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

# FORM 10-Q

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

For the quarterly period ended September 30, 2021

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: 001-39614

# TARSUS PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

15440 Laguna Canyon Road, Suite 160 Irvine, California (Address of principal executive offices) 81-4717861 (I.R.S. Employer Identification Number)

> 92618 (Zip Code)

> > Smaller reporting company

Emerging growth company

 $\boxtimes$ 

(949) 409-9820 (Registrant's telephone number, including area code)

(Registrant's telephone number, including area

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	TARS	The Nasdaq Global Market LLC (Nasdaq Global Select 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "scelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer
Accelerated filer
Accelerated filer

Large accelerated filer	
Non-accelerated filer	$\boxtimes$

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 🗵

20,676,992 shares of common stock, \$0.0001 par value, outstanding as of November 4, 2021.

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# PART I-FINANCIAL INFORMATION

# Item I. Financial Statements (Unaudited)

# TARSUS PHARMACEUTICALS, INC. INDEX TO THE FINANCIAL STATEMENTS

Condensed Balance Sheets

Condensed Statements of Operations and Comprehensive (Loss) Income Condensed Statements of Preferred Stock and Stockholders' Equity (Deficit) Condensed Statements of Cash Flows Notes to Condensed Financial Statements Pages F-2 F-3 F-4 F-5

# CONDENSED BALANCE SHEETS

# (In thousands, except share and par value amounts)

	Septe	mber 30, 2021	Dece	mber 31, 2020
	(u	inaudited)		
Assets				
Current assets:				
Cash and cash equivalents	\$	183,801	\$	168,129
Restricted cash		—		20
Other receivables		139		20
Prepaid expenses and other current assets		3,148		2,486
Total current assets		187,088		170,655
Property and equipment, net of accumulated depreciation		519		548
Operating lease right-of-use asset		1,190		688
Other assets		1,615		81
Total assets	\$	190,412	\$	171,972
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable and other accrued liabilities	\$	8,119	\$	4,347
Accrued payroll and benefits		2,246		1,040
Total current liabilities		10,365		5,387
Other long-term liabilities		905		605
Total liabilities		11,270		5,992
Commitments and contingencies (Note 9)				
Stockholders' equity:				
Preferred stock, \$0.0001 par value; 10,000,000 authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020		_		_
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 20,714,228 shares issued and 20,671,079 outstanding, which excludes 43,149 shares subject to repurchase at September 30, 2021 (unaudited); 20,502,576 shares issued and 20,323,301 outstanding, which excludes 179,375 shares subject to repurchase at December 31, 2020		4		4
Additional paid-in capital		210,959		198,821
Accumulated deficit		(31,821)		(32,845)
Total stockholders' equity		179,142		165,980
Total liabilities and stockholders' equity	\$	190,412	\$	171,972

See accompanying notes to these unaudited condensed financial statements.

# CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME (Unaudited)

	Three Months Ended September 30,				Nine Months Ended September 30,				
	 2021 2020			2021		2020			
Revenues:									
License fees	\$ 708	\$	—	\$	53,067	\$	—		
Collaboration revenue	 532				3,622		—		
Total revenues (Note 9)	1,240		—		56,689		_		
Operating expenses:									
Cost of license fees and collaboration revenue	65		_		2,099		_		
Research and development	10,209		7,991		33,674		11,239		
General and administrative	6,671		2,150		18,625		4,282		
Total operating expenses	 16,945		10,141		54,398		15,521		
(Loss) income from operations before other income (expense) and income taxes	 (15,705)		(10,141)		2,291		(15,521)		
Other income (expense):									
Interest income, net	8		4		24		178		
Other income (expense), net	5		—		(68)		_		
Change in fair value of equity warrant rights (Note 9)	 (346)		—		(1,222)		—		
Total other (expense) income	 (333)		4		(1,266)		178		
Benefit (provision) for income taxes	 341		(1)		(1)		(1)		
Net (loss) income and comprehensive (loss) income	\$ (15,697)	\$	(10,138)	\$	1,024	\$	(15,344)		
Net (loss) income per share	 	-							
Basic	\$ (0.76)	\$	(3.71)	\$	0.05	\$	(5.73)		
Diluted	\$ (0.76)	\$	(3.71)	\$	0.05	\$	(5.73)		
Weighted-average shares outstanding									
Basic	 20,641,285		2,729,685		20,511,973		2,677,315		
Diluted	 20,641,285		2,729,685		22,032,487		2,677,315		
		_				-			

See accompanying notes to these unaudited condensed financial statements.

# CONDENSED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (Unaudited)

(In thousands, except share data)

	Preferred	l Stock Amount	Common		iount	Additional Paid-In Capita	1	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2020		\$ _	20,323,201	\$	4	\$ 198,82		(32,845)	\$ 165,980
Net income				Ψ		¢ 100,02		10,376	10,376
Recognition of stock-based compensation expense	_	_	_		_	1,36	3		1,363
Exercise of vested stock options		_	13,773		_	1	)		19
Shares issued as consideration for in-license rights ( <i>Note 8(b)</i> )	_	_	187,500		—	5,494	l I	_	5,494
Balance as of March 31, 2021	_	\$ _	20,524,474	\$	4	\$ 205,69	7 \$	(22,469)	\$ 183,232
Net income								6,345	6,345
Recognition of stock-based compensation expense	_	_	—		_	2,79	l.	_	2,794
Lapse of repurchase rights related to common stock issued pursuant to stock option exercises prior to vesting	_	_	49,222		_	99	)	_	99
Exercise of vested stock options	_	—	255		—		L	_	1
Balance as of June 30, 2021		\$	20,573,951	\$	4	\$ 208,59	\$	(16,124)	\$ 192,471
Net loss	_	_				-		(15,697)	(15,697)
Recognition of stock-based compensation expense	_	_	_		—	2,11	)	_	2,119
Lapse of repurchase rights related to common stock issued pursuant to stock option exercises prior to vesting	_	_	87,004		_	174	Ļ	_	174
Exercise of vested stock options			10,124			7	5		75
Balance as of September 30, 2021		\$ —	20,671,079	\$	4	\$ 210,95	) \$	(31,821)	\$ 179,142

				1																										
	Preferred Stock		Common Stock			- Additional		Accumulated		Total Stockholders'																				
	Shares		Amount	Shares	Shares Amount P		Amount		Amount		Shares Amount		Paid-In Capital															Deficit		Deficit
Balance as of December 31, 2019	8,249,939	\$	63,402	2,646,619	\$	2	\$	27	\$	(6,034)	\$	(6,005)																		
Net loss	_		_					_		(1,957)		(1,957)																		
Recognition of stock-based compensation expense	_		—	_		—		4		—		4																		
Lapse of repurchase rights related to common stock issued pursuant to stock option exercises prior to vesting	_		_	4,300		_		_		_		_																		
Balance as of March 31, 2020	8,249,939	\$	63,402	2,650,919	\$	2	\$	31		(7,991)	\$	(7,958)																		
Net loss	_		_		_	_				(3,250)		(3,250)																		
Recognition of stock-based compensation expense	_		_	_		_		173		_		173																		
Exercise of vested stock options	—		_	1,077		_		_		—		—																		
Balance as of June 30, 2020	8,249,939	\$	63,402	2,651,996	\$	2	\$	204		(11,241)	\$	(11,035)																		
Net loss	_		_			_		_		(10,138)		(10,138)																		
Recognition of stock-based compensation expense		\$	_	_	\$	_	\$	223	\$		\$	223																		
Exercise of vested stock options	_		—	13,532		—		6		—		6																		
Shares issued as consideration for in-license rights	—		—	222,460		—		3,115		—		3,115																		
Issuance of Series C Preferred Stock in September 2020 at \$14.0003 per share for cash, net of issuance costs of \$243	2,857,079		39,757	_		_		_		_		_																		
Balance as of September 30, 2020	11,107,018	\$	103,159	2,887,988	\$	2	\$	3,548	\$	(21,379)	\$	(17,829)																		

See accompanying notes to these unaudited condensed financial statements.

# CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Nine Mon Septen	ths Ended ber 30,		
	2021	2020		
Cash Flows From Operating Activities:	<b>•</b> • • • • • • • • • • • • • • • • • •			
Net income (loss)	\$ 1,024	\$ (15,344		
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		50		
Depreciation and amortization	272	56		
Stock-based compensation (Note 5)	6,276	401		
Non-cash lease expense	178 70	94		
Loss on disposal of property and equipment	2			
Loss on lease termination	1.222			
Change in fair value of derivative assets	,			
Unrealized gain from transactions denominated in a foreign currency	(4)			
Issuance of common stock pursuant to in-license agreement ( <i>Note 8(b)</i> )	5,494	3,115		
Changes in operating assets and liabilities: Other receivables	(119)	34		
Prepaid expenses and other current assets	(663)	(2,700)		
Other non-current assets	(003)	(2,700)		
Accounts payable and other accrued liabilities	3,523	3,025		
Accounts payable and other account admittees	1,206	221		
Other long-term liabilities	1,200	221		
Net cash provided by (used in) operating activities	15.869	(11.125		
Cash Flows From Investing Activities:	15,809	(11,125)		
Purchases of property and equipment	(212)	(EOG)		
Cash used in investing activities	(312)	(506)		
5	(512)	(500		
Cash Flows From Financing Activities: Proceeds from issuance of preferred stock, net of issuance costs		39,972		
Issuance costs for initial public offering	_	(330)		
Proceeds from exercise of vested stock options		(330)		
Proceeds from stock option exercises prior to vesting	90	360		
Net cash provided by financing activities	95	40,008		
Net increase in cash, cash equivalents and restricted cash				
Cash, cash equivalents, and restricted cash — beginning of year	15,652	28,377		
	168,149	57,972		
Cash, cash equivalents, and restricted cash — end of period	\$ 183,801	\$ 86,349		
Reconciliation of cash, cash equivalents and restricted cash				
Cash and cash equivalents	\$ 183,801	\$ 86,329		
Restricted cash		20		
Cash, cash equivalents and restricted cash	\$ 183,801	\$ 86,349		
Supplemental Disclosures Noncash Investing and Financing Activities:				
Operating lease right-of-use asset obtained in exchange for operating lease liability	\$ 741	\$ 726		
Expense of right-of-use asset upon lease termination	\$ (38)	\$ —		
Stock issued to licensor pursuant to execution of out-license agreement	\$ 5,494	\$ —		
Series C Preferred Stock issuance costs in accounts payable and other accrued liabilities	\$	\$ 243		
Deferred offering costs included in accounts payable and accrued liabilities	\$ —	\$ 1,388		

See accompanying notes to these unaudited condensed financial statements.

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

## 1. DESCRIPTION OF BUSINESS AND PRESENTATION OF FINANCIAL STATEMENTS

#### (a) Description of Business

Tarsus Pharmaceuticals, Inc. ("Tarsus" or the "Company") is a biopharmaceutical company that applies proven science to new technology for patients, starting with eye care.

