conditions. For example, in cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable in the U.S. population and U.S. medical practice; and (ii) the clinical trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. In addition, when studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there

is an additional risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which would likely require us to conduct additional clinical trials, in which case our development plans will be delayed, which could materially harm our business.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- evolving global geopolitical tension, armed conflicts and macroeconomic developments; and
- diminished protection of intellectual property in some countries.
- Further, the integrity of data from any clinical trials conducted outside of the United States may not be acceptable to the FDA.

We may face CDMO manufacturing stoppages and other CDMO challenges associated with the clinical or commercial manufacture of our product candidates or regulatory activities required for a biologics license application (BLA) submission.*

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our CDMOs for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or use in late-stage clinical trials must be manufactured in accordance with current good manufacturing practices (cGMPs). These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our CDMOs must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's Good Laboratory Practices and cGMP regulations enforced by the FDA through its facilities inspection program. The facilities and quality systems of our CDMOs and other CROs must pass a pre-approval inspection for compliance with applicable regulations as a condition of regulatory approval of our product candidates. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted. If anything were to prevent the FDA or other regulatory authorities from conducting their regular inspections, it could impact the ability of our CDMOs to provide us with product for clinical trials.

The regulatory authorities also may, at any time following approval of a product for sale, audit the facilities in which the product is manufactured. If any such inspection or audit of our facilities or those of our CDMOs and CROs identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independently of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. For example, in March 2026, the FDA issued our current CDMO a Notice of Inspectional Observations (commonly referred to as a Form 483), which requires our CDMO to address the observations in such notice to the FDA's satisfaction. Our CDMO may not address those observations in a timely manner or at all, and any of our CDMOs may receive a similar notice in the future. Any remedial measures imposed upon us or third parties with whom we contract as a result of inspections or audits could materially harm our business.

If we or any of our CDMOs and CROs fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new biologic product, or revocation of a pre-existing approval. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in clinical or commercial supply. An alternative manufacturer would need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

In addition, the manufacture of our product candidates presents challenges associated with biologics production, including the inherent instability of larger, more complex molecules and the need to ensure uniformity of the drug substance produced in different facilities or across different batches. The process of manufacturing biologics is extremely susceptible to product loss and delays due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. We have incurred such product losses and delays due to these types of deviations with our current CDMO. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. Furthermore, although tRNA synthetases represent a class of proteins that may share immunomodulatory properties in various physiological pathways, each tRNA synthetase has a different structure and may have unique manufacturing requirements that

are not applicable across the entire class. For example, fusion proteins, such as efzofitimod, include an additional antibody domain to improve PK characteristics, and may therefore require a more complex and time-consuming manufacturing process than other tRNA synthetase-based therapeutic candidates. Currently, we are producing our efzofitimod molecule in *E.coli*. The manufacturing processes for one of our product candidates may not be readily adaptable to other product candidates that we develop, and we may need to engage multiple third-party manufacturers to produce our product candidates.

For example, we engaged an additional CDMO to manufacture efzofitimod and completed a technology transfer and validation process before the CDMO was able to produce additional bulk drug substance. Even if we successfully complete technology transfers and validation processes with third-party manufacturers, we may still experience manufacturing setbacks. For example, during 2024, we initiated preparatory work with the additional CDMO engaged to manufacture efzofitimod on three process performance qualification drug substance batches that will be required as part of our potential BLA submission for efzofitimod. During the first quarter of 2025, the first upstream batch did not meet process performance qualification specifications, and was replaced by the CDMO. During the third quarter of 2025, we initiated and successfully completed the required three process performance qualification batches. The drug substance material generated from these batches has been forward processed into drug product. The deviations in the initial drug substance batch were due to operational errors at the CDMO and not related to the underlying process nor the drug substance. In the future, we may experience deviations with this or other CDMOs for any number of reasons, whether due to operational errors or otherwise.

Additionally, we have been informed by our CDMO that it will be relocating the microbial manufacturing site we used to conduct our manufacturing batches. We are currently assessing the impact of this transition, including potentially conducting future manufacturing batches with this CDMO at a different site, or with a new CDMO. We believe we have sufficient drug product supply for all planned clinical studies, which includes our Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis. However, we expect our commercial supply planning and funding needs may be significantly impacted by the transition to the CDMO's other site, or by transitioning to a new CDMO for commercial supply purposes. We rely on the manufacturers of our product candidates (and will rely on manufacturers of our products, if approved) to purchase from third-party suppliers the materials necessary to produce the pharmaceutical ingredients, including finished drug product, for our nonclinical and clinical studies. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms and all such prices are susceptible to fluctuations in price and availability due to transportation costs, government regulations, price controls, and changes in economic climate or other foreseen circumstances. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. In addition, the U.S. has implemented, and has proposed to further implement, tariffs that may affect the availability of imported raw materials used in the production of our product candidates and/or increase the costs to our CDMO and the expense to us to produce our product candidates. Additionally, other governments have enacted, and may continue to enact, retaliatory measures in response to such tariffs. Any additional adverse developments, changes in legislation or other economic policy changes affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product which could delay the development of our product candidates, the timing of our potential BLA submission for efzofitimod and could require significant additional funding. We may also have to write off inventory, incur other charges and expenses for supply of drug substance and drug product that fails to meet specifications or expires, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Any manufacturing stoppage or delay, or any inability to consistently manufacture adequate supplies of our product candidates for our clinical trials or on a commercial scale will harm our business, prospects, financial condition and results of operations.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate, and the scope of any approval may be narrower than we expect.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval.

Additional delays may result if an FDA advisory committee or regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested, may impose restrictions on dosing or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Although we have obtained orphan drug designation for efzofitimod for the treatment of sarcoidosis and systemic sclerosis in the United States and for the treatment of sarcoidosis in the European Union (EU), we may not receive orphan drug designation for efzofitimod in other jurisdictions or for other indications that we may pursue, or for any other product candidates we may develop under any new applications for orphan drug designation that we may submit, and any orphan drug designations that we have received or may receive may not confer marketing exclusivity or other expected commercial benefits.*

The FDA granted orphan drug designation to efzofitimod for the treatment of sarcoidosis in January 2022 and SSc in April 2022. The European Commission, on the basis of the opinion of the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) granted orphan drug designation to efzofitimod for the treatment of sarcoidosis in January 2023 and for the treatment of SSc in June 2023. We may apply for orphan drug designation for efzofitimod for other indications and product candidates in the United States and the EU.

Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA's COMP grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

Orphan drug status confers up to ten years of marketing exclusivity in Europe, and up to seven years of marketing exclusivity in the United States, for a particular product in a specified indication. Obtaining an orphan drug designation can be difficult and we cannot assure you that we will be able to obtain orphan drug designation in other jurisdictions or for other indications, or rely on orphan drug or similar designations to exclude other companies from manufacturing or selling products using the same principal mechanisms of action for the same indications that we pursue beyond these timeframes. Furthermore, marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product. Even if we are the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during the period of marketing exclusivity, such as if the later product is shown to be clinically superior to the orphan product, or if the later product is deemed a different product than ours. Further, the marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

A breakthrough therapy or Fast Track designation by the FDA, including the Fast Track designation we received for efzofitimod, may not lead to expedited development or regulatory review or approval.

In 2022, the FDA granted Fast Track designation to efzofitimod for the treatment of pulmonary sarcoidosis and for the treatment of SSc-ILD. We may seek, from time to time, breakthrough therapy or Fast Track designation for our product candidates. A breakthrough therapy designation is for a product candidate intended to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. A Fast Track designation is for a product candidate that treats a serious or life-threatening condition, and preclinical or clinical data demonstrate the potential to address an unmet medical need. The FDA has broad discretion whether or not to grant these designations. Accordingly, even if we believe a particular product candidate is eligible for breakthrough therapy or Fast Track designation, we cannot assure you that the FDA would decide to grant it. Even if we receive breakthrough therapy or Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy or Fast Track designation if it believes that the product no longer meets the qualifying criteria. As a result, we cannot be certain whether any of our product candidates can or will qualify for breakthrough therapy designation. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

Disruptions at the FDA and other government agencies caused by layoffs, funding shortages or global health concerns could negatively impact our business.

The ability of the FDA to review and approve proposed clinical trials or new products can be affected by a variety of factors, including government budget and funding levels, layoffs, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, including executive and congressional priorities, the impacts of which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical government employees and stop critical activities to the extent they are not funded by existing available user fees. In addition, the current administration has enacted substantial reductions in force at various government agencies that, if applied in a material way, could significantly reduce the FDA's and other agencies' capacities to perform their functions in a manner consistent with past practices and could negatively impact our business. Repeated or prolonged government shutdowns or material layoffs of agency personnel could significantly impact the ability of the FDA to timely review and process our regulatory submissions and negatively impact other government operations on which we rely, which could have a material adverse effect on our business.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Even if we obtain regulatory approval for a product candidate, such product will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, adverse event reporting and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

We and our CDMOs will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any BLA or marketing authorization application (MAA). Accordingly, we and others with whom we work will need to continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. If new safety issues emerge, we may be required to change our labeling. Any new legislation addressing drug safety or efficacy issues could result in delays in product development or commercialization, or increased costs to assure compliance.

We will have to comply with requirements concerning advertising and promotion for our products. Violations, including actual or alleged promotion of our products for unapproved, or off-label, uses are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business. In the United States, engaging in impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements that would materially restrict the manner in which we promote or distribute our drug products and exclusion from Medicare, Medicaid and other federal and state healthcare programs. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable.

The holder of an approved BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval were obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue untitled or warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;

- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our CDMOs' facilities; or
- seize or detain products, or require or request a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Our current product candidates and any other product candidates that we may develop from our discovery platform represent novel therapeutic approaches, which may cause significant delays or may not result in any commercially viable drugs.*

We have concentrated the bulk of our research and development efforts to date on studying extracellular functions of tRNA synthetase biology, a newly discovered area of biology. Our future success is highly dependent on the successful development of product candidates based on this new area of biology, including efzofitimod, and additional product candidates arising from proteins derived from tRNA synthetases, including aspartyl-tRNA synthetase (DARS). ATYR0101, a fusion protein derived from a domain of DARS, is a product candidate from our tRNA synthetase biology program that we are continuing to advance in preclinical studies. Extracellular tRNA synthetase-based biology represents a novel approach to drug discovery and development, and to our knowledge, no drugs have been developed using, or based upon, this approach. Despite the successful development of other naturally occurring proteins, such as erythropoietin and insulin, as therapeutics, proteins derived from the HARS or DARS families and from other tRNA synthetase pathways represent a novel class of protein therapeutics, and our development of these therapeutics is based on our new understanding of human physiology. In particular, the mechanism of action of tRNA synthetases has not been studied extensively, nor has the safety of this class of protein therapeutics been evaluated extensively in humans. The therapeutic product candidates that we elect to develop may not have the physiological functions that we currently ascribe to them, may have limited or no therapeutic applications, or may present safety problems of which we are not yet aware. We cannot be sure that our discovery platform will yield therapeutic product candidates that are safe, effective, approvable by regulatory authorities, manufacturable, scalable, or profitable.

Because our work represents a new therapeutic approach, developing and commercializing our product candidates, including efzofitimod, subjects us to a number of challenges, including:

- defining indications within our targeted diseases and clinical endpoints within each indication that are appropriate to support regulatory approval, including with respect to our Planned Phase 3 Study for efzofitimod in pulmonary sarcoidosis and the EFZO-CONNECT study, and prioritization of outcome measurements that would best support the evaluation of efzofitimod's efficacy;
- obtaining regulatory approval from the FDA and other regulatory authorities that have little or no experience with the development of extracellular tRNA synthetase-based therapeutics;
- educating medical personnel regarding the potential side effect profile of each of our product candidates, such as the potential for the development of antibodies against our purified protein therapeutics;
- developing processes for the safe administration of these product candidates, including long-term follow-up for all patients who receive our product candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a manufacturing process and distribution network that ensures consistent manufacture of our product candidates in compliance with cGMPs and related requirements, with a cost of goods that allows for an attractive return on investment;
- obtaining and maintaining third-party coverage and adequate reimbursement of our product candidates;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance; and
- developing therapeutics for diseases or indications beyond those addressed by our current product candidates.

Moreover, public perception of safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to adopt and prescribe novel therapeutics. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices. Physicians may decide the therapy is too complex or unproven to adopt and may choose not to administer the therapy. Based on these and other factors, healthcare providers and payors may decide that the benefits of any therapeutic candidates for which we receive regulatory approval do not or will not outweigh its costs. Any inability to successfully develop commercially viable drugs would have an adverse impact on our business, prospects, financial condition and results of operations.

Data generated in our preclinical studies and patient sample data relating to the immunomodulatory domain of HARS, including efzofitimod, may not be predictive or indicative of the immunomodulatory activity or therapeutic effects, if any, of our product candidates in patients.*

Our scientists discovered the activity of the immunomodulatory domain of HARS, including efzofitimod, using *in vitro* and *in vivo* screening systems designed to test potential immunomodulatory activity in animal models of immune activity or inflammation. Translational medicine, or the application of basic scientific findings to develop therapeutics that promote human health, is subject to a number of inherent risks. In particular, scientific hypotheses formed from preclinical observations may prove to be incorrect, and the data generated in animal models or observed in limited patient populations may be of limited value, and may not be applicable in clinical trials conducted under the controlled conditions required by applicable regulatory requirements and our protocols. For example, we have not extensively studied the activity of efzofitimod in patients with ILD.

Our classification of diseases based on the existence of excessive immune cell activation or lack thereof and our hypothesis that these represent potential indications for our product candidates may not prove to be therapeutically relevant. Accordingly, the conclusions that we have drawn from animal studies and patient sample data regarding the potential immunomodulatory activity of efzofitimod may not be substantiated in other animal models or in clinical trials. Further, based on the discovery of the involvement of neuropilin-2 (NRP2) in the mechanism of action of efzofitimod, we are still expanding our knowledge of the role of the NRP2 pathway in regulating immune responses. Although we were able to establish clinical proof-of-concept for efzofitimod in our Phase 1b/2a clinical trial in patients with pulmonary sarcoidosis, this may not be validated in other clinical trials. For example, we did not meet the primary endpoint in our EFZO-FIT study. Any failure to demonstrate in controlled clinical trials the requisite safety and efficacy of our product candidates will adversely affect our business, prospects, financial condition and results of operations.

Our therapeutic product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.*

Undesirable side effects caused by our product candidates, or safety, tolerability or toxicity issues that may occur in our preclinical studies, clinical trials or in the future, could cause us or regulatory authorities to interrupt, restrict, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For instance, as part of our discussion with the FDA regarding the benefit risk profile for efzofitimod, we plan to increase the frequency of dosing of 5.0 mg/kg efzofitimod or placebo from once every four weeks in past trials to once every three weeks in the next trial. Although we plan to include additional risk mitigation strategies, enhanced safety surveillance for the potential development of anti-synthetase syndrome and a data safety monitoring committee, these may not mitigate some or all of the safety risks. Generalized infusion related reactions (IRRs) and other complications or side effects could harm further development and/or commercialization of our product candidates, including efzofitimod. Additionally, our product candidates are designed to be administered by intravenous injection, which may cause side effects, including acute immune responses and injection site reactions. The risk of adverse immune responses remains a significant concern for protein therapeutics, and we cannot assure you that these or other risks will not occur in any clinical trials for our product candidates. There is also a risk of delayed adverse events as a result of long-term exposure to protein therapeutics that must be administered repeatedly for the management of chronic conditions, such as the development of antibodies, which may occur over time. If any such adverse events occur, which may include the development of anti-synthetase syndrome from antibodies or the occurrence of IRRs associated with antibodies, further advancement of our clinical trials could be halted or delayed, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

If one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or other safety concerns caused by such products, a number of potentially significant negative consequences could result.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, prospects, financial condition and results of operations.

We may not be successful in our efforts to identify or discover additional product candidates.

A key element of our strategy is to expand applications of efzofitimod to additional immune-mediated diseases and leverage our discovery platform to identify the therapeutic potential of extracellular proteins derived from tRNA synthetases to help identify or discover additional product candidates. A significant portion of the research that we are conducting involves new compounds and drug discovery methods, including our proprietary technology. Our drug discovery activities using our proprietary technology may not be successful in identifying product candidates that are useful in treating diseases. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying appropriate potential product candidates; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify suitable product candidates for preclinical and clinical development and regulatory approval, we will not be able to generate product revenues, which would have an adverse impact on our business, prospects, financial condition and results of operations.

Risks related to our reliance on third parties

We have depended and may again in the future depend on collaborations with third parties for the development and commercialization of certain of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.*

We have entered into, and may continue to enter into, research collaborations for the research and development of specified product candidates. Our sole source of revenue depends upon the performance by these collaborators of their responsibilities under these arrangements. The development efforts of our collaborators are subject to the same risks and uncertainties described above with respect to our independently developed product candidates.

Some collaborators may not succeed in their product development efforts. It is possible that our collaborators may be unable to obtain regulatory approval of our product candidates or successfully market and commercialize any such products for which regulatory approval is obtained. Other collaborators may not devote sufficient time or resources to the programs covered by these arrangements, and we may have limited or no control over the time or resources allocated by these collaborators to these programs. The occurrence of any of these events may cause us to derive little or no revenue from these arrangements, lose opportunities to validate our product candidates, or force us to curtail or cease our development efforts in these areas.

Our collaborators may breach or terminate their agreements with us, including termination without cause, subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development of product candidates. For example, the collaboration and license agreement (the Kyorin Agreement) with Kyorin Pharmaceutical Co., Ltd. (Kyorin) has been terminated. As a result of the termination of the Kyorin Agreement, we will not be entitled to receive any further milestone or other payments, including $155.0 million in the aggregate that would have been due upon achievement of certain development, regulatory and sales milestones, as well as tiered royalties on any net sales in Japan. As of the Termination Date, neither party has any development or commercialization obligations and the licenses we granted to Kyorin pursuant to the Kyorin Agreement have terminated. Following the Termination Date, the rights to develop and commercialize efzofitimod in Japan for all forms of ILD have reverted to us. Consequently, we hold the rights to develop and commercialize efzofitimod globally. In addition, if we are unable to maintain existing collaboration arrangements or enter into new ones, our ability to generate licensing, milestone or royalty revenues would be materially impaired.