# (b) Reverse Stock Split and Initial Public Offering

On October 8, 2020, the Tarsus Board of Directors approved a 1-for-7.4276 reverse stock split and a certificate of amendment was filed to amend the Company's certificate of incorporation to effect this reverse split. The par value was not adjusted as a result of the reverse stock split. All share and per share information included in the accompanying financial statements give retroactive effect to this reverse stock split for all periods presented.

On October 20, 2020, the Company completed its initial public offering ("IPO") through an underwritten sale of 6,325,000 shares of its common stock at a price of \$16.00 per share, inclusive of an additional 825,000 shares of its common stock sold upon the full exercise of the underwriters' purchase option. The aggregate net proceeds by the Company from the offering totaled \$91.7 million, after deducting underwriting discounts and commissions and other offering expenses.

Concurrent with the closing of the Company's IPO, all then-outstanding shares of its convertible preferred stock (see *Note 4*) were automatically converted into an aggregate of 11,107,018 issued shares of common stock.

# (c) Liquidity

The Company currently has no product sales, and has accumulated losses and negative cash flows from operations since inception (other than consideration received from an out-licensing agreement, as discussed in *Note 9*), resulting in an accumulated deficit of \$31.8 million as of September 30, 2021 and \$32.8 million as of December 31, 2020. The Company's cash and cash equivalents were \$183.8 million and \$168.1 million as of September 30, 2021 and December 31, 2020, respectively. The Company has funded its inception-to-date operations primarily through equity capital raises and proceeds from its out-license agreement. The Company believes that its existing capital resources will be sufficient to meet projected operating requirements beyond at least 12 months from the filing date of this Form 10-Q. Accordingly, the accompanying financial statements in this Form 10-Q have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company's operations currently consist of its corporate organization build-out, intellectual property licensing activities, and preclinical and clinical study progression. The Company faces the clinical, business, and liquidity risks that are typically associated with biotechnology companies; it must complete expensive research and development activities, achieve research and development outcomes that are inherently uncertain, recruit and retain skilled personnel (including executive management), and expand and defend its intellectual property rights.

Management expects the Company to continue to incur losses in the foreseeable future as a result of research and development activities and other operating expenses. The Company will be required to raise additional capital to fund its future operations. However, no assurance can be given as to whether financing will be available on terms acceptable to the Company, if at all. If the Company raises additional funds by issuing equity securities, its stockholders may experience dilution. Any future debt financing into which the Company enters may impose additional covenants that restrict operations, including limitations on its ability to incur liens or additional debt, pay dividends, repurchase common stock, make certain investments, or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity raise may contain terms that are not favorable to the Company or its stockholders. The Company is unable to raise additional funds as required, it may need to delay, reduce, or terminate some or all its development programs and clinical trials. The Company may also be required to sell or license its rights to product candidates in certain territories or

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

indications that it would otherwise prefer to develop and commercialize on its own. If the Company is required to enter into collaborations and other arrangements to address its liquidity needs, it may have to give up certain rights that limit its ability to develop and commercialize product candidates or may have other terms that are not favorable to the Company or its stockholders, which could materially and adversely affect its business and financial prospects. These factors may adversely impact the Company's ability to achieve its business objectives and would likely have an adverse effect on its future business prospects, or even its ability to remain a going concern.

#### (d) Operating Segment

To date, the Company has operated and managed its business and financial information on an aggregate basis for the purposes of evaluating financial performance and the allocation of capital and personnel resources. Accordingly, the Company's management determined that it has one reportable operating segment. This single segment is focused exclusively on developing pharmaceutical products for eventual commercialization.

## (e) Emerging Growth Company Status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to not take this exemption. As a result, it will adopt new or revised accounting standards on the relevant effective dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES

## (i) Basis of Presentation

The Company's condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP") for interim financial information and pursuant to Form 10-Q and *Article 10 of Regulation S-X* of the Securities and Exchange Commission ("SEC"). Accordingly, the accompanying condensed financial statements do not include all of the information and footnotes required by GAAP for complete financial statements.

The interim condensed balance sheet as of September 30, 2021, the interim condensed statements of operations and comprehensive (loss) income, and stockholders' equity for the three and nine months ended September 30, 2021 and 2020, and the interim condensed cash flows for the nine months ended September 30, 2021 and 2020 are unaudited. These unaudited interim financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, which consist of only normal and recurring adjustments for the fair presentation of its financial information.

The financial data and other information disclosed in these notes related to the three and nine-month periods are also unaudited. The condensed balance sheet as of December 31, 2020 has been derived from the audited financial statements at that date but does not include all information and footnotes required by GAAP for annual financial statements. The condensed interim operating results for three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021 or any other interim or annual period.

The accompanying interim unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2020 in the Company's Annual Report on Form 10-K ("Annual Report") for the fiscal year ended December 31, 2020, as filed with the SEC on March 31, 2021.

The preparation of financial statements in conformity with GAAP and with the rules and regulations of the SEC requires management to make informed estimates and assumptions that affect the amounts reported in these financial statements and accompanying notes. These amounts may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption.



## NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

On an on-going basis, management evaluates its most critical estimates and assumptions, including those related to the (i) fair value of equity-based awards and periodic recognition of stock-based compensation, (ii) the realization of income tax assets and estimates of tax liabilities, and (iii) expense accruals related to research and development activities, including clinical trials. The accounting policies and estimates that most significantly impact the presented amounts within the accompanying condensed financial statements are further described below:

#### (ii) Cash and Cash Equivalents

Cash and cash equivalents consist of bank deposits and highly liquid investments, including money market fund accounts, with original maturities of three months or less from the purchase date.

#### (iii) Restricted Cash

Restricted cash represents cash held as collateral for the Company's corporate credit card program. Any cash that is legally or contractually restricted from immediate use is classified as restricted cash.

#### (iv) Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents in deposits at financial institutions that exceed federally insured limits.

In March 2020, the World Health Organization declared a pandemic related to the global novel coronavirus disease 2019 ("COVID-19") outbreak. To date, the Company's operations have not been significantly impacted by the COVID-19 pandemic, though the Company continues to monitor the potential impact COVID-19 may have on its ongoing and planned clinical trials. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak may have on these activities or its financial condition.

The Company's results of operations involve numerous risks and uncertainties. Factors that could adversely impact the Company's operating results and business objectives include, but are not limited to, (1) uncertainty of results of clinical trials, (2) uncertainty of regulatory approval of the Company's potential product candidates, including TP-03 for ophthalmic conditions, TP-04 for treatment of rosacea, and TP-05 for prophylaxis of Lyme and community malaria reduction, (3) uncertainty of market acceptance of its product candidates, (4) competition from substitute products and other companies, (5) securing and protecting proprietary technology and strategic relationships, and (6) dependence on key individuals and sole source suppliers.

The Company's product candidates require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive these necessary approvals. If the Company is denied approval, approval is delayed, or is unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company's business.

#### (v) Property and Equipment

Property and equipment is stated at historical cost and is depreciated on a straight-line basis over an estimated useful life that corresponds with its designated asset category. Leasehold improvements are amortized on a straight-line basis over the shorter of the remaining lease term or the estimated useful lives of related improvements. The Company evaluates the recoverability of "long-lived assets" (which includes property and equipment) whenever events or changes in circumstances in the business indicate that the asset's carrying amount may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the sum of the future undiscounted cash flows the assets are expected to generate over the remaining useful lives of the assets. If a long-lived asset fails a recoverability test, the Company measures the amount by which the carrying value of the asset exceeds its fair value. Other than the right-of-use ("ROU") asset impairment discussed in *Note 8*, there were no events or changes in business circumstances during the three and nine months ended September 30, 2021 or year ended December 31, 2020 that indicated the carrying amounts of any long-lived assets were not fully recoverable.

#### (vi) Revenue Recognition for Out-License Arrangements



## NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

#### Overview

The Company currently has one out-license arrangement that allows the licensee to market the Company's TP-03 product (representing "functional intellectual property") in certain territories for a certain field of use and for a stated term - see *Note 9*. The accounting and reporting of revenue for out-license arrangements requires significant judgment for: (a) identification of the number of performance obligations within the contract, (b) the contract's transaction price for allocation (including variable consideration), (c) the stand-alone selling price for each identified performance obligation, and (d) the timing and amount of revenue recognition in each period.

The Company's out-license arrangement, as described in *Note 9*, was analyzed under GAAP to determine whether the promised goods or services (which include the license, and know-how, data, and information necessary or reasonably useful for the research, development, manufacture, or commercialization of any license product, and governance committee services) are distinct or must be accounted for as part of a combined performance obligation. In making these assessments, the Company considers factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own, and/or whether the required expertise is readily available. If the license is considered to not be distinct, the license is combined with other promised goods or services as a combined performance obligation for revenue recognition.

The Company's out-license arrangement is in exchange for the following forms of consideration: (i) upfront cash payments, (ii) equity-based consideration, (iii) sales royalties, (iv) sales threshold milestones, (v) development milestone fees, and (vi) regulatory milestone fees. Revenue is recognized in proportion to the allocated transaction price when (or as) the respective performance obligation is satisfied. The Company evaluates the progress related to each milestone at each reporting period and, if necessary, also adjusts the probability of achievement and related revenue recognition. The measure of progress, and thereby periods over which revenue is recognized, is subject to estimates by management and may change over the course of the agreement.

#### **Contractual Terms for Receipt of Payments**

The contractual terms that establish the Company's right to collect specified amounts from its customers and that require contemporaneous evaluation and documentation under GAAP for the corresponding timing and amount of revenue recognition, as follows:

(1) **Upfront License Fees:** The Company determines whether non-refundable license consideration is recognized at the time of contract execution (i.e., when the license is transferred to the customer and customer is able to use and benefit from the license) or over the actual (or implied) contractual period of the out-license. The Company also evaluates whether it has any other requirements to provide substantive services that are inseparable from the performance obligation of the license transfer to determine whether any combined performance obligation is satisfied over time or at a point in time.

(2) **Development Milestones:** The Company utilizes the "most likely amount" method to estimate the amount of consideration to which it will be entitled for achievement of development milestones. For those payments based on development milestones (e.g., patient dosing in a clinical study or the achievement of statistically significant clinical results), the Company assesses the probability that the milestone will be achieved, including its ability to control the timing or likelihood of achievement, and any associated revenue constraint. At each reporting period, the Company re-evaluates this associated revenue recognition constraint. Any resulting adjustments are recorded to revenue on a cumulative catch-up basis, thus reflected in the financial statements in the period of adjustment.

(3) *Regulatory Milestones:* The Company utilizes the "most likely amount" method to estimate the consideration to which it will be entitled and recognizes revenue in the period regulatory approval occurs (the performance obligation is satisfied). Amounts constrained as variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company evaluates whether the milestones are considered probable of being reached and not otherwise constrained. Accordingly, due to the inherent uncertainty of achieving regulatory approval, associated milestones are constrained for revenue recognition until achievement.