We may decide to enter into additional strategic partnerships, including collaborations with pharmaceutical and biotechnology companies, to enhance and accelerate the development and potential commercialization of our product candidates. We face significant competition in seeking appropriate partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish any new strategic partnership or other collaborative arrangement for any of our product candidates and programs for a variety of reasons, including strategic fit with partners and differences in analysis of commercial value and regulatory risk. We may not be able to negotiate strategic partnerships on a timely basis, on acceptable terms or at all. We are unable to predict when, if ever, we will enter into any new strategic partnership because of the numerous risks and uncertainties associated with establishing strategic partnerships. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, we encounter unfavorable results or delays during development or approval of a product candidate or sales of an approved product are lower than expectations.

We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, protocol development, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We currently rely, and expect to continue to rely, on third parties to conduct some or all aspects of product manufacturing, protocol development, research and preclinical and clinical testing with respect to our product candidates. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for any product candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable study plan and protocols and GCPs so long as we continue to develop and commercialize on our own.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our research and development activities, including clinical trials, in accordance with regulatory requirements or our stated study plans and protocols, we

will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future BLA submissions and approval of our product candidates.

We rely and intend to rely on third parties to produce preclinical, clinical and commercial supplies of our product candidates.

Other than some internal capacity to support preclinical activities, we do not have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical quantities of our product candidates, and we lack the internal resources and capability to manufacture any of our product candidates on a clinical or commercial scale. Reliance on CDMOs entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party CDMOs for all aspects of manufacturing activities;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our CDMOs or suppliers caused by conditions unrelated to our business or operations, including the insolvency or bankruptcy of the CDMOs or suppliers.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

Additionally, each CDMO may require licenses to manufacture our product candidates or components thereof if the applicable manufacturing processes are not owned by the CDMO or in the public domain, and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities. These factors could cause the delay of clinical development, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully.

We do not have long-term contracts with our CDMOs, and our CDMOs may terminate their agreements with us for a variety of reasons including technical issues or our material breach of our obligations under the applicable agreement. Furthermore, our CDMOs may reallocate resources away from the production of our product candidates if we delay manufacturing under certain circumstances, and the manufacturing facilities in which our product candidates are made could be closed by our CDMO for strategic reasons related to the CDMO's business, or adversely affected by earthquakes and other natural disasters, labor shortages, power failures, economic slowdowns, higher interest rates, inflation and monetary supply shifts, evolving global geopolitical tension and numerous other factors. For example, we have been informed by our CDMO engaged to manufacture drug substance material for efzofitimod that it will be relocating the microbial manufacturing site we used to conduct prior batches of drug substance material. If our CDMOs fail to meet contractual requirements, and we are unable to secure one or more replacement CDMOs capable of production at a substantially equivalent cost, our clinical development activities may be delayed, or we could lose potential revenue. Manufacturing biologic drugs is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative CDMOs with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative CDMOs, transfer manufacturing procedures to these alternative CDMOs, and demonstrate comparability of material produced by such new CDMOs. New CDMOs of any product would be required to comply with applicable regulatory requirements. These CDMOs may not be able to manufacture our product candidates at costs, or in quantities, or in a timely manner necessary to complete the clinical development of our product candidates or make commercially successful products.

We previously relied on a single CDMO for process development and scale-up of efzofitimod, including the manufacture of bulk drug substance for our projected needs for planned clinical trials. We have entered into an agreement with another CDMO for the transfer of the process, scale-up and manufacturing of bulk drug substance. If we want to eventually utilize product manufactured by the new CDMO for commercial purposes, the FDA will require us to demonstrate that the product manufactured by the new CDMO is comparable in quality, safety and efficacy to the product used in the EFZO-FIT and EFZO-CONNECT studies.

The supply of efzofitimod for the EFZO-FIT and EFZO-CONNECT studies was produced by a prior CDMO. We have transitioned to a new CDMO that completed its first two commercial-scale cGMP runs during 2023. Full quality release testing has been completed and all release specifications were met, supporting the new CDMO's ability to produce bulk drug substance of efzofitimod for commercial purposes if we receive regulatory approval for efzofitimod. Because the change in CDMO has been introduced at an advanced stage of development of efzofitimod, the FDA will require a comparability assessment, which may include additional nonclinical or clinical studies utilizing the product manufactured by the new CDMO. We have completed an analytical comparability assessment. The FDA has reviewed this analytical comparability assessment and no additional data was requested.

We rely, and expect to continue to rely, on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We have relied, and expect to continue to rely, on third-party CROs, clinical investigators and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we have and will continue to enter into agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our investigators and CROs are required to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our investigators and CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA may require us to perform additional unanticipated clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our product candidates. Accordingly, if our investigators and CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our investigators and CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and preclinical programs. They may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our investigators or CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, enrollment and data integrity from monitoring of the trial may suffer, our financial results could be harmed, our costs could increase, our ability to generate revenues could be delayed and the commercial prospects for our product candidates could be adversely affected.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on third parties to manufacture our product candidates, and we collaborate with both industry and various academic institutions in the development of our discovery platform for therapeutic applications based on tRNA synthetase biology. In connection with these activities, we are required, at times, to share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, prospects, financial condition and results of operations.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure intellectual property rights to which we are entitled arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, prospects, financial condition and results of operations.

Risks related to our intellectual property

If we are unable to obtain, maintain or protect intellectual property rights related to our product candidates, or if the scope of such intellectual property protection is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' abilities to obtain and maintain patent and other intellectual property protection in the United States and in other countries for our proprietary technology and product candidates.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patentability of inventions, and the validity, enforceability and scope of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. As a result, patent applications that we own or in-license may not issue as patents with claims that cover our product candidates, or at all, in the United States or in foreign countries for many reasons. For example, there is no assurance that we were the first to invent or the first to file patent applications in respect of the inventions claimed in our patent applications or that our patent applications claim patentable subject matter. We may also be unaware of potentially relevant prior art relating to our patents and patent applications, and this prior art, if any, may be used by third parties as grounds to seek to invalidate a patent or to prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents disclose aspects of our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market any of our product candidates under patent protection, if approved, would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Changes to the patent laws in the United States and other jurisdictions could also diminish the value of our patents and patent applications or narrow the scope of our patent protection. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse effect on our business.

If the patent applications we own or have in-licensed that relate to our programs or product candidates do not issue as patents, if their breadth or strength of protection is threatened, or if they fail to provide exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future products. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. In addition, patents have a limited term. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if a patent does issue for any of our pending patent applications, possible delays in regulatory approvals could mean that the period of time during which we could market a product candidate under patent protection could be reduced from what we generally would expect. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Even if patents covering aspects of our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into

confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps we take to maintain the confidentiality of our trade secrets are inadequate, we may have insufficient recourse against third parties for misappropriating our proprietary information and processes. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

If due to the effects on our operations of general political and economic conditions, including global geopolitical tension, armed conflicts, potential future health pandemics, labor shortages, economic slowdowns, recessions or market corrections, inflation and monetary supply shifts, tariffs and trade tensions, higher interest rates and tightening of credit markets, or another cause, we are unable to generate new animal, or *in vitro* data, in time to support new, or updated patent application filings, or prior to patent conversion deadlines, it could materially impact the enforceability or scope of those patent filings.

If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in preventing third parties from practicing our inventions in countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Claims that our product candidates or the manufacture, sale or use of our future products infringe the patent or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the United States Patent and Trademark Office (USPTO) and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the formulations for, or the manufacturing process or methods of use of, any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to develop and commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may not be able to be obtained on reasonable commercial terms or at all, or require substantial time and monetary expenditure.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we

may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be successful in obtaining or maintaining necessary rights to our therapeutic product candidates and processes for our development pipeline through acquisitions and in-licenses.

We believe that we have rights to intellectual property, through licenses from third parties and under patents that we own, that is necessary or useful to develop our product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify on reasonable commercial terms or at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to the institution's rights in technology resulting from the collaboration. Regardless of any such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable commercial terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly.

In some cases, patent prosecution of our licensed technology is controlled by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using such intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensors. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our sublicensees or partners, if any; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications or those of our licensors. We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership, or we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even

if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse effect on our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with many other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining, maintaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, recent legislative and judicial developments in the United States and elsewhere have in some cases removed the protection afforded to patent owners, made patents more difficult to obtain, or increased the uncertainty regarding the ability to obtain, maintain and enforce patents. For example, Congress has recently passed, and the United States is currently implementing, wide-ranging patent reform legislation, and may pass further patent reform legislation in the future. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, Congress, or the USPTO may impact the value of our patents. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents generally, once obtained. Depending on decisions and actions by Congress, the federal courts, the USPTO and their respective foreign counterparts, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to maintain and enforce our existing patents and patents that we might obtain in the future.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the validity or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, were enacted March 16, 2013. Although it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of

our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks related to our business operations

We may use our financial and human resources to pursue a particular business strategy, research program or product candidate and fail to capitalize on strategies, programs or product candidates that may be more profitable or for which there is a greater likelihood of success.*

Because we have limited resources, we may forego or delay pursuit of certain strategic opportunities or opportunities with certain programs, product candidates or indications that later prove to have greater commercial potential. We may focus on or pursue one indication over another potential indication and such development efforts may not be successful, which would cause us to delay the clinical development and approval of efzofitimod and other product candidates. In addition, our decisions as to which of our discovery programs to advance into preclinical and clinical development could preclude us from advancing others. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, based upon analyses from independent consultants that we have engaged and our own modeling, we estimate that there is a $2-5 billion market opportunity in pulmonary sarcoidosis and SSc-ILD. We estimate the target patient population for pulmonary sarcoidosis is approximately 38,000 restrictive lung disease patients, and approximately 24,000 mixed / diffusion-limited lung disease patients. We estimate the target patient population for Ssc-ILD is 60,000 patients. Depending on the accuracy of this estimate, we may not be most efficiently allocating resources toward the advancement of efzofitimod versus the advancement of other development efforts. In addition, we may elect to pursue a research, clinical or commercial strategy that ultimately does not yield the results that we desire. Our spending on current and future research and development programs for product candidates may not result in any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area or market in which it would have been more advantageous to enter into a partnering arrangement. Any failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.*

We are highly dependent on principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success.