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

(4) **Royalties:** Under the "sales-or-usage-based royalty exception" the Company recognizes revenue based on the contractual percentage of the licensee's sales to its customers at the later of (i) the occurrence of the related sales or (ii) the date upon which the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue from its out-licensing arrangements.

(5) *Sales Threshold Milestones:* Similar to royalties, applying the "sales-or-usage-based royalty exception", the Company recognizes revenue from sales threshold milestones at the later of (i) the period the licensee achieves the one-time annual product sales levels in their territories for which the Company is contractually entitled to a specified lump-sum receipt, or (ii) the date upon which the performance obligation to which some or all of the milestone has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales threshold milestone revenue from out-licensing arrangements.

# (vii) Research and Development Costs

Research and development costs are expensed as incurred or as certain upfront or milestone payments become contractually due to licensors upon the achievement of clinical or regulatory events. These expenses also include internal costs directly attributable to in-development programs, including cost of certain salaries, payroll taxes, employee benefits, and stock-based compensation expense, as well as laboratory and clinical supplies, pre-clinical and clinical trial related expenses, and the cost of services provided by outside contractors. The Company recognizes expense for pre-clinical studies and clinical trial activities performed by these third parties. This is typically based upon estimates of the proportion of work completed over the term of the individual study or trial, as well as patient enrollment and dosing events in accordance with agreements established with clinical research organizations ("CROs") and clinical trial or pre-clinical study sites.

The Company has entered, and may continue to enter into, license agreements to access and utilize intellectual property for drug development. In each case, the Company evaluates if the assets acquired in a transaction represent the acquisition of an asset or a business, as defined under applicable GAAP. The Company's executed in-license agreements (see *Note 8(b)*) were evaluated and determined to represent asset acquisitions. Because these assets have not yet received regulatory approval and have no alternative future uses, the purchase price for each was immediately recognized as research and development expense. In addition, any future milestone payments (whether in the form of cash or stock) made before product regulatory approval (that do not meet the definition of a derivative) will also be immediately recognized as research and development expense when paid or becomes payable, provided there is no alternative future use of the rights in other research and development projects.

#### (viii) Stock-Based Compensation

The Company recognizes stock-based compensation expense for equity awards granted to employees, consultants, and members of its Board of Directors. The Black-Scholes pricing model is used to estimate the fair value of stock option awards as of the date of grant. The fair value of restricted stock units is representative of the closing share price preceding the date of grant.

For stock-based awards that vest subject to the satisfaction of a service requirement, the related expense is recognized on a straight-line basis over each award's actual or implied vesting period. For stock-based awards that vest subject to a performance condition, the Company recognizes related expense on an accelerated attribution method, if and when it concludes that it is highly probable that the performance condition will be achieved. As applicable, the Company reverses previously recognized expense in the same period of the forfeiture of unvested awards.

The measurement of the fair value of stock-based awards and recognition of stock-based compensation expense requires assumptions to be estimated by management that involve inherent uncertainties and the application of management's judgment, including (a) the fair value of the Company's common stock on the date of the option grant, (b) the expected term of the stock option until its exercise by the recipient, (c) stock price volatility over the expected term, (d) the prevailing risk-free interest rate over the expected term, and (e) expected dividend payments over the expected term.

# NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

Management estimates the expected term of awarded stock options utilizing the "simplified method" for awards as the Company does not yet have sufficient exercise history since its November 2016 formation. Further, prior to the IPO, the Company was privately-held and therefore lacked company-specific historical and implied volatility information of its stock. Accordingly, management estimated this expected volatility based on a designated peer-group of publiclytraded companies for a look-back period, as of the date of grant, that corresponded with the expected term of the awarded stock option. The Company estimates the risk-free interest rate based upon the U.S. Department of the Treasury yield curve in effect at award grant for time periods that correspond with the expected term of the awarded stock option. The Company's expected dividend yield is zero because it has never paid cash dividends and does not expect to for the foreseeable future.

Prior to the IPO, given the absence of a public trading market, the Company's Board of Directors, with input from management, considered numerous objective and subjective factors to determine the fair value of its common stock. The factors included: (i) third-party valuations of the Company's common stock; (ii) the Company's stage of development; (iii) the status of research and development efforts; (iv) the rights, preferences and privileges of the Company's preferred stock relative to common stock; (v) the Company's operating results and financial condition, including the Company's levels of available capital resources; (vi) equity market conditions affecting comparable public companies; (vii) general U.S. market conditions; and (viii) the lack of current marketability of the Company's common stock. Subsequent to the IPO, the fair value of the Company's common stock is based on the closing quoted market price of its common stock as reported by the Nasdaq Global Select Market on the date of grant.

All stock-based compensation expense is reported in the Statements of Operations and Comprehensive (Loss) Income within "research and development" expense or "general and administrative" expense, based upon the assigned department of the award recipient.

#### (ix) Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carryforwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain due to the Company's historical operating performance and recorded cumulative net losses in prior fiscal periods.

A valuation allowance is recorded to reduce deferred tax assets, because based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized. If and when the Company were to determine that deferred tax assets are realizable, an adjustment to the corresponding valuation allowance would increase the net income in the period that such determination was made.

In the event that the Company is assessed interest and/or penalties from taxing authorities that have not been previously accrued, such amounts would be included as a component of "income tax expense" within the Statements of Operations and Comprehensive (Loss) Income in the period the notice was received. To date there have been no interest or penalties charged.

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740)*. *ASU 2019-12* removes certain exceptions for performing intraperiod tax allocations, recognizing deferred taxes for investments, and calculating income taxes in interim periods. The guidance also simplifies the accounting for franchise taxes, transactions that result in a step-up in the tax basis of goodwill, and the effect of enacted changes in tax laws or rates in interim periods. The Company adopted ASU 2019-12 in the first quarter of 2021, which had no material impact to its financial statements.

## (x) Net (Loss) Income per Share Attributable to Common Stockholders

## NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

Basic net (loss) income per share attributable to common stockholders is calculated by dividing the net (loss) income by the weighted-average number of shares of common stock outstanding for the period, without the consideration for potential dilutive shares of common stock. Diluted net (loss) income per share is computed by dividing the net (loss) income by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method and if-converted method, as applicable.

The Company's participating securities include unvested common stock awards issued upon early exercise of certain stock options, as early exercised unvested common stock awards have a non-forfeitable right to dividends. The Company's participating securities do not have a contractual obligation to share in the Company's losses, so in periods of net losses, the "two-class method" of calculating basic and diluted earnings per share is not required. In periods of net income, basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. Also, net income is attributed to both common stockholders and participating security holders, and therefore, net income is allocated to shares of common stock and participating securities, as if all of the earnings for the period had been distributed. Diluted earnings per share under the two-class method is calculated using the more dilutive of the treasury stock or the two-class method.

For the nine months ended September 30, 2021, the "two-class method" was utilized to calculate diluted net income per share as it was more dilutive than the "treasury stock method". Due to a net loss for the three months ended September 30, 2021, and the three and nine months ended September 30, 2020, all otherwise potentially dilutive securities are antidilutive, and accordingly, the reported basic net loss per share equals the reported diluted net loss per share in these periods.

#### (xi) Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are publicly accessible at the measurement date.
- *Level 2:* Observable prices that are based on inputs not quoted on active markets, but that are corroborated by market data. These inputs may include quoted prices for similar assets or liabilities or quoted market prices in markets that are not active to the general public.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts for financial instruments consisting of cash and cash equivalents, accounts payable and accrued liabilities approximate fair value due to their short maturities. Derivative instruments (see *Note 7*) are carried at fair value based on unobservable market inputs.

#### (xii) Comprehensive (Loss) Income

Comprehensive (loss) income represents all changes in stockholders' equity (deficit), except those resulting from distributions to stockholders. For all periods presented, comprehensive (loss) income was the same as reported net (loss) income.

# (xiii) Recently Issued or Effective Accounting Standards

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

Recently issued or effective accounting pronouncements that impact, or may have an impact, on the Company's financial statements have been discussed within the footnote to which each relates. Other recent accounting pronouncements not disclosed in these Condensed Financial Statements have been determined by the Company's management to have no impact, or an immaterial impact, on its current and expected future financial position, results of operations, or cash flows.

#### **3. BALANCE SHEET ACCOUNT DETAIL**

The composition of selected captions within the accompanying Condensed Balance Sheets are summarized below:

# (a) Property and Equipment, net of Accumulated Depreciation

"Property and equipment, net of accumulated depreciation" consists of the following:

	September 30, 2021	December 31, 2020
Furniture and fixtures	\$ 450	\$ 294
Office equipment	67	74
Laboratory equipment	167	173
Leasehold improvements	185	141
Property and equipment, at cost	869	682
(Less): Accumulated depreciation and amortization	350	134
Property and equipment, net of accumulated depreciation and amortization	\$ 519	\$ 548

Depreciation expense (included within "total operating expenses" in the accompanying Statements of Operations and Comprehensive (Loss) Income) for the three months ended September 30, 2021 and 2020 was \$0.1 million and \$24 thousand, respectively, and for the nine months ended September 30, 2021 and 2020 was \$0.3 million and \$0.1 million, respectively.

#### (b) Other Assets

"Other assets" consists of the following:

	September 30, 2021	December 31, 2020
Deposits	\$ 72	\$ 33
Equity warrant rights* ( <i>Note 7</i> )	1,501	_
Other long term assets	42	48
Other assets	\$ 1,615	\$ 81

\*In January 2020, the FASB issued Accounting Standards Update No. 2020-01, Investments—Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)—Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the Emerging Issues Task Force), which clarifies the interaction of the accounting for equity securities, investments accounted for under the equity method, and certain forward contracts and purchased options. This update is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years. The Company is in the process of determining the impact the adoption will have on its financial statements, beginning as of and for the three months ending March 31, 2022.

## (c) Accounts Payable and Other Accrued Liabilities

"Accounts payable and other accrued liabilities" consists of the following:

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

	September 30, 2021	December 31, 2020
Trade accounts payable and other	\$ 2,010	\$ 2,237
Operating lease liability, current portion	538	282
Accrued clinical studies	4,450	1,524
Contract liability	1,034	_
Income taxes payable	—	
Employee stock option pre-vesting exercise liability, current portion	87	304
Accounts payable and other accrued liabilities	\$ 8,119	\$ 4,347

#### (d) Other Long-Term Liabilities

"Other long-term liabilities" consists of the following:

	Septen	ıber 30, 2021	December 31, 2020	
Operating lease liability, non-current portion	\$	755	\$	549
Derivative liability		150		_
Employee stock option pre-vesting exercise liability, non-current portion		_		56
Other long-term liabilities	\$	905	\$	605

#### 4. STOCKHOLDERS' EQUITY

#### Authorized Stock

Under the October 2020 Amended and Restated Certificate of Incorporation, the Company is authorized to issue two classes of stock: common and preferred. The total number of shares authorized for issuance is 200.0 million shares of common stock and 10.0 million shares of preferred stock.