In connection with the Restructuring Plan, our board of directors approved the separation of employment of Jill M. Broadfoot as our Chief Financial Officer and Nancy E. Denyes as our General Counsel, expected to be effective September 30, 2026. While we expect

Brandon Yaras, our Vice President, Finance, to succeed Ms. Broadfoot as our Chief Financial Officer, effective as of Ms. Broadfoot's separation of employment, we cannot predict the impact that these changes to our executive team will have on our operations or our ability to achieve our objectives. We expect Ms. Broadfoot and Ms. Denyes to serve as consultants for a transition period following the separation of their employment with us, but either can terminate their respective consulting arrangements with us upon 15 days' notice, and we expect there to be some inefficiencies in our operations as well as loss of continuity and accumulated knowledge during and after the transition period. We also expect the Restructuring Plan may result in the diversion of time and focus from our remaining executive team and other employees.

In response to competition, higher rates of inflation, labor shortages and the current price of our common stock, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing stockholders. Because our equity compensation has historically consisted of stock options, given the drop in the price of our common stock, we may need to provide existing employees with additional equity compensation, which would negatively affect our outstanding share count and cause dilution to existing stockholders. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. The Restructuring Plan may also make it more difficult to attract qualified personnel, and it may make it more difficult to motivate or retain our remaining personnel. In addition, the available pool of skilled employees may be further reduced if immigration laws or their application continue to change in a manner that further increases restrictions on immigration. Further, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives.

We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition. *

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our business strategy and long-term operating plans. For example, in August 2026, our board of directors approved implementation of the Restructuring Plan. Any such restructuring activities may, result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we have undertaken or undertake in the future will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity and accumulated knowledge and add inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations. If any internal restructuring activities we have undertaken or undertake in the future fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

We are subject to a variety of risks associated with international operations that could materially adversely affect our business.*

We currently conduct certain research activities through Pangu BioPharma Limited, in collaboration with the Hong Kong University of Science and Technology. Additionally, we have conducted clinical trials in the United States, EU, Brazil, Japan and in Australia and may conduct future clinical trials internationally. Some countries, such as Brazil, require that clinical trial participants receive the product candidate at no cost even after the clinical trial has ended. We would not be able to recover any profit for these patients and depending on the number of patients, duration of the treatment and numerous other factors, such regulations could harm our business, prospects, financial condition and results of operations significantly. Further, if any of our product candidates are approved for commercialization outside of the United States, we expect to either use our own sales organization or selectively enter into agreements with third parties to market our products on a worldwide basis or in more limited geographical regions. We are, and we expect that we will continue to be, subject to a variety of risks related to international operations, including, but not limited to: liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets; tariffs and trade tensions; different regulatory requirements for approval of drugs and biologics in foreign countries; reduced or uncertain protection for intellectual property; unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including labor shortages, economic slowdowns, recessions, inflation, monetary supply shifts, higher interest rates and tightening of credit markets; political instability in particular foreign economies and markets, including global geopolitical tension and armed conflicts; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in reduced revenues and other obligations incident to doing business in another country; and the global impacts of potential future health pandemics.

Any failure to continue our international operations or to commercialize our product candidates outside of the United States may impair our ability to generate revenues and harm our business, prospects and results of operations.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in significant regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We have been, and could be in the future, subject to securities class action litigation.*

Securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because pharmaceutical companies, including our company, have experienced significant stock price volatility. As described in this report under the caption "Legal Proceedings," we, our chief executive officer and our chief financial officer are subject to securities class action complaints that were filed in October 2025. If we are not successful in the defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if we are successful in the defense of these claims, such litigation has resulted, and could result in the future, in substantial costs and diversion of our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harm patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance for our clinical trials covering $10.0 million per occurrence and up to $10.0 million in the aggregate, subject to certain deductibles and exclusions. Although we believe the amount of our insurance coverage is typical for companies similar to us in our industry, we may not have adequate insurance coverage or be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and adversely affect our reputation and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and may have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We (and the third parties with whom we work) are, or may become, subject to stringent and evolving U.S. and foreign laws, regulations, rules, policies, contractual obligations, industry standards, and other obligations related to data privacy and security. Our (or the third-parties with whom we work) actual or perceived failure to comply with such obligations could have a material adverse effect on our business and financial condition, including a disruption of clinical trials or commercialization of products; regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; reputational harm; loss of revenue or profits; and other adverse business consequences. *

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (Process or Processing) personal data and other sensitive information, including information we or the third parties with whom we work (such as CROs and clinical trial sites) collect about patients and healthcare providers in connection with clinical trials necessary to operate our business.

Therefore, our data Processing activities subject us to numerous data privacy and security laws, regulations, rules, guidance, and industry standards as well as external and internal data privacy and security policies, contractual requirements and other obligations that apply to the Processing of personal (and other sensitive) data both by us and the third parties with whom we work (collectively, Data Protection Requirements). The number and scope of the Data Protection Requirements are changing, becoming increasingly stringent, creating uncertainty, subject to differing applications and interpretations, and may be inconsistent between jurisdictions. These Data Protection Requirements may require us to change our business model. New Data Protection Requirements may be proposed or enacted. Additionally, given the breadth and evolving nature of Data Protection Requirements (and consumers' data privacy expectations), preparing for and complying with these requirements is rigorous, time-intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third parties with whom we work. We may at times fail (or be perceived to have failed) in our efforts to comply with our Data Protection Requirements. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture.

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with Data Protection Requirements, this could result in government enforcement actions against us that could include investigations, fines, penalties, audits and inspections, additional reporting requirements and/or oversight, temporary or permanent bans on all or some Processing of personal data, or orders to destroy or not use personal data. Further, individuals or other relevant stakeholders could bring a variety of claims (including class claims and mass arbitration demands) against us for our actual or perceived failure to comply with the Data Protection Requirements. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, and could lead to a loss of actual or prospective customers, or third parties with whom we work; interrupt or stop our clinical trials; result in an inability to Process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; require us to revise, restructure or substantially change our operations; or otherwise materially adversely affect our operations (each, a Material Adverse Impact).

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g. wiretapping laws). Numerous U.S. states have enacted comprehensive information privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA), (collectively, CCPA) applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, such as those noted below. The CCPA provides for fines for intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data Processed in the context of clinical trials, the CCPA may increase

compliance costs and potential liability with respect to other personal data maintained about California residents. In addition, the CPRA expanded the CCPA's requirements and established a regulatory agency to implement and enforce the law. Other states have also passed or are considering comprehensive privacy laws, with actions also being considered at the federal and local levels, and we expect more states to pass similar laws in the future. These state laws and the CCPA provide individuals with certain rights concerning their personal data, including the right to access, correct, or delete certain personal data, and opt-out of certain data Processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. While these states, like the CCPA, also exempt some data Processed in the context of clinical trials, these developments may further complicate compliance efforts, and may increase legal risk and compliance costs for us and the third parties with whom we work.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018) and China's Personal Information Protection Law (PIPL) impose strict requirements for Processing personal data. We may become subject to an increasing number of foreign privacy laws, particularly as we have begun to sponsor clinical trials in foreign jurisdictions, including in Europe. For example, failure to comply with the requirements of the EU and UK GDPR may result in warning letters, litigation, orders banning the Processing of personal data, mandatory audits and financial penalties, including fines of up to 4% of the total worldwide annual turnover, or €20,000,000 under the EU GDPR (17,500,000 British Pounds under the UK GDPR), in either case, whichever is greater; or private litigation related to Processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. As another example, the LGPD broadly regulates Processing personal data of individuals in Brazil and imposes compliance obligations and penalties comparable to those of the EU GDPR.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the EU and UK GDPR's cross-border data transfer limitations.

Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we are, or may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the EU and UK GDPR and the CCPA, may require our customers to impose specific contractual restrictions on their service providers. We also publish privacy policies, marketing materials, white papers, and other statements, related to, compliance with certain certifications, concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Unfavorable macroeconomic conditions could adversely affect our business, financial condition or results of operations.*

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused volatility and disruptions in the capital and credit markets. In addition, due to

general political and economic conditions, including global geopolitical tension, armed conflicts, including the ongoing Ukraine-Russia conflict and conflicts in the Middle East, increasing tensions between the U.S. and China, liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets, tariffs and trade tensions, the recent and potential future shutdowns of the federal government and the resulting effects on its regulatory agencies, higher interest rates and financial and credit market fluctuations, volatility in the capital markets, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, volatility in unemployment rates, inflation and uncertainty about economic stability. Further, due to the escalation of the ongoing conflict involving the U.S. and Iran, the closure and risk of further closures of the Strait of Hormuz have imposed significant constraints on global oil and energy transportation and production. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy and rapid changes in U.S. or foreign trade policy (such as the imposition of tariffs and trade barriers) could also strain our CDMOs and CROs, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, droughts, floods, fires, hurricanes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We are located in San Diego, California and our manufacturing activities are conducted by CDMOs and our clinical trials are conducted at various locations in the United States and abroad. Some of these geographic locations have in the past experienced natural disasters, including severe earthquakes. Earthquakes, droughts, floods, fires, hurricanes, disease epidemics or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as the manufacturing facilities of our CDMOs and clinical sites utilized by our CROs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, as well as limits on our insurance coverage, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.*

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. Additionally, the Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report.