# Common Stock Overview and Reserve for Future Issuance

Common stockholders have one vote for each share of common stock held and are entitled to receive any dividends declared by the Company's Board of Directors when legally available for distribution, then-subject to the dividend rights of the holders of preferred stock. For the three and nine months ended September 30, 2021 and for the year ended December 31, 2020, no dividends were declared.

As of September 30, 2021 and December 31, 2020, the Company had 20.7 million and 20.5 million shares of common stock issued, respectively. At September 30, 2021 and December 31, 2020, the Company had 20.7 million, and 20.3 million shares of common stock outstanding, respectively. The following shares of common stock were reserved for issuance:

	September 30, 2021	December 31, 2020
Stock options issued and outstanding	2,663,356	1,836,739
Common stock awards reserved for future grant	9,376,475	9,414,091
Restricted stock units outstanding	4,257	
Total shares of common stock reserved	12,044,088	11,250,830

# 5. STOCK-BASED COMPENSATION



## NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

#### 2020 and 2016 Equity Incentive Plans

The Company's Board of Directors and stockholders adopted and approved the Company's 2020 Equity Incentive Plan (the "2020 Plan") on October 8, 2020. The 2020 Plan replaced the Company's 2016 Equity Incentive Plan that was earlier adopted in December 2016 (the "2016 Plan"). However, awards outstanding under the 2016 Plan will continue to be governed by its original terms. The number of shares of the Company's common stock that were initially available for issuance under the 2020 Plan equaled the initial sum of 9,000,000 shares *plus* 2,432,980 shares that were then available for issuance under the 2016 Plan. The 2020 Plan provides for the following types of awards: incentive and non-statutory stock options, stock appreciation rights, restricted shares, and restricted stock units.

The number of shares of common stock reserved for issuance under the 2020 Plan are increased automatically on the first business day of each fiscal year, commencing in 2021 and ending in 2030, by a number equal to the *lesser of*: (i) 4% of the shares of common stock outstanding on the last day of the prior fiscal year; or (ii) the number of shares determined by the Company's Board of Directors. In general, to the extent that any awards under the 2020 Plan are forfeited, terminate, expire or lapse without the issuance of shares, or if the Company reacquires the shares subject to awards granted under the 2020 Plan, those shares will again become available for issuance under the 2020 Plan, as will shares applied to pay the exercise or purchase price of an award or to satisfy tax withholding obligations related to any award.

Stock-based awards are governed by agreements between the Company and the recipients. Incentive stock options and nonqualified stock options may be granted under the 2020 Plan (and previously the 2016 Plan) at an exercise price of not less than 100% of the fair market value of common stock on the respective date of grant. The grant date is the date the terms of the award are formally approved by the Company's Board of Directors or its designee.

Through September 30, 2021, all awards issued under the 2020 Plan and 2016 Plan were in the form of stock options and restricted stock units. These stock award agreements have service and/or performance conditions for vesting, unless immediately vested on the date of grant. Stock awards granted typically have one to four-year service conditions for full vesting. Any performance conditions for vesting are explicitly stated in each award agreement and are associated with clinical, business development, or operational milestones.

Stock options must be exercised, if at all, no later than 10 years from the date of grant. Upon termination of employment, vested stock options may be exercised within 12 months after the date of termination upon death, six months after the date of termination upon disability, and three months after the date of termination for all other separations.

#### **Employee Stock Purchase Plan**

Under the terms of the Company's 2020 Employee Stock Purchase Plan (the "ESPP"), eligible employees can purchase common stock through scheduled payroll deductions. The purchase price is equal to the closing price of the Company's common stock on the first or last day of the offering period (whichever is less), *minus* a 15% discount. To determine the value of ESPP expense to be recognized during each offering period, the Black-Scholes option-pricing model is used, in combination with the discounted employee price. A participant may purchase a maximum of 3,000 shares of common stock during a six-month offering period, not to exceed \$25,000 at full market value on the offering date during each ESPP year.

As of September 30, 2021, a total of 2.5 million shares of common stock are authorized and remain available for issuance under the ESPP. Beginning on January 1, 2021, and each January 1st thereafter, the number of common stock available for issuance under the ESPP shall automatically increase by an amount equal to the *lessor of* (i) one percent of the total number of shares of common stock outstanding on the last day of the year, (ii) 2.5 million shares, or (iii) a number determined by our board of directors.

#### Stock-Based Compensation Summary

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

Stock-based compensation expense (inclusive of ESPP) is recorded in the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income based on the designated department of the award recipient. Stock-based compensation expense for the three and nine months ended September 30, 2021 and 2020 was as follows:

	Three months ended September 30,				Nine Months Ended September			
	2021		2020		2021		2020	
Research and development	\$	544	\$ 102	\$	1,315	\$	118	
General and administrative	1,5	575	121		4,961		283	
Total stock-based compensation	\$ 2,	119	\$ 223	\$	6,276	\$	401	

#### Pre-Vesting Exercise Feature of Certain Stock Options

The 2016 Plan permitted certain option holders to exercise awarded options prior to vesting. Upon this early exercise, the options became subject to a restricted stock agreement and remain subject to the same vesting provisions in the corresponding stock option award. These unvested options are subject to repurchase by the Company upon employee termination at the same price exercised. These unvested shares of common stock are reported as issued (but not outstanding) on the accompanying Condensed Balance Sheets while subject to repurchase by the Company. These shares are also excluded from the basic net (loss) income per share until the repurchase right lapses upon vesting, but are included in the diluted net income per share for the nine months ended September 30, 2021.

The Company initially records a liability for these early exercises that is subsequently reclassified into stockholders' equity on a pro rata basis as vesting occurs. As of September 30, 2021 and December 31, 2020, the Company recorded the unvested portion of the exercise proceeds of \$0.1 million and \$0.4 million, respectively, as a liability from pre-vesting exercises in the accompanying Condensed Balance Sheets.

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

## 6. NET (LOSS) INCOME PER SHARE

The Company permits certain option holders to exercise awarded options prior to vesting (see *Note 5*) and upon early exercise, become subject to a restricted stock agreement and remain subject to the same vesting provisions in the corresponding stock option award. These pre-vested option exercises are considered to be "participating securities" as restricted stock due to non-forfeitable right to dividends (i.e., even prior to vesting).

The following table sets forth the computation of basic and diluted net (loss) income per share attributable to common stockholders:

	Three Months Ended September 30,				Nine Months End	ded September 30,		
		2021		2020	 2021		2020	
Basic EPS								
Net (loss) income	\$	(15,697)	\$	(10,138)	\$ 1,024	\$	(15,344)	
Less: undistributed income allocated to participating securities		_		—	7		_	
Net (loss) income available to common shareholders	\$	(15,697)	\$	(10,138)	\$ 1,017	\$	(15,344)	
Basic weighted average shares outstanding		20,641,285		2,729,685	 20,511,973		2,677,315	
Net (loss) income per share attributable to common stockholders—basic	\$	(0.76)	\$	(3.71)	\$ 0.05	\$	(5.73)	
Diluted EPS								
Net (loss) income	\$	(15,697)	\$	(10,138)	\$ 1,024	\$	(15,344)	
Less: undistributed income reallocated to participating securities		—		—	7		—	
Net (loss) income available to common shareholders	\$	(15,697)	\$	(10,138)	\$ 1,017	\$	(15,344)	
Basic weighted average shares outstanding		20,641,285		2,729,685	20,511,973		2,677,315	
Effect of dilutive securities:								
Common stock options		—		—	1,520,514		—	
Diluted weighted average shares outstanding		20,641,285		2,729,685	22,032,487		2,677,315	
Net (loss) income per share attributable to common stockholders—diluted	\$	(0.76)	\$	(3.71)	\$ 0.05	\$	(5.73)	

During the nine months ended September 30, 2021, 0.9 million shares of unexercised stock options were excluded from the computation of net income per share because the effect would have been anti-dilutive. Additionally, during the three and nine months ended September 30, 2020, 1.8 million unexercised stock options, 8.5 million and 8.3 million shares respectively, of preferred stock, and 179 thousand early-exercised and unvested stock options were excluded from the calculation of diluted net loss per share attributable to common stockholders because their impact under the "treasury stock method" and "if-converted method" would have been anti-dilutive.



#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

# 7. FAIR VALUE MEASUREMENTS

The table below summarizes certain financial instruments measured at fair value that are included within the accompanying balance sheets, and their designation among the three fair value measurement categories (see *Note 2(xiii)*):

	September 30, 2021 Fair Value Measurements								
	Level 1		Level 2		Level 2 Level 3			Total	
Assets:									
Money market funds	\$	183,801	\$	_	\$	—	\$	183,801	
Equity warrant rights		—		—		1,501		1,501	
Total assets measured at fair value	\$	183,801	\$	_	\$	1,501	\$	185,302	
			Decen	ıber 31, 2020 Fa	ir Value I	Measurements			
		Level 1	]	Level 2		Level 3		Total	
Assets:									
Money market funds	\$	168,129		—		—	\$	168,129	
Total assets measured at fair value	\$	168,129		_		_	\$	168,129	

#### Money Market Funds

Money market fund holdings are included in "cash and cash equivalents" on the accompanying Balance Sheets and are classified within *Level 1* of the fair value hierarchy because of their readily-available market prices in active markets that are publicly accessible at the measurement date. These money market funds are invested in U.S. Treasury, bills, notes, and other obligations issued or guaranteed as to principal and interest by the U.S. Government or its agencies.

#### **Equity Warrant Rights**

In March 2021, contemporaneous with the China Out-License transaction (see *Note 9*), the Company and LianBio Ophthalmology Limited ("LianBio"), executed a warrant agreement for the Company to purchase a stated number of equity securities of LianBio, a then privately-held pharmaceutical company focused on China, at fair value (on a per share basis at the time of issuance). The warrants will vest upon the achievement of certain clinical and regulatory events.

These warrants are classified as *Level 3* in the fair value measurement hierarchy. The most significant assumptions used in the option pricing valuation model to determine the fair value as of September 30, 2021, include: the estimated fair value of LianBio common stock (that since had its IPO on November 1, 2021), LianBio stock volatility (based on the historical volatility of similar companies), and the probability of achievement of discrete clinical and regulatory milestones for the vesting of each of the three warrants. As of September 30, 2021, one of these three milestones was met for vesting of the respective warrant.

These warrants allow for "noncash settlement" and therefore met the criteria to be recognized as a "derivative asset" on the accompanying Condensed Balance Sheets and are presented within "other assets" as of September 30, 2021 (see *Note* 3(*b*)). These warrants will be remeasured with a corresponding amount reported in "other (expense) income, net" on the Statement of Operations and Comprehensive (Loss) Income at each reporting date, until exercised or expired.