Risks related to the commercialization of our product candidates

If we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.

We do not currently have any infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are risks

involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we enter into arrangements or collaborations with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market, sell or distribute any medicines that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our medicines effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We rely on third-party manufacturers to produce our product candidates, but we have not entered into agreements with any such manufacturers to support commercialization.

We have not yet secured manufacturing capabilities for commercial quantities of any of our product candidates. Although we intend to rely on third-party manufacturers for commercialization, we have not yet entered into a long-term commercial supply agreement to support full scale commercial production, and we or our CDMOs may be unable to process validation activities necessary to enter into commercial supply agreements or otherwise negotiate agreements with the manufacturers to support our commercialization activities at commercially reasonable terms.

We may run into technical or scientific issues related to development or manufacturing that we may be unable to resolve in a timely manner or with available funds. For example, in 2021, we engaged an additional CDMO to manufacture efzofitimod bulk drug substance. If the new CDMO experiences additional issues in validating the manufacturing process, particularly delays in producing efzofitimod in compliance with cGMP regulations, we could be forced to delay future clinical trials or the submission of regulatory approval applications to the FDA. In addition, due to the fact that all prior cGMP batches of efzofitimod, including those that we used in the EFZO-FIT study, have been produced by our prior CDMO, we will be required to complete comparability studies prior to using efzofitimod produced at the new CDMO's facilities in subsequent clinical trials or submitting regulatory approval applications to the FDA. If we are unable to demonstrate such comparability to the satisfaction of the FDA, it may result in delays to future clinical trials or a deficiency in future regulatory applications. We have completed an analytical comparability assessment. The FDA has reviewed this analytical comparability assessment and no additional data was requested. If we or our CDMOs are unable to scale the manufacturing process to produce commercial quantities of our product candidates, or our CDMOs do not pass required regulatory pre-approval inspections, our commercialization efforts will be harmed.

In addition, any significant disruption in our relationships with our CDMOs could harm our business. There are a relatively small number of potential manufacturers for our product candidates, and such manufacturers may not be able to supply our drug products at the times we need them or on commercially reasonable terms. Any disruption to our relationship with our current CDMOs and any manufacturers that we contract with in the future will result in delays in our ability to complete the clinical development of, or to commercialize, our product candidates, and may require us to incur additional costs.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors both in the United States and internationally, including major multi-national pharmaceutical companies, biotechnology companies and universities and other research institutions. We are aware of other companies that could compete with our product candidates in their target therapeutic indications, such as our lead candidate, efzofitimod, for the treatment of pulmonary sarcoidosis, SSc-ILD and other ILD.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, safer, more convenient or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than us. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

The commercial success of any current product candidate or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approval from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients, and third-party payors accepting our product candidates as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors, and our competitors may have substantially greater resources or brand recognition to effectively market their products. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products, if approved, could limit our ability to market those products and decrease our ability to generate revenue.*

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often follow CMS with respect to coverage policy and payment limitations in setting their own reimbursement policies. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. For example, the United States Department of Health and Human Services (HHS) imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS also has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years and single-course biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year, up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition. One third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Reimbursement agencies in Europe may be more conservative than third-party payors in the United States. For example, a number of cancer drugs have been approved for reimbursement in the United States, but have not been approved for reimbursement in certain European countries. There may be significant delays in obtaining reimbursement for newly approved medicines, and our inability to promptly obtain coverage and profitable payment rates from third-party payors for any approved medicines could have a material adverse effect on our business, prospects, financial condition and results of operations.

Outside the United States, international sales are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may

be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that currently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. It is unclear how reform measures in the United States will impact prices of medical products in other countries.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) was passed in March 2010, and substantially changed the way healthcare is financed by both governmental and private insurers. There have been amendments and executive, judicial and congressional challenges to certain aspects of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act" (OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits, that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. In the United States, we expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform (sometimes referred to as TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan" to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in *Loper Bright Enterprises v. Raimondo*, the United States Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process, amend existing or enact new healthcare laws, and make changes to the Medicare Drug Price Negotiation Program We cannot predict what additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products, if approved, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, drug prices are under significant scrutiny in the markets in which our products may be sold. Drug pricing and other health care costs continues to be subject to intense political and societal pressures which we anticipate will continue and escalate on a global basis. If coverage and reimbursement is available only to limited levels, we may not be able to successfully commercialize our product candidates for which we obtain marketing approval. As a result, we may have difficulty raising capital and our results of operations may be adversely impacted.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.*

Although we do not currently have any products on the market, our current and future operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various federal and state healthcare laws and regulations. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities, i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates and covered subcontractors that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations.

Further, in order to distribute products commercially, we will need to comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in an applicable state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also require pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical studies and other activities, and/or register their sales and medical representatives.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations.

Risks related to the ownership of our common stock

The market price of our common stock historically has been highly volatile and is likely to continue to be volatile, and you could lose all or part of your investment.*

The market price of our common stock has been volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, these factors include:

- adverse results or delays in preclinical studies or clinical trials;
- manufacturing sufficient quantities of product candidates for use in clinical trials or for commercial purposes;
- the imposition of a clinical hold on our product candidates or our inability to cause the clinical hold to be lifted;
- any delay in filing an IND or BLA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- failure of our strategic partners to perform under our collaborations or early termination of collaborations;
- inability to realize the anticipated efficiencies or other benefits from the Restructuring Plan;
- failure to successfully develop and commercialize our product candidates;
- limited market sizes and pricing for our product candidates;
- failure by us or our licensors to prosecute, maintain or enforce intellectual property rights covering our product candidates and processes;
- changes in laws or regulations applicable to current or future products;
- inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- inability to obtain additional capital;
- failure to meet or exceed financial or operational projections we may provide to the public;
- failure to meet or exceed the financial or operational projections of the investment community;
- the perception of the biopharmaceutical industry by the public, politicians, legislatures, regulators and the investment community;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts issue an adverse or misleading opinion regarding our common stock;
- changes in the market valuations of similar companies;
- changes in the structure of healthcare payment systems;
- sales of our common stock by us or our stockholders in the future;
- a potential additional reverse stock split if we are unable to maintain a stock price above $1.00 per share of common stock;
- trading volume of our common stock; and
- general political and macroeconomic conditions, including global geopolitical tension, armed conflicts, potential future health pandemics, liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets, tariffs and trade tensions, the recent and potential future shutdowns of the federal government and the resulting effects on its regulatory agencies, higher interest rates and financial and credit market fluctuations, volatility in the capital markets, and other geopolitical and macroeconomic conditions, including labor

shortages, economic slowdowns, recessions, inflation and monetary supply shifts, rising interest rates and tightening of credit markets, and the resulting impacts on our business operations or financial condition.

In addition, companies trading in the stock market in general, and on the Nasdaq Capital Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations, and we have in the past experienced volatility that has been unrelated or disproportionate to our operating performance. From January 1, 2025 through August 6, 2026 the closing price of our common stock has ranged between $0.40 and $6.61 per share. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our executive officers, directors, 5% holders and their affiliates currently own a significant percentage of our stock and will be able to exert significant control over matters submitted to stockholders for approval.*

As of August 6, 2026 based on the latest information available to us, our executive officers, directors, holders known by us to own 5% of our voting stock and their affiliates own approximately 9.0% of our voting stock. Therefore, our executive officers, directors, holders known by us to own 5% of our voting stock and their affiliates may have the ability to influence us through their ownership positions and may be able to influence all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Future sales and issuances of equity securities could result in dilution to our stockholders, impose restrictions or limitations on our business and could cause our stock price to fall.*

We will need additional capital in the future to continue our planned operations, and we may seek additional funding through a combination of equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements.

In April 2022, we entered into an Open Market Sale Agreement[SM] with Jefferies implementing the Jefferies ATM Offering Program. In December 2024, we amended the Jefferies ATM Offering Program. Under the Jefferies ATM Offering Program we may offer and sell, from time to time and at our option, up to an aggregate of $215.0 million of shares of our common stock (inclusive of $65.0 million of sales made prior to the amendment) through Jefferies, acting as sales agent. Jefferies is entitled to a fixed commission rate of up to 3.0% of the gross sales proceeds of shares sold under the Jefferies ATM Offering Program. During the year ended December 31, 2025, we sold an aggregate of 13,887,177 shares of common stock at a weighted-average price of $4.94 per share for net proceeds of approximately $66.4 million under the Jefferies ATM Offering Program. We did not utilize the ATM Offering Program during the six months ended June 30, 2026.

These financing activities may have an adverse effect on our stockholders' rights, the market price of our common stock and on our operations, and may require us to relinquish rights to some of our technologies, intellectual property or product candidates, issue additional equity or debt securities, or otherwise agree to terms unfavorable to us.