The following table sets forth a summary of the changes in fair value of the equity warrant rights presented in "other assets" on the accompanying Condensed Balance Sheets. The measurement of the equity warrant rights represents a *Level 3* financial instrument:

#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

	pres Condens	Warrant Rights, ented on the ed Consolidated ance Sheets
Fair value as of December 31, 2020	\$	
Initial fair value estimate of equity warrant rights upon issuance		1,233
Fair value as of March 31, 2021	\$	1,233
Revaluation of equity warrant rights upon achievement of first development milestone, included in "total revenues" within the Condensed Statement of Operations for the three months ended June 30, 2021		719
Revaluation of equity warrant rights included in "other (expense) income, net" within the Condensed Statement of Operations for the three months ended June 30, 2021		(876)
Fair value as of June 30, 2021	\$	1,076
Revaluation of equity warrant rights included in "total revenues" within the Condensed Statement of Operations for the three months ended September 30, 2021		771
Revaluation of equity warrant rights included in "other (expense) income, net" within the Condensed Statement of Operations for the three months ended September 30, 2021		(346)
Fair value as of September 30, 2021	\$	1,501

# 8. COMMITMENTS & CONTINGENCIES

# (a) Facility Leases

#### Overview

In the ordinary course of business, the Company enters lease agreements with unaffiliated parties for facilities and office equipment. As of September 30, 2021 and December 31, 2020, the Company had three active leases in Irvine, California for adjacent office and laboratory suites.

In January 2021, the Company entered into a six-month lease for an additional administrative office suite that was not then capitalized due to its under 12month term. On July 30, 2021, the Company executed an amendment to extend the term of this lease and a new office suite, both expiring January 31, 2024. This amendment was accounted for as a "lease modification" and resulted in the recognition of an "operating lease right-of-use asset" valued at \$0.7 million as of the execution date. The Company's two other capitalized facility leases commenced on June 1, 2020 and also expire on January 31, 2024. One includes a renewal option that was not reasonably certain to be exercised at the time of lease commencement for purposes of accounting and reporting.

The Company's facility leases are capitalized and reported within "operating lease right-of-use asset" and the corresponding lease liability within "accounts payable and other accrued liabilities" and "other long-term liabilities" on the accompanying Condensed Balance Sheets; each amounted to a total of \$1.3 million as of September 30, 2021. These operating leases have annual rent that is payable monthly and carry fixed annual increases. Also, under these arrangements, real estate taxes, certain operating expenses, and common area maintenance are paid by the Company. Since these costs are variable in nature, they are excluded from the measurement of the reported right-of-use asset and liability and are expensed as incurred.

In December 2020, the Company recorded a \$15 thousand impairment of its "operating lease right-of-use lease asset" in connection with its decision to early terminate one of the leases, which was completed in January 2021. During the year ended December 31, 2020 and for the three and nine months ended September 30, 2021, the Company had no sublease arrangements with it as lessor.

## Components of Lease Expense

The liability associated with each lease is amortized over the respective lease term using the "effective interest rate method." The Company's right-of-use asset is amortized over the lease term on a straight-line basis to lease expense, as reported on an allocated basis within "research and development" and "general and administrative" expenses on the



#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

accompanying Condensed Statements of Operations and Comprehensive (Loss) Income. The components of lease cost were as follows:

		ended September 30,	Nine mont	hs ended September 30,				
-	2	2021		2021		)20	2021	2
Operating lease cost	\$	118	\$	79	\$ 238	\$		
Variable lease cost		33		38	104			
Short-term lease cost		21		—	116			
Total lease cost	\$	172	\$	117	\$ 458	\$		

Sentember 20, 2021

#### Weighted-Average Remaining Lease Term and Applied Discount Rate

As of September 30, 2021 and December 31, 2020, the Company's active facility leases had a weighted average remaining lease term of 2 years, 4 months and 2 years, 10 months, respectively. The weighted average estimated incremental borrowing rate of 10% was utilized to present value future minimum lease payments since an implicit interest rate was not readily determinable.

#### Future Contractual Lease Payments

The below table summarizes the (i) minimum lease payments over the next five years and thereafter, (ii) lease arrangement imputed interest, and (iii) present value of future lease payments:

# Operating Leases - future payments

Operating Leases - Inture payments	September 50, 2021	
2021 (remaining three months)	\$ 129	
2022	515	
2023	761	
2024	66	
2025	—	
Total future lease payments, undiscounted	\$ 1,471	
(Less): Imputed interest	(178)	
Present value of operating lease payments	\$ 1,293	

#### (b) In-License Agreements for Lotilaner

#### Agreement for Skin and Eye Disease or Conditions in Humans

In January 2019, the Company entered into an in-license agreement with Elanco Tiergesundheit AG ("Elanco") for exclusive worldwide rights to certain intellectual property for the development and commercialization of lotilaner in the treatment or cure of any eye or skin disease or condition in humans (the "January 2019 Agreement"). The Company has sole financial responsibility for related development, regulatory, and commercialization activities.

The Company made a \$1.0 million upfront payment at execution of the January 2019 Agreement. In September 2020, the Company made a required \$1.0 million clinical milestone payment associated with the first of two U.S. pivotal trials for the treatment of Demodex blepharitis. The Company paid an additional \$2.0 million for its second pivotal trial milestone in April 2021, which was recorded within "research and development" expense in the accompanying Statements of Operations and Comprehensive (Loss) Income for the nine months ended September 30, 2021.

The Company may make further cash payments to Elanco under this January 2019 Agreement upon the achievement of certain clinical milestones in the treatment of human skin diseases using lotilaner for an aggregate maximum of \$3.0 million and various commercial and sales threshold milestones for an aggregate maximum of \$79.0 million. In addition,



#### NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

the Company will be obligated to pay tiered contractual royalties to Elanco in the mid to high single digits of its net sales. If the Company receives certain types of payments from its sublicensees, it will also be obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which the Company achieved applicable regulatory approval prior to sublicense execution.

As part of the China Out-License discussed in *Note* 9, the Company made a required contractual payment in the amount of \$2.5 million to Elanco as part of the receipt of \$25 million of initial proceeds from LianBio during the second quarter of 2021.

## Agreement for All Other Diseases or Conditions in Humans

In September 2020, the Company executed an expanded in-license agreement with Elanco, granting the Company a worldwide license to certain intellectual property for the development and commercialization of lotilaner for the treatment, palliation, prevention, or cure of "all other" diseases and conditions in humans (i.e., beyond that of the eye or skin), the "September 2020 Agreement." The Company issued Elanco 222,460 shares of its common stock at the execution of the September 2020 Agreement. The value of these shares was \$3.1 million (\$14.0003 per share, approximating the issuance price of the Company's Series C preferred stock in September 2020).

The Company is required to make further cash payments to Elanco under the September 2020 Agreement upon the achievement of various clinical milestones for an aggregate maximum of \$4.5 million and various commercial and sales threshold milestones for an aggregate maximum of \$77.0 million. In addition, the Company will be obligated to pay contractual royalties to Elanco in the single digits of its net sales. If the Company receives certain types of payments from its sublicensees, it will also be obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which the Company achieved applicable regulatory approval prior to sublicense execution.

In March 2021, the Company entered into an out-license agreement with LianBio (see *Note 9*), which obligated it to grant Elanco an additional fixed 187,500 shares of the Company's common stock that were otherwise required to be granted no later than the 18-month anniversary of the September 2020 Agreement for the Company's continued license exclusivity. These additional shares were valued at \$5.5 million based on the Company's stock closing price of \$29.30 per share (on the date the issuance became contractually required) and is reported within "research and development" expense within the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income for the nine months ended September 30, 2021.

#### (c) Employment Agreements

The Company has entered into employment agreements with seven of its named executive officers. These agreements provide for the payment of certain benefits upon separation of employment under specified circumstances, such as termination without cause, or termination in connection with a change in control event.

#### (d) Litigation Contingencies

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company is currently not aware of any such matters where there is at least a reasonable probability that a material loss, if any, has been or will be incurred for financial statement recognition.

# (e) Indemnities and Guarantees

The Company has certain indemnity commitments, under which it may be required to make payments to its officers and directors in relation to certain transactions to the maximum extent permitted under applicable laws. The duration of these indemnities varies, and in certain cases, is indefinite and does not provide for any limitation of maximum payments. The Company has not been obligated to make any such payments to date and no liabilities have been recorded for this contingency in the accompanying Condensed Balance Sheets.



## NOTES TO THE FINANCIAL STATEMENTS (all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

#### 9. OUT-LICENSE AGREEMENT

#### Out-License of TP-03 Commercial Rights in Greater China in March 2021

On March 26, 2021, the Company entered into an out-license agreement with LianBio for its exclusive development and commercialization rights of TP-03 (lotilaner ophthalmic solution, 0.25%) in the People's Republic of China, Hong Kong, Macau, and Taiwan (the "China Territory") for the treatment of Demodex blepharitis and Meibomian Gland Disease (the "China Out-License"). LianBio is contractually responsible for all clinical development and commercialization activities and costs within the China Territory.

The Company received payments from LianBio totaling \$25.0 million in April and May 2021 as initial consideration, and a total of \$30.0 million in June and August 2021 for the achievement of two clinical development milestones.

The Company is also eligible to receive other payments and consideration from LianBio upon achievement of certain additional milestones, including: (i) TP-03 clinical development and regulatory milestones of up to \$45.0 million, (ii) TP-03 sales-based milestones for the China Territory of up to \$100.0 million, (iii) tiered mid-to-high-teen royalties for China Territory TP-03 sales, and (iv) LianBio equity securities, subject to three TP-03 clinical/regulatory achievements for complete vesting, of which one tranche vested in June 2021.

The Company recognized "license fees" and "collaboration revenue" for the three months ended September 30, 2021 of \$0.7 million and \$0.5 million, respectively, in the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income, in accordance with the revenue recognition accounting policy described in *Note 2(vi)*. These amounts represent separately valued "performance obligations" in the China Out-License. For the nine months ended September 30, 2021, the Company recognized \$53.1 million and \$3.6 million, respectively, for "license fees" and "collaboration revenue".

These revenue amounts were each recognized upon (i) the transfer of TP-03 license rights in the China Territory to LianBio and (ii) the actual or partial completion of clinical activities and related data for the Company's pivotal trials of TP-03 in the treatment of Demodex blepharitis (each representing separately valued "performance obligations" in the China Out-License). As part of this revenue recognition model, the Company was required to value the LianBio equity warrants, applying a discounted cash flow model with highly subjective inputs for this then privately-held, pre-revenue company. The Company also considered the probability of achievement of requisite vesting events for these warrants. Subsequent adjustments to the estimated initial fair value of these warrants are reported within "total revenues" and "other (expense) income, net" on the accompanying Condensed Statements of Operations for the three and nine months ended September 30, 2021 (*Note 7*).

In future periods, the Company may recognize additional revenue from contractual receipts due from LianBio as (1) performance obligations are satisfied related to the completion of the TP-03 pivotal trial and as associated clinical data and reports are delivered, (2) regulatory approval events are achieved, and (3) LianBio has sales of TP-03 in the China Territory.

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

#### **Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains certain forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, future revenue, business strategy, prospects, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," contemplate," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these terms or other similar expressions are intended to identify forward looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- · the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates, and other positive results;
- the timing and progress of our current clinical trials and timing of initiation of our future clinical trials, and the reporting of data from our current and future trials;
- our plans relating to the clinical development of our current and future product candidates, including the size, number and disease areas to be evaluated;
- the prevalence of Demodex blepharitis and the size of the market opportunity for our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our plans relating to commercializing our product candidates, if approved, including sales strategy;
- the impact of COVID-19 on our business and operations;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients in the United States or globally, as applicable, who suffer from Demodex blepharitis, Meibomian Gland Disease ("MGD"), rosacea, Lyme disease and malaria and the number of patients that will enroll in our clinical trials;
- · the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our product candidates;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and our product candidates to meet existing or future regulatory standards;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the expected potential benefits of strategic collaborations with third parties (including, for example, the receipt of payments, achievement and timing of
  milestones under license agreements, and the ability of our third party collaborators to commercialize our product candidates in the territories under
  license) and our ability to attract collaborators with development, regulatory and commercialization expertise;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- the need to hire additional personnel, in particular sales personnel, and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

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- our financial performance;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our competitive position;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from our IPO.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled "Risk Factors" elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the SEC as exhibits to this report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

#### **Overview of our Business**

We are a biopharmaceutical company that applies proven science and new technology for patients, starting with eye care. Our lead product candidate, TP-03, is a novel therapeutic in Phase 3 that is being developed for the treatment of blepharitis caused by the infestation of Demodex mites, which is referred to as Demodex blepharitis. Blepharitis ("Blephar" is a reference to eyelid and "itis" is a reference to inflammation) is a condition characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes. The healthy interaction of the eyelid and the surface of the eye is crucial to ocular health. Poorly controlled and progressive blepharitis can lead to worsening of corneal damage over time and, in extreme cases, blindness.

We estimate there are approximately 25 million people in the United States who suffer from Demodex blepharitis, based on our Titan study, approximately 58% of patients presenting to eye care clinics have collarettes and a published study estimating that at least 45 million people annually visit an eye care clinic.

We believe that TP-03 has the potential to be the first therapeutic approved by the United States Food and Drug Administration ("FDA") for the treatment of Demodex blepharitis and become the standard of care. The active pharmaceutical ingredient ("API") of TP-03, lotilaner, is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific gamma-aminobutyric acid-gated chloride ("GABA-Cl") channels.

To date, we have completed four Phase 2 trials and one Phase 2b/3 trial for TP-03 in Demodex blepharitis, all of which met their primary, secondary and/or exploratory endpoints, and TP-03 was well tolerated. We commenced our second pivotal trial, Saturn-2, in May 2021. Saturn-2 has the same primary and secondary endpoints as Saturn-1. These TP-03 pivotal trials are expected to support our submission of a new drug application ("NDA") with the FDA for TP-03 for the treatment of Demodex blepharitis in 2022.

We intend to further advance our pipeline with the lotilaner API to address several diseases across therapeutic categories in human medicine, including eye care, dermatology, and other diseases. These targeted diseases with high unmet medical needs currently include TP-03 for the treatment of MGD, TP-04 for the potential treatment of rosacea, and TP-05 for potential Lyme disease prophylaxis and community malaria reduction.

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## **Recent Business and Clinical Highlights**

TP-03 Demodex Blepharitis Pivotal Trials, Saturn-1 & Saturn-2: On July 24, 2021, we presented additional data from the Saturn-1 Phase 2b/3 pivotal trial (the "Saturn-1 trial") at the American Society of Cataract and Refractive Surgery 2021 Annual Meeting demonstrating high treatment response rates, and reinforcing the potential of TP-03 to be the standard of care for Demodex blepharitis patients.

- 95% of TP-03 patients showed a significant improvement in mite count, achieving ≤0.5 mites per lash
- 93% of TP-03 patients improved by at least one collarette grade

We also announced results from additional Saturn-1 safety analysis, which reinforced TP-03's positive safety profile, revealing that TP-03 had no clinically significant adverse effect on multiple safety measures including Corrected Distance Visual Acuity ("CDVA"), corneal staining, and intraocular pressure ("IOP"), and no significant findings from slit lamp biomicroscopy or fundus exam. In addition, no impact to endothelial cell density ("ECD") was seen in a subset of 21 patients. ECD will be further evaluated as part of the Saturn-2 trial plan. We believe that the results from our Saturn-1 trial, along with previously announced data, reinforce that TP-03 is potentially safe to use in a broad patient population.

In June 2021, we announced positive results of the Saturn-1 trial. The pre-specified primary and secondary endpoints were met, and complete resolution of Demodex blepharitis signs was demonstrated in patients treated with TP-03 (lotilaner ophthalmic solution, 0.25%).

- 44% of patients on TP-03 achieved the primary endpoint of complete collarette cure, defined as 0-2 collarettes per lid at day 43, compared to 7% on vehicle (p<0.0001).</li>
- 81% of patients on TP-03 achieved a clinically meaningful collarette cure, defined as 0-10 collarettes per lid at day 43 compared to 23% of those on vehicle (p<0.0001).
- 68% of patients on TP-03 achieved mite eradication defined as 0 mites per lash at day 43, compared to 18% on vehicle (p<0.0001).</li>
   Additionally, significant efficacy in lid erythema (redness) was demonstrated across multiple measures including complete and clinically meaningful composite cures, and in erythema alone. Results showed 45% of patients improved erythema by one (1) grade or more (compared to 28% of patients on vehicle, p=0.0002) and 19% of patients on TP-03 achieved a complete erythema cure (compared to 7% of patients on vehicle, p<0.0001).</li>
- TP-03 was well tolerated with a safety profile similar to the vehicle group. Additionally, 92% of TP-03 patients reported that the drop comfort was neutral to very comfortable. There were no serious treatment-related adverse events nor any treatment-related adverse events leading to treatment discontinuation.

In May 2021, we initiated our second pivotal trial, Saturn-2. This Phase 3 trial is similar in design to Saturn-1 (same primary and secondary endpoints) and is expected to enroll approximately 418 participants across 15-20 sites in the U.S. We are on track to complete enrollment by year end 2021 and report topline data results from Saturn-2 in the first quarter of 2022. If Saturn-2 results are positive, we expect to use the data from the Saturn-1 and Saturn-2 trials to support our submission of an NDA with the FDA for TP-03 for the treatment of Demodex blepharitis in 2022.

TP-03 Demodex Blepharitis Trials, Titan and Atlas: On November 4, 2021, data from two pioneering studies on the prevalence and impact of Demodex blepharitis were presented at the American Academy of Optometry ("AAO") 2021 Annual Meeting.

- Titan, a real-world prevalence study, revealed that Demodex blepharitis accounts for 69% of blepharitis cases and is present in many commonly seen
  patient groups. Additionally, 75% of patients using tea tree oil and 57% of those using lid wipes still had collarettes, showing these current
  management tools are ineffective at treating Demodex blepharitis.
- Atlas is the first multi-centered observational study to evaluate the impact of Demodex blepharitis and showed that Demodex blepharitis is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in 80% of patients.

TP-03 China Territory Out-License: On March 26, 2021, we executed an out-license agreement (the "China Out-License") with LianBio Ophthalmology Limited ("LianBio"), granting exclusive commercial rights to TP-03 for the treatment of Demodex blepharitis and MGD within The People's Republic of China, Macau, Hong Kong, and Taiwan (the "China Territory").



We received contractual proceeds of \$20 million from LianBio during the three months ended September 30, 2021 (recognized within "license fees" on the condensed consolidated statements of operations during the three months ended June 30, 2021) for our achieved Saturn-1 clinical milestone for a total of \$55 million in contractual proceeds received for the nine months ended September 30, 2021. In March 2021, also as part of the China Out-License, we received warrant rights in LianBio, subject to clinical and regulatory vesting provisions.

We are further eligible to receive (i) a Saturn-2 clinical milestone of \$15 million (expected achievement during the first half of 2022), (ii) China-based clinical and regulatory milestones totaling \$30 million, and (iii) China Territory sales threshold milestones totaling \$100 million. We are also entitled to receive tiered royalties in the low double-digits on the net sales of TP-03 within the China Territory.

TP-05 Initiation of Phase 1 Trial, Callisto: We continued to advance our Phase 1 Callisto trial, evaluating TP-05, a novel, oral, non-vaccine therapeutic, for the prevention of Lyme disease with data expected in the first half of 2022. In June 2021, we initiated the Callisto trial, a single ascending dose and multiple ascending dose trial to evaluate the safety, tolerability and pharmacokinetics ("PK") of TP-05 in healthy volunteers. There are currently no FDA-approved pharmacological prophylactic options for Lyme disease, which is the most common vector-borne disease in the U.S., transmitted to humans via Borrelia burgdorferi bacterium infection following the bite of a tick vector.

We believe TP-05 is currently the only non-vaccine, drug-based, preventive therapeutic in development that targets the ticks, and potentially prevents Lyme disease transmission. It is designed to rapidly provide systemic blood levels of lotilaner potentially sufficient to kill infected ticks attached to the human body before they can transmit the Borrelia bacteria that causes Lyme disease.

# **Corporate and Financial Overview**

We were incorporated as a Delaware corporation in November 2016, and our headquarters is located in Irvine, California. Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, acquiring intellectual property, clinical development of our product candidates, building our research and development capabilities, raising capital, and enhancing our corporate infrastructure.

To date we have financed our operations through private placements of preferred stock, convertible promissory notes, the net proceeds from our IPO (as defined below), and out-licensing arrangements. From inception through September 30, 2021, we raised net proceeds of approximately \$103.2 million through private placements of preferred stock.

In advance of our IPO, on October 8, 2020, our board of directors approved a 1-for-7.4276 reverse stock split of our capital stock. All share and per share information included in the accompanying financial statements has been adjusted to reflect this reverse stock split. On October 20, 2020, we completed our initial public offering ("IPO") through an underwritten sale of 6,325,000 shares of our common stock at a price of \$16.00 per share, inclusive of an additional 825,000 shares of common stock sold upon the full exercise of the underwriters' purchase option. The aggregate net proceeds from the offering after deducting underwriting discounts and commissions and other offering expenses were \$91.7 million. Concurrent with the IPO, all then-outstanding shares of our convertible preferred stock automatically converted into an aggregate of 11,107,018 issued shares of common stock.

In March 2021, we executed an out-license of TP-03 for the China Territory (see *Note 9*). During the nine months ended September 30, 2021, we received cash proceeds of \$55.0 million from our licensee. We expect to receive additional cash proceeds of \$15.0 million in the first half of 2022 upon achievement of our remaining TP-03 U.S. clinical milestone (for initial consideration totaling \$70.0 million for this out-license).