In addition, sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock, even if there is no relationship between such sales and the performance of our business.

We have also registered or plan to register all common stock that we may issue under our employee benefits plans as well as shares of common stock underlying options to purchase shares of our common stock that were granted as inducement grants. As a result, once registered, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers have established and may establish in the future programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934 (Exchange Act) for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

We may not be able to comply with all applicable listing requirements or standards of The Nasdaq Capital Market and Nasdaq could delist our common stock.*

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards. One such requirement is that we maintain a minimum bid price of at least $1.00 per share for our common stock. On December 4, 2025, we received a deficiency notice (the Notice) from the listing qualifications staff (the Staff) of The Nasdaq Stock Market LLC (Nasdaq) notifying us that, for the last 30 consecutive business days preceding the date of the Notice, the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550(a)(2). The Notice had no immediate effect on the listing of

our common stock on The Nasdaq Capital Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until June 2, 2026 (the Initial Compliance Date), to regain compliance with the minimum bid price requirement by having shares of our common stock maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days before the Initial Compliance Date. On June 3, 2026, we received a letter from the Staff (the Letter) notifying us that we are eligible for an additional 180-day period, or until November 30, 2026 (the Compliance Date), to regain compliance, based on the Staff's determination of us meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and our written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. The Letter has no immediate impact on the listing of our common stock on The Nasdaq Capital Market. If at any time during the second compliance period the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days (which may be extended to be a period of up to 20 consecutive business days in the discretion of the Staff), Nasdaq will provide us with written confirmation of compliance. However, if it appears to the Staff that we will not be able to cure the deficiency, and we do not regain compliance by the Compliance Date, the Staff will provide written notification that our common stock is subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq listing rules. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by Nasdaq to the panel, such appeal would be successful.

If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence in us from our collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

In the event that our common stock is not eligible for continued listing on Nasdaq or another national securities exchange, trading of our common stock could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by security analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses during our history, we do not expect to become profitable in the near future and we may never achieve profitability. Net operating loss (NOL) carryforwards that expire unused will be unavailable to offset future income tax liabilities. Federal NOLs incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of taxable income in such year.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (Code) a corporation that undergoes an "ownership change" (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOL carryforwards to offset post-change taxable income. We have experienced ownership changes in the past, and may experience future ownership changes, under Section 382 of the Code that could affect our ability to utilize our NOL carryforwards to offset our income. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, portions of our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027. For these reasons, we may not be able to utilize a material portion of our NOLs, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

We do not intend to pay dividends on our common stock, and therefore any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

In addition, future debt instruments may materially restrict our ability to pay dividends on our common stock. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, tax considerations, legal or contractual restrictions, business prospects, the requirements of current or then-existing debt instruments, general economic conditions and other factors our board of directors may deem relevant.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to remove our current management, acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, (iii) any action asserting a claim against our company arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or bylaws, or (iv) any action asserting a claim against our company governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

This choice of forum provision may limit a stockholder's ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If our information technology systems or data, or those maintained by the third parties with whom we work, are or were compromised, this could result in a Material Adverse Impact.

In the ordinary course of our business, we and the third parties with whom we work Process (as defined above) proprietary, confidential and sensitive information, including personal data (including key-coded data, health information and other special categories of personal data), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other third party partners (collectively, Sensitive Information).

We and the third parties with whom we work utilize information technology systems to Process Sensitive Information in connection with our business activities, and we face a variety of evolving threats that could cause security incidents.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity and availability of our Sensitive Information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent, continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation state supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to conduct our business.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to software bugs; malicious code (such as viruses and worms); denial-of-service attacks; credential stuffing; credential harvesting; malware (including as a result of advanced persistent threat intrusions; natural disasters; terrorism; war; telecommunication and electrical failures; ransomware attacks; social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks); server malfunctions; software or hardware failures; supply-chain attacks; loss of data or other computer assets; attacks enhanced or facilitated by AI; and other similar threats. Particularly, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials, loss of data (including data related to clinical trials), and other Material Adverse Impacts (as defined above). To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). It may be difficult and/or costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain and remediate a security incident could result in outages, data losses and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Additionally, remote work has increased the risk to our information technology assets and data, as more of our employees utilize network connections, computers and devices outside of our premises and networks, including working at home, while in transit and public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We use third parties, including service providers and subprocessors, to help us operate our business and engage in Processing or otherwise share Sensitive Information with our partners or other third parties in conjunction with our business. These third parties and their technologies operate critical business systems to Process Sensitive Information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience Material Adverse Impacts. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Sensitive Information or our information technology systems, or those of the third parties with whom we work. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of phishing attempts in the past, and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services.

We may expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security incidents and to mitigate, detect, and remediate actual and potential vulnerabilities. Applicable Data Protection Requirements (as defined above) may require us to implement specific security measures to protect against security incidents.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that we, or the third parties with whom we work, will be successful in preventing a security incident or mitigating their effects. We take steps designed to detect, mitigate and remediate vulnerabilities in our information technology systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including that of third parties with whom we work, on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. These vulnerabilities, bugs, errors or defects alone, or a combination of them, could pose material risks to our business.

Furthermore, applicable Data Protection Requirements may require us, or we may voluntarily choose, to notify relevant stakeholders of security incidents, or take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosures or the failure to comply with such applicable requirements could lead to Material Adverse Impacts.

If we or the third parties with whom we work experience or in the future experience (or are perceived to have experienced) any security incident(s), we could suffer reputational harm, face litigation or adverse regulatory actions, fines, other penalties, audits, inspections, additional reporting requirements and/or oversight, restrictions on Processing Sensitive Information, indemnification obligations, negative publicity, business interruptions, and diversion of funds. For example, the loss of data from completed clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. As a result, we could experience Material Adverse Impacts.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Furthermore, we cannot be sure that our insurance coverage, will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or Material Adverse Impacts arising out of our Processing operations, data privacy and security practices, or security incidents we may experience. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co-insurance requirements), could have a Material Adverse Impact.

In addition to experiencing a security incident, third parties may gather, collect, or infer Sensitive Information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, Sensitive Information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We are subject to anti-corruption laws in the jurisdictions in which we operate.

We are subject to a number of anti-corruption laws, including the Foreign Corrupt Practices Act of 1977, as amended (FCPA), and various other anti-corruption laws. The FCPA generally prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or keeping business and/or other benefits. Our business relies on approvals and licenses from government and regulatory entities, and as a result, we are subject to certain elevated risks associated with interactions with these entities. Although we have adopted a code of business conduct and ethics that includes provisions governing the interactions of employees with government entities to mitigate these risks, there can be no assurance that this will be successful in preventing violations of anti-corruption laws. If we are not in compliance with anti-corruption laws and other laws governing the conduct of business with government entities (including local laws), we may be subject to criminal and civil penalties and other remedial measures, which could harm our reputation and have a material adverse effect on our business, financial condition, results of operations and prospects. Any investigation of any actual or alleged violations of such laws could also harm our reputation or have an adverse impact on our business, prospects, financial condition and results of operations.

We have incurred and will continue to incur significant costs as a result of laws, rules, regulations and standards relating to various aspects of our business, including corporate governance, work force initiatives and operating as a public company, and failure to comply with such laws, rules, regulations and standards could adversely affect our business.

Laws, rules, regulations and standards affecting various aspects of our business have resulted in and will continue to result in significant costs to us as we evaluate their implications and respond to their requirements. Such laws, rules, regulations and standards include the Sarbanes-Oxley Act of 2002, rules subsequently implemented by the SEC, The Nasdaq Stock Market, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) enacted in July 2010 and executive orders. Certain laws, rules, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure, policies and governance practices. For example, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. If we fail, or are perceived to fail, to comply with these laws, rules, regulations and standards, our reputation may be harmed and we might be subject to litigation, sanctions, investigations or other regulatory proceedings, which would adversely affect our financial results and our business.

In addition, our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these laws, rules, regulations and standards increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, they make it more difficult and more expensive for us to maintain director and officer liability insurance and we have been required to incur substantial costs to maintain our current levels of such coverage. In the future, we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain coverage that is the same or similar to our current coverage. The impact of these events could make it more difficult for us to attract and retain qualified persons to serve as

executive officers or on our board of directors and board committees. We cannot predict or estimate the total costs we may incur or the timing of such costs to comply with these laws, rules, regulations and standards.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts commence coverage or continue coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We have broad discretion in the use of our cash, cash equivalents and available-for-sale investments and are exposed to risks related to the marketable securities we may purchase.

We have considerable discretion in the application of our existing cash, cash equivalents and available-for-sale investments. We expect to use our existing cash to fund research and development activities and for working capital and general corporate purposes, including funding the costs of operating as a public company. In addition, pending their use, we may invest our existing cash in certain short-term investments, including but not limited to investment-grade, interest-bearing securities. Historically, investment in these securities has been highly liquid and has experienced only very limited defaults. However, volatility in the financial markets in recent years has created additional uncertainty regarding the liquidity and safety of these investments. Additionally, we may use this cash, cash equivalents and available-for-sale investments for purposes that do not yield a significant return or any return at all for our stockholders.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

10b5-1 Trading Arrangements

During the quarter ended June 30, 2026, no director or officer (as defined in Exchange Act Rule 16a-1(f)) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" as those terms are defined in Item 408 of Regulation S-K.

Costs Associated with Exit or Disposal Activities

On August 7, 2026, our board of directors approved the implementation of a corporate restructuring and program prioritization plan (the Restructuring Plan) to streamline our operations and conserve capital prior to the potential initiation of the Planned Phase 3 Study. In connection with the Restructuring Plan, we committed to a reduction in our total workforce by approximately 60% to 20 full-time employees, and we estimate that the Restructuring Plan will reduce annualized operating expenses by approximately $13 million, beginning in the fourth quarter of 2026. We began notifying affected employees on August 7, 2026 and expect the Restructuring Plan to be substantially completed in the second half of 2026. We estimate that we will record charges of approximately $4.2 million for employee severance, employee health benefit obligations and other related termination benefits. Severance payments are expected to be paid in full between August 2026 and September 2027, and we expect to incur the charges in the third quarter of 2026. The charges that we expect to incur in connection with, or as a result of, the Restructuring Plan, are subject to a number of assumptions, and actual results may differ materially. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the Restructuring Plan.

Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Chief Financial Officer and General Counsel Separation and Consulting Agreements

On August 7, 2026, in connection with the Restructuring Plan, our board of directors approved the separation of employment of Jill M. Broadfoot as our Chief Financial Officer and Nancy E. Denyes as our General Counsel, expected to be effective September 30, 2026 (the actual date of such separation of employment, the Transition Date). We have offered Ms. Broadfoot and Ms. Denyes

Separation Agreements in connection with the separation of their employment (the Separation Agreements). Additionally, in connection with the transition support that Ms. Broadfoot and Ms. Denyes have agreed to provide, we, Ms. Broadfoot and Ms. Denyes will enter into Consulting Agreements expected to take effect October 1, 2026 (the Consulting Agreements).

The Separation Agreements generally provide that, subject to Ms. Broadfoot's and Ms. Denyes's execution of a general release and waiver of claims, we will provide Ms. Broadfoot and Ms. Denyes the following severance benefits in connection with the separation of their employment, consistent with our Executive Severance and Change in Control Policy (the Policy): we will pay Ms. Broadfoot and Ms. Denyes twelve months of their base salary, less taxes and withholdings, in installments over the twelve-month period following the Transition Date, we will reimburse Ms. Broadfoot's and Ms. Denyes's premiums to continue healthcare coverage under COBRA for up to twelve months, and each of Ms. Broadfoot and Ms. Denyes will be entitled to acceleration of the time-based vesting provision of outstanding stock options for an additional twelve months following the date of separation. The Consulting Agreements generally provide that Ms. Broadfoot and Ms. Denyes will provide consulting assistance and transition support to us for up to twelve months following the Transition Date, or September 30, 2027, which may be extended upon mutual agreement by us, on the one hand, and Ms. Broadfoot or Ms. Denyes, on the other. The respective Consulting Agreement may be terminated by either us, Ms. Broadfoot or Ms. Denyes, as applicable, upon 15 days' notice to the other party. We will pay Ms. Broadfoot and Ms. Denyes an hourly rate for the services they provide under the Consulting Agreements. Additionally, our board of directors approved extending the post-termination exercise periods of Ms. Broadfoot's and Ms. Denyes's vested and outstanding stock options granted by us until three months following termination of their services under the Consulting Agreements.

Receipt of the foregoing benefits are contingent upon Ms. Broadfoot and Ms. Denyes satisfying certain customary conditions as required by their respective Separation Agreement.

The foregoing description of the Separation Agreements and the Consulting Agreements are only a summary of the terms thereof, do not purport to be complete and are each subject to, and qualified in their entirety by the complete text of the Separation Agreements and the Consulting Agreements, which we anticipate filing with our Quarterly Report on Form 10-Q for the three months ending September 30, 2026.

Appointment of new Chief Financial Officer

On August 7, 2026, our board of directors appointed Brandon Yaras, our Vice President, Finance, to succeed Ms. Broadfoot as our Chief Financial Officer and designated him as our "principal financial officer" and "principal accounting officer," each within the meaning of Rule 16a-1(f) under the Exchange Act, all effective as of October 1, 2026.

Mr. Yaras, age 40, has served as our Vice President, Finance since May 2022. Mr. Yaras has nearly 20 years of corporate finance and accounting experience, having overseen internal and external SEC reporting, forecasting and valuation, Sarbanes-Oxley compliance, payroll and equity administration and accounts payable. Prior to joining aTyr, from 2014 to 2022, he served as Director of Finance and Accounting for Arrowhead Pharmaceuticals, Inc., where he oversaw similar finance and accounting operations as well as procurement. Prior to that, he was Manager of Financial Planning and Analysis for Tutor Perini Corporation from 2009 to 2014. He began his career in the assurance practice at Deloitte & Touche LLP (Deloitte) and was an Audit Senior prior to leaving Deloitte. Mr. Yaras holds a B.A. in business economics with a minor in accounting from the University of California, Los Angeles and is a certified public accountant.

There are no understandings or arrangements between Mr. Yaras and any other person pursuant to which he was appointed as our Chief Financial Officer, and there are no actual or proposed transactions between us and Mr. Yaras or any related person that would require disclosure under Item 404(a) of Regulation S-K. Mr. Yaras has no family relationship with any of our directors or executive officers.

In connection with Mr. Yaras's appointment, we entered into an at-will employment offer letter with Mr. Yaras, dated August 7, 2026 and effective as of October 1, 2026 (the Employment Offer Letter), pursuant to which Mr. Yaras would become employed as the Chief Financial Officer of our company. Pursuant to the Employment Offer Letter, Mr. Yaras's annual base salary will be $350,000. Mr. Yaras is also eligible for a discretionary bonus target of up to 40% of his base salary based upon certain performance achievement goals. Pursuant to the Employment Offer Letter, Mr. Yaras will continue to be eligible to participate in our annual equity incentive award grants and will be granted an option to purchase 410,000 shares of our common stock (the Option) under our 2015 Stock Option and Incentive Plan, as amended, and subject to the terms and conditions set forth in the applicable notice of the award, with an exercise price equal to the closing price per share of our common stock as reported on the Nasdaq Capital Market on October 1, 2026. The Option is a non-qualified stock option and the shares subject to the Option will vest over a period of four years in equal monthly installments, subject to Mr. Yaras's continued employment on the applicable vesting date. We will also enter into our standard form of indemnification agreement with Mr. Yaras.

In addition, Mr. Yaras is eligible to participate in the Policy as in effect from time to time. The purpose of the Policy is to

provide certain of our senior management employees with compensation and benefits in the event of a termination of employment without Cause or for Good Reason (as such terms are defined in the Policy). The post-termination compensation and benefits under the Policy include (i) acceleration of time-based vesting provisions of outstanding equity awards that would have vested within 12 months of the termination, (ii) severance in a lump sum in the amount of 12 months of base salary, and (iii) monthly payment of the employer portion of group health care benefits under COBRA for up to 12 months after termination. In addition, if the termination occurs within two months prior to or one year after the closing of a Sale Event (as defined in the Policy), then, in lieu of the benefits described above, the post-termination compensation and benefits under the Policy include (i) full acceleration of time-based vesting provisions of all outstanding equity awards, (ii) severance in a lump sum in the amount of 12 months of base salary, (iii) payment of the bonus target for the calendar year in which the termination occurred, and (iv) monthly payment of the employer portion of group health care benefits under COBRA for up to 12 months after termination. In each case, receipt of any compensation or benefits under the Policy is subject to Mr. Yaras's execution of a severance agreement and release of claims.

The foregoing description of the Employment Offer Letter is only a summary of the terms thereof, does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Employment Offer Letter, which is attached hereto as Exhibit 10.2 and incorporated into this Item 5 under the heading "Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers—Appointment of new Chief Financial Officer" by reference.

The foregoing description of the Policy is only a summary of the terms thereof, does not purport to be complete and is subject to, and qualified in its entirety by the full text of the Policy, which we filed as Exhibit 10.16 to our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 30, 2016, and which was most recently described in our definitive proxy statement on Schedule 14A, filed with the SEC on March 26, 2026, and is incorporated into this Item 5 under the heading "Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers" by reference.

Item 6. Exhibits

Index to Exhibits

Exhibit Number	Exhibit Title	Form	Incorporated by Reference File No.	Exhibit	Filing Date
3.1	Restated Certificate of Incorporation of the Registrant	10-Q	001-37378	3.1	November 14, 2022
3.2	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant	8-K	001-37378	3.1	June 28, 2019
3.3	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant	10-Q	001-37378	3.3	May 12, 2020
3.4	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant	8-K	001-37378	3.1	May 4, 2021
3.5	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant	8-K	001-37378	3.1	April 29, 2022
3.6	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant	8-K	001-37378	3.1	May 19, 2023
3.7	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant	10-Q	001-37378	3.7	May 15, 2026
3.8	Amended and Restated Bylaws of the Registrant	10-Q	333-203272	3.6	November 14, 2022
4.1	Specimen Common Stock Certificate	S-1/A	333-203272	4.1	April 27, 2015
10.1	aTyr Pharma, Inc. 2015 Stock Option and Incentive Plan, as amended	10-Q	001-37378	10.1	May 15, 2026
10.2	Employment Offer Letter by and between the Registrant and Brandon Yaras, dated August 7, 2026	—	—	—	Filed herewith
10.3	Termination Agreement dated July 30, 2026, entered between aTyr Pharma, Inc. and Kyorin Pharmaceutical Co., Ltd.	8-K	001-37378	99.1	July 31, 2026
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Furnished herewith
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Furnished herewith

Exhibit Number	Exhibit Title	Form	Incorporated by Reference File No.	Exhibit	Filing Date
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	—	—	—	Filed herewith

The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

aTyr Pharma, Inc.