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant operating expenses and, other than the effect of license fee revenue from the China Out-License Agreement, increasing operating losses for the foreseeable future. Our net losses were \$15.7 million and \$10.1 million for the three months ended September 30, 2021 and 2020, respectively, and \$15.3 million for the nine months ended September 30, 2021 we had net income of \$1.0 million. Our net losses and any net income we may generate may fluctuate significantly from quarter to quarter and year to year and could be substantial. As of September 30, 2021 and December 31, 2020, we had an accumulated deficit of \$31.8 million and \$32.8 million, respectively, from our research and development and general and administrative activities since inception. We anticipate that our operating expenses will increase significantly as we:

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- conduct clinical trials of our lead product candidate, TP-03, for the treatment of Demodex blepharitis including our Phase 3 trial, Saturn-2;
- advance the clinical development of TP-03 for the treatment of MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical development, if any;
- · establish our own sales force in the United States to commercialize our products for which we obtain regulatory approval;
- engage with contract manufacturers to ensure a sufficient supply chain capacity to provide commercial quantities of any products for which we may
  obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory, marketing, operations, financial, and other support personnel, to execute our business plan; and
- add information systems and personnel to support our product development and potential future commercialization efforts, and to enable us to operate as
  a public company.

We do not have any products approved for sale and we have not yet generated any revenue from product sales. However, we recognized "license fees" and "collaboration revenue" from our China Out-License for the three and nine months ended September 30, 2021 of an aggregate \$1.2 million and \$56.7 million, respectively (see *Note 9*), and expect to recognize additional revenue under these captions from this arrangement in future periods.

We do not expect to generate revenues from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate and commercially launch such product. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, or collaborations, strategic alliances, or licensing arrangements with third parties. Adequate funding may not be available to us when needed on acceptable terms, or at all. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital or enter into such agreements as and when needed, we could be forced to significantly delay, scale back, or discontinue our product development and/or commercialization plans, which would negatively and adversely affect our financial condition.

Because of the numerous risks and uncertainties associated with drug product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels.

As of September 30, 2021, our aggregate cash and cash equivalents was \$183.8 million – see the section below titled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources."

## Impact of the COVID-19 Pandemic on our Operations

Efforts to contain the spread of COVID-19 in the United States (including in California where our corporate headquarters and laboratory facility are located) and other countries have included quarantines, shelter-in-place orders, and various other government restrictions in order to control the spread of this virus.

We have been carefully monitoring the COVID-19 pandemic as it continues to progress and its potential impact on our business. We have taken important steps to ensure the workplace safety of our employees when working within our laboratory and administrative offices, or when traveling to our clinical trial sites. We have also implemented a vaccination policy and we may take further actions as may be required by federal, state or local authorities.



To date, we have been able to continue our key business activities and advance our clinical programs. However, in the future, it is possible that our clinical development timelines and business plans could be adversely affected. We maintain regular communication with our vendors and clinical sites to appropriately plan for, and mitigate, the impact of the COVID-19 pandemic on our operations. Specifically, for our Phase 3 Saturn-2 trial, we have instituted various protocols for our sites, including increasing health screening of individuals and providing enhanced communication and training to staff regarding COVID-19. However, the ultimate effect from this pandemic on our development timelines for TP-03 (including clinical trial enrollment) and our other product candidates is inherently uncertain.

See the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 31, 2021, for a further discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

#### **Result of Operations**

# Comparison of the Three Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended September 30,					
	2021			2020		Change
			(	in thousands)		
Revenues:						
License fees and collaboration revenue	\$	1,240	\$		\$	1,240
Total revenues		1,240		—		1,240
Operating expenses:						
Cost of license fees and collaboration revenue		65				65
Research and development		10,209		7,991		2,218
General and administrative		6,671		2,150		4,521
Total operating expenses		16,945		10,141		6,804
(Loss) income from operations before other (expense) income and income taxes		(15,705)		(10,141)		(5,564)
Other (expense) income:						
Interest income, net		8		4		4
Other income, net		5		_		5
Change in fair value of equity warrant rights		(346)				(346)
Total other (expense) income, net		(333)		4		(337)
Benefit (provision) for income taxes		341		(1)		342
Net loss	\$	(15,697)	\$	(10,138)	\$	(5,559)

# License Fees and Collaboration Revenue

License fees and collaboration revenue was \$1.2 million for the three months ended September 30, 2021, which was attributable to the portion of the China Out-License (see *Note 9*) contractual milestones that were fully or partially complete by September 30, 2021. These amounts respectively represent the satisfaction of the transfer of license rights to LianBio and the partial completion of clinical-related "performance obligations" stated in the China Out-License.

We will recognize additional "license fee and collaboration revenue" as these performance obligations are further satisfied or other events occur, specifically related to (i) TP-03 pivotal trial completion and the delivery of associated clinical data and reports to our licensee, (ii) achievement of certain clinical and regulatory events in China, and (iii) sales by our licensee of TP-03 in the China Territory.

# Cost of License Fees and Collaboration Revenue

Cost of license fees and collaboration revenue was \$0.1 million for the three months ended September 30, 2021. Under the terms of the China Out-License and our in-license agreement for lotilaner (see *Note 8(b)*), we recognized \$0.1 million of associated expense in proportion to our recognized "license fee" and "collaboration revenue" in the same period.

# **Research and Development Expenses**

Research and development expenses increased by \$2.2 million for the three months ended September 30, 2021 as compared to the prior year period. The increase was primarily due to (i) increased clinical and preclinical study costs of \$3.5 million, (ii) increased manufacturing and formulation costs of \$1.4 million, and (iii) increased payroll and personnel-related costs, including stock-based compensation, of \$1.2 million for 10 employee additions period over period to drive our product development initiatives. These increases were partially offset by non-recurring costs in the prior year period including (i) an upfront payment to our licensor (in the form of our common stock issuance) then valued at \$3.1 million, and (ii) TP-03 clinical milestone achievement for Saturn-1 in September 2020 requiring a \$1.0 million payment to our licensor.

#### General and Administrative Expenses

General and administrative expenses increased by \$4.5 million for the three months ended September 30, 2021, as compared to the prior year period. The increase was primarily due to (i) a \$2.5 million increase in payroll and personnel-related costs, including stock-based compensation, for 16 employee additions period over period to support our business growth, (ii) increased insurance and other administrative costs of \$0.9 million, (iii) increased professional and legal fees of \$0.6 million, and (iv) increased commercial and market research costs of \$0.2 million.

#### Other (Expense) Income, Net

Other (expense) income, net increased by \$0.3 million primarily due to a change in estimated fair value of the equity warrant rights we received as part of our China Out-License in March 2021.

### Benefit (Provision) for Income Taxes

We maintain a full "valuation allowance" against our net deferred tax assets as of September 30, 2021 and 2020 since we cannot conclude that these future benefits will be realized through the offset of our potential taxable income in the future. For the three months ended September 30, 2021, we recorded an income tax benefit of \$0.3 million attributable to decreases in our projected earnings which eliminated federal and state income tax expenses previously provided through the prior quarter ended June 30, 2021. For the three months ended September 30, 2020, we recorded a nominal \$1 thousand income tax expense due to the losses we incurred in that period.

#### Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the periods indicated:

	Ni	ne Months End		
	2	021	2020	Change
			(in thousands)	
Revenues:				
License fees and collaboration revenue	\$	56,689	\$	\$ 56,689
Total revenues		56,689	_	56,689
Operating expenses:				
Cost of license fees and collaboration revenue		2,099	—	2,099
Research and development		33,674	11,239	22,435
General and administrative		18,625	4,282	14,343
Total operating expenses		54,398	15,521	38,877
Income (loss) from operations before other (expense) income and income taxes		2,291	(15,521)	17,812
Other (expense) income:				
Interest income, net		24	178	(154)
Other expense, net		(68)	_	(68)
Change in fair value of equity warrant rights		(1,222)	—	(1,222)
Total other (expense) income, net		(1,266)	178	(1,444)
Benefit for income taxes		(1)	(1)	
Net income (loss)	\$	1,024	\$ (15,344)	\$ 16,368

#### License Fees and Collaboration Revenue



License fees and collaboration revenue was \$56.7 million for the nine months ended September 30, 2021, which was attributable to the portion of the China Out-License (see *Note 9*) contractual milestones that are fully or partially complete by September 30, 2021. These amounts respectively represent the satisfaction of the transfer of license rights to LianBio and the partial completion of clinical-related "performance obligations" stated in the China Out-License.

We will recognize additional "license fee and collaboration revenue" as these performance obligations are further satisfied or other events occur, specifically related to (i) milestone payments upon TP-03 pivotal trial completion and the delivery of associated clinical data and reports to our licensee, (ii) achievement of regulatory events that trigger milestone payments, and (iii) our licensee's sales of TP-03 in the China Territory.

#### Cost of License Fees and Collaboration Revenue

Cost of license fees and collaboration revenue was \$2.1 million for the nine months ended September 30, 2021. Under the terms of the China Out-License, and our in-license agreement for lotilaner (see *Note 8(b)*), we recognized \$2.1 million of associated expense in proportion to our recognized "license fee" and "collaboration revenue" in the same period.

#### **Research and Development Expenses**

Research and development expenses increased by \$22.4 million for the nine months ended September 30, 2021 as compared to the prior year period. The increase was primarily due to (i) payment to our licensor in the form of issuance of 187,500 shares of our common stock valued at \$5.5 million in March 2021 (at our early-extension of exclusive rights to lotilaner in "all other" diseases and conditions in humans), (ii) clinical milestone expense of \$2.0 million due to our licensor in connection with the commencement of Saturn-2, our second U.S. pivotal trial for the treatment of Demodex blepharitis, (iii) increased clinical and preclinical study costs of \$11.5 million, (iv) increased manufacturing and formulation costs of \$3.6 million, and (v) increased payroll and personnel-related costs, including stock-based compensation, of \$3.5 million for 10 additional employees to drive our product development initiatives. These increases were partially offset by non-recurring costs in the prior year period including (i) an upfront payment to our licensor (in the form of our common stock issuance) then valued at \$3.1 million, and (ii) TP-03 clinical milestone achievement for Saturn-1 in September 2020 requiring a \$1.0 million payment to our licensor.

# General and Administrative Expenses

General and administrative expenses increased by \$14.3 million for the nine months ended September 30, 2021. The increase was primarily due to (i) \$7.8 million increase in payroll and personnel-related costs, including stock-based compensation, for 16 employee additions to support our business growth, (ii) increased insurance and other administrative costs of \$2.5 million, (iii) increased professional and legal fees of \$1.9 million, (iv) increased commercial and market research costs of \$1.6 million, and (v) \$0.6 million of increased computer systems and facility costs.

#### Other (Expense) Income, Net

Other (expense) income, net increased by \$1.4 million primarily due to a change in estimated fair value of the equity warrant rights we received as part of our China Out-License in March 2021.