Date: August 7, 2026

By: /s/ Sanjay S. Shukla
Sanjay S. Shukla, M.D., M.S.
President, Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ Jill M. Broadfoot
Jill M. Broadfoot
Chief Financial Officer
(Principal Financial and Accounting Officer)

August 7, 2026

Mr. Brandon Yaras, CPA
[***]
[***]

Re: Amended and Restated Offer of Employment

Dear Brandon,

This letter (this "Amended and Restated Offer Letter") amends and restates in its entirety your prior offer letter with aTyr Pharma, Inc. ("aTyr" or the "Company") dated March 9, 2022. This Amended and Restated Offer Letter sets forth the principal terms for your continued employment with the Company, located in San Diego, California.

New Position:	Promotion to Chief Financial Officer from Vice President, Finance
Location:	San Diego, California
Status:	Full-Time, Exempt. This means you are paid for the job and not by the hour. Accordingly, you will not receive overtime pay if you work more than 8 hours in a workday or 40 hours in a work week.
Reporting to:	Sanjay S. Shukla, M.D., M.S., President and CEO
Base Salary Rate:	$14,583.33 semi-monthly (which equals $350,000.00 per year) less applicable withholdings, paid in accordance with the Company's normal payroll practices during your Full-Time employment. Future adjustments in compensation, if any, will be made by the Company in its sole and absolute discretion.
Target Bonus:	Your annual target bonus will be 40% of your base salary based upon the achievement of your individual goals, the achievement of team goals and the achievement of corporate goals. Your annual target bonus is subject to review and approval by the aTyr Board of Directors or Compensation Committee of the Board of Directors. You must be employed by the Company at the time the bonus is paid out to receive the bonus.
Equity:	As promptly as practicable after commencement of your new role with the Company, and subject to approval by the Board of Directors (or the Compensation Committee of the Board of Directors), you will be granted an additional option to purchase 410,000 shares of the Common Stock of the Company (the "Option"). Subject to your continued full-time employment with the Company, the shares subject to the Option shall vest over a four (4) year

period from your promotion start date, in equal monthly installments. The exercise price per share of the Option shall be determined based on the closing price of the Common Stock as reported on NASDAQ on the effective date of the grant. The specific terms and conditions of your Option will be subject to the terms set forth in a Stock Option Agreement between you and the Company.

Severance Policy: You are eligible for aTyr's Executive Severance and Change in Control Policy, including severance provisions for "Not for Cause" separations as well as "Change in Control" separations. The specifics of the plan will be provided to you.

Benefits: You are entitled to receive standard medical, life and dental insurance benefits for yourself and your dependents in accordance with Company policy. The Company reserves the right to change or eliminate these benefits on a prospective basis at any time.

401(k) Plan: You are eligible to participate in the aTyr Pharma, Inc. 401(k) Savings Plan.

Vacation & Sick Time: You are currently entitled to accrue 20 days of vacation per year as a Full-Time employee. You will have 6 days of sick time available each year.

Holidays: You are eligible for aTyr's paid holidays. The schedule is published prior to the beginning of each calendar year.

Employment at Will: Your employment is at-will, which means it may be terminated at any time by you or the Company for any reason, with or without cause, and that your employment is not for any specific period of time. Any change to the at-will employment relationship must be by a specific, written agreement signed by you and the Company's President and Chief Executive Officer.

Promotion Start Date: October 1, 2026 or a mutually agreed upon date.

Your will continue to (i) be bound by that certain Employee Nondisclosure and Assignment Agreement effective as of May 9, 2022 (the "Employee NDA"), and (ii) abide by the Company's code of conduct and other policies applicable to employees as set forth in the Company's employee handbook in effect from time to time.

To aid the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, and in exchange for the mutual promises contained in this Amended and Restated Offer Letter, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Amended and Restated Offer Letter, your employment with the Company, or the termination of your employment, shall be resolved to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. ("JAMS") or its successor, under JAMS'

then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web address: (i) https://www.jamsadr.com/rules-employment-arbitration/ and (ii) https://www.jamsadr.com/rules-comprehensive-arbitration/) at a location closest to where you last worked for the Company or another mutually agreeable location. Any demand for arbitration must be made within the statute of limitations applicable to the claim asserted as if such claim were asserted in court. Failure to demand arbitration (or, where applicable, file a counterclaim, crossclaim, or third-party claim) within such time limitation shall serve as a waiver and release with respect to all such claims. **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge.** The Federal Arbitration Act, 9 U.S.C. § 1 et seq., will, to the fullest extent permitted by law, govern the interpretation and enforcement of this arbitration agreement and any arbitration proceedings. This provision shall not be mandatory for any claim or cause of action to the extent applicable law prohibits subjecting such claim or cause of action to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "Excluded Claims"), such as non-individual claims that cannot be waived under applicable law, claims or causes of action alleging sexual harassment or a nonconsensual sexual act or sexual contact, or unemployment or workers' compensation claims brought before the applicable state governmental agency. In the event you or the Company intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. You acknowledge and agree that proceedings of any non-individual claim(s) under the California Private Attorneys General Act ("PAGA") that may be brought in court shall be stayed for the duration and pending a final resolution of the arbitration of any individual or individual PAGA claim. Nothing herein prevents you from filing and pursuing proceedings before a federal or state governmental agency, although if you choose to pursue a claim following the exhaustion of any applicable administrative remedies, that claim would be subject to this provision. In addition, with the exception of Excluded Claims arising out of 9 U.S.C. § 401 et seq., all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class, representative, or collective proceeding, nor joined or consolidated with the claims of any other person or entity. **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive all rights to have any dispute be brought, heard, administered, resolved, or arbitrated on a class, representative, or collective action basis.** The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. If a court finds, by means of a final decision, not subject to any further appeal or recourse, that the preceding sentences regarding class, representative, or collective claims or proceedings violate applicable law or are otherwise unenforceable, as to a particular claim or request for relief, the parties agree that any such claim(s) or request(s) for relief be severed from the arbitration and may proceed in a court of law rather than by arbitration. All other claims or requests for relief shall be arbitrated. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration and procedural questions which grow out of the dispute and bear on the final disposition are matters for the arbitrator to decide; provided, however, that if required by applicable law, a court and not the arbitrator may determine the enforceability of this paragraph with respect to Excluded Claims. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as you or the Company would otherwise be entitled to seek in a court of law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the

reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company shall pay all JAMS arbitration administrative fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Each party is responsible for its own attorneys' fees, except as may be expressly set forth in your Employee NDA or as otherwise provided under applicable law. Nothing in this Amended and Restated Offer Letter is intended to prevent either you or the Company from seeking or obtaining injunctive relief, or provisional remedies as permitted under applicable law, in court to prevent irreparable harm pending the conclusion of any such arbitration. The pursuit of injunctive relief shall not be deemed incompatible with or constitute a waiver of rights under this Amended and Restated Offer Letter. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

It is aTyr's policy to respect fully the rights of your previous employers in their proprietary or confidential information. No employee is expected to disclose, or is allowed to use for aTyr's purposes, any confidential or proprietary information he or she may have acquired as a result of previous employment.

I am pleased to extend this promotion offer to you and look forward to your acceptance. Please sign and return the enclosed copy of this Amended and Restated Offer Letter as soon as possible to indicate your agreement with the terms of this offer. This offer will lapse if not signed and returned by Friday, August 7, 2026.

Once signed by you, this letter, together with the Employee NDA, will constitute the complete agreement between you and the Company regarding employment matters and will supersede all prior written or oral agreements or understandings on these matters, including without limitation your prior offer letter dated March 9, 2022.

Yours sincerely,

/s/ Sanjay S. Shukla
Sanjay S. Shukla, M.D., M.S.
President and Chief Executive Officer

I accept the terms of employment as described in this Amended and Restated Offer Letter dated August 7, 2026. I confirm that by my promotion start date at aTyr Pharma, Inc. I will be under no contract or agreement with any other entity which would in any way restrict my ability to work at aTyr Pharma, Inc. or perform the functions of my job for aTyr, including, but not limited to, any employment agreement and/or non-compete agreement.

/s/ Brandon Yaras *Date August 7, 2026*
Brandon Yaras

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sanjay S. Shukla, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of aTyr Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2026

/s/ Sanjay S. Shukla
Sanjay S. Shukla, M.D., M.S.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jill M. Broadfoot, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of aTyr Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2026

/s/ Jill M. Broadfoot
Jill M. Broadfoot
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of aTyr Pharma, Inc. (the "Company") for the period ended June 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sanjay S. Shukla, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 7, 2026

/s/ Sanjay S. Shukla
Sanjay S. Shukla, M.D., M.S.
President, Chief Executive Officer and Director
(*Principal Executive Officer*)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, is not being filed for purposes of Section 18 of the Exchange Act, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of aTyr Pharma, Inc. (the "Company") for the period ended June 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jill M. Broadfoot, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 7, 2026

/s/ Jill M. Broadfoot
Jill M. Broadfoot
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, is not being filed for purposes of Section 18 of the Exchange Act, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.