# **Benefit for Income Taxes**

We maintain a full "valuation allowance" against our net deferred tax assets as of September 30, 2021 and 2020 since we cannot conclude that these future benefits will be realized through the offset of our potential taxable income in the future. For the nine months ended September 30, 2021 and 2020, we recorded nominal \$1 thousand income tax expenses due to the losses we incurred in each of those periods.

#### Liquidity and Capital Resources

## Sources of Liquidity

We will continue to be dependent upon equity, debt financing, and/or other forms of capital raises at least until we are able to generate significant ongoing positive cash flows from our operations. As of September 30, 2021, we had cash and cash equivalents of \$183.8 million.



Since our inception in 2016 through September 30, 2021, our operations have been substantially financed by cash proceeds from private placements of preferred stock, our IPO proceeds, and China Out-License consideration. As part of our IPO, we sold 6,325,000 shares of our common stock (inclusive of the full exercise of the underwriters' option to purchase an additional 825,000 shares of our common stock). After deducting underwriting discounts and commissions and other related expenses, our IPO proceeds were \$91.7 million.

In April and May 2021, we received \$25.0 million of initial proceeds from our licensee as part of the execution of our China Out-License (see *Note* 9). In June and August 2021, we received \$30.0 million for the achievement of clinical development milestones. We expect to receive \$15.0 million during the first half of 2022 for the achievement of an additional clinical development milestone, for a total of \$70.0 million of milestone receipts since agreement execution in March 2021. The remaining \$130.0 million of potential milestones under this out-license will be received upon future clinical, regulatory and sales achievements within the China Territory.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees.

#### **Funding Requirements**

Our current cash balance funds our operating expenditures and other working capital requirements. Our operating expenditures currently consist of research and development expenses (including activities within our preclinical, clinical, regulatory, and drug manufacturing initiatives) and general and administrative expenses. Our use of cash is impacted by the timing and extent of payments for each of these activities and other business requirements.

We believe that our cash and cash equivalents of \$183.8 million as of September 30, 2021 and our expected \$15 million of additional proceeds in the first half of 2022 as part of the China Out-License, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2023. We based this cash runway estimate on our current assumptions that may require future adjustments as part of our ongoing business decisions within pipeline development and our other corporate initiatives. Accordingly, we may require additional capital resources earlier than we currently expect.

On November 1, 2021, we filed a shelf registration statement (the "Shelf Registration Statement") on Form S-3 with the SEC (that was declared effective by the SEC on November 5, 2021), which permits us to offer up to \$300.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, including in units from time to time. Our Shelf Registration Statement is intended to provide us with additional flexibility to access capital markets for general corporate purposes, which may include working capital, capital expenditures, other corporate expenses and acquisitions of complementary products, technologies, or businesses.

On November 1, 2021, as part of the Shelf Registration Statement, we also filed a sale agreement prospectus covering the sale of up to \$100.0 million of the Company's common stock pursuant to an Open Market Sale Agreement<sup>SM</sup> (the "Sale Agreement") with Jefferies LLC. Through the date of this filing, we have not sold any shares of our common stock in at the market transactions pursuant to the Sale Agreement or any securities under the Shelf Registration Statement.

To date, we have not generated any product sales (separate from our reported "license fee and collaboration revenue" discussed above). We do not expect to report any product revenue unless and until we (1) complete development of any of our product candidates; (2) obtain applicable regulatory approvals; and then (3) successfully commercialize or enter into other collaborative agreements for our product candidates with third parties. We do not know with certainty when, or if, any of these items will ultimately occur.

We expect to incur significant operating losses for the foreseeable future, and expect these losses to further increase, as we ramp up our clinical development programs and begin activities for commercial launch readiness. We may also encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business.

We will require additional capital to fully develop our product candidates and to execute our business strategy. Our requirements of a future capital raise will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;



- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- · the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent and trademark applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development
  of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of various computerized information systems;
- impact of COVID-19 on our clinical development or operations; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. Our potential inability to raise capital when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds as required, we may need to delay, reduce, or terminate some or all development programs and clinical trials. We may also be required to sell or license our rights to product candidates in certain territories or indications that we would otherwise prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to address our liquidity needs, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially and adversely affect our business and financial prospects. See the section titled "Risk Factors" in this report for additional risks associated with our substantial capital requirements.

#### Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for each of the periods presented below:

	 Nine Months Ended September 30,			
	2021		2020	
	 (in thousands)			
Net cash provided by (used in) :				
Operating activities	\$ 15,869	\$	(11,125)	
Investing activities	(312)		(506)	
Financing activities	95		40,008	
Net increase in cash, cash equivalents and restricted cash	\$ 15,652	\$	28,377	

#### Net Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities was \$15.9 million for the nine months ended September 30, 2021. We recognized \$56.7 million of license fee and collaboration revenue, though we received \$55 million in cash in the current nine-month period in connection with the China Out-License transaction. In the current nine-month period, our cash payments to vendors for our operating activities totaled \$32.6 million and payroll-related cash payments (inclusive of 2020 bonus payouts) totaled \$6.9 million. In addition, we made contractual payments of \$4.5 million to our intellectual property licensor (see *Note 8(b)*).

Net cash used in operating activities was \$11.1 million for the nine months ended September 30, 2020 and primarily represented a net loss of \$15.3 million associated with our operating expenses in that period.

# Net Cash Used in Investing Activities

Net cash used in investing activities was \$0.3 million for the nine months ended September 30, 2021, which consisted of leasehold improvements for our laboratory and administrative offices and various purchases of computer hardware, software, and office equipment.

Net cash used in investing activities was \$0.5 million for the nine months ended September 30, 2020, which also consisted of various purchases of computer hardware, software, and office equipment.

## Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$95 thousand for the nine months ended September 30, 2021, which was attributable to proceeds from the exercise of stock options.

Net cash provided by financing activities was \$40.0 million for the nine months ended September 30, 2020, and primarily relates to our issuance of Series C preferred stock for net proceeds of \$39.8 million and proceeds from pre-vesting exercises of stock options totaling \$0.4 million.

## Critical Accounting Policies, Significant Judgments and Use of Estimates

The preparation of our condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates are different assumptions and conditions. A summary of our critical accounting policies is presented in our filed Annual Report on Form 10-K for the year ended December 31, 2020.

There were no material changes to our previously reported "Critical Accounting Policies" during the three and nine months ended September 30, 2021, except for:

# **Revenue Recognition for Out-Licenses and Collaborative Agreements**



The terms of our out-licenses and collaborative agreements include upfront license fees, milestones, and other contingent payments for the achievement of defined development, regulatory and sales-based events, as well as royalties on sales of commercialized products. Arrangements that include upfront payments may require deferral of revenue recognition to a future period until we perform obligations under these arrangements. The event-based milestone and other contingent payments represent variable consideration, and we use the "most likely amount method" to estimate this variable consideration. Given the high degree of uncertainty around the occurrence of these events, we determine the milestone and other contingent amounts to be "constrained" until the uncertainty associated with these payments is resolved. We will recognize revenue from sales-based royalty payments when or as our licensee sales occur. We will re-evaluate our determined "transaction price" in each reporting period as uncertain events are resolved and other changes in circumstances occur. A "performance obligation" is a promise in a contract to transfer a distinct good or service and is the unit of accounting. A contract's "transaction price" is allocated among each distinct performance obligation based on relative standalone selling price and recognized when, or as, the applicable performance obligation is satisfied.

#### **Recent Accounting Pronouncements**

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows are disclosed in the footnote to which each relates within these accompanying Condensed Financial Statements.

#### **Off-Balance Sheet Arrangements**

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

#### **Contractual Obligations and Commitments**

There have been no material changes outside the ordinary course of business to the Company's contractual obligations disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC.

#### **Indemnification Agreements**

As permitted under Delaware law and in accordance with our amended and restated bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our officers and directors. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of September 30, 2021.

# **JOBS Act Accounting Election**

The Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act") permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

We will remain an emerging growth company until the *earliest of* (1) the last day of our first fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million of the prior June 30th and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

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#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

#### Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2021, we had cash and cash equivalents of \$183.8 million, consisting of interest-bearing money market accounts, for which the fair market value would be affected by changes in the general level of United States interest rates. However, due to the short-term maturities and the low-risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents.

We do not believe that inflation, interest rate changes, or foreign currency exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

#### **Item 4. Controls and Procedures**

## **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended ("Exchange Act")) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we 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 to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

# **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Inherent Limitations on Effectiveness of Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.



# PART II—OTHER INFORMATION

# Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

#### Item 1A. Risk Factors

As of the date of this filing, there have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 31, 2021.

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

None.

# **Use of Proceeds**

There has been no material change in the planned use of proceeds from our IPO as described in the Registration Statement on Form S-1 (File No. 333-249076), declared effective by the SEC on October 15, 2020, and the related final prospectus, dated October 15, 2020, filed with the SEC on October 16, 2020, pursuant to Rule 424(b) of the Securities Act.

# Item 3. Defaults Upon Senior Securities.

None.

#### Item 4. Mine Safety Disclosures.

None.

#### Item 5. Other Information.

None.



# Item 6. Exhibits

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Registrant.	8-K	001-39614	3.1	10/20/2020	
3.2	Amended and Restated Bylaws of Registrant.	8-K	001-39614	3.2	10/20/2020	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					х
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					Х
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.					Х
32.2*	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to</u> Section 906 of the Sarbanes-Oxley Act of 2002.					Х
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.					Х
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					Х
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					Х
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					Х
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					Х
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					Х
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					Х

\* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Tarsus Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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# SIGNATURES

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

# TARSUS PHARMACEUTICALS, INC.

Date:	November 10, 2021	/s/ Bobak Azamian, M.D., Ph.D.
		Bobak Azamian, M.D., Ph.D.
		President and Chief Executive Officer
		(Principal Executive Director)

Date:

November 10, 2021

/s/ Leonard M. Greenstein

Leonard M. Greenstein Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

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

I, Bobak Azamian, M.D., Ph.D., certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Tarsus Pharmaceuticals, 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)) 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) 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
  - (c) 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: November 10, 2021

By:

/s/ Bobak Azamian, M.D., Ph.D.

Bobak Azamian, M.D., Ph.D. President and Chief Executive Officer (Principal Executive Officer)

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

I, Leo M. Greenstein, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Tarsus Pharmaceuticals, 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)) 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) 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
  - (c) 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: November 10, 2021

By:

/s/ Leo M. Greenstein

Leo M. Greenstein Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

#### Exhibit 32.1

#### CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER 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 of Tarsus Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Bobak Azamian, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 10, 2021

By:

/s/ Bobak Azamian, M.D., Ph.D. Bobak Azamian, M.D., Ph.D. President and Chief Executive Officer (Principal Executive Officer)

#### CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER 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 of Tarsus Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leo M. Greenstein, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 10, 2021

By:

/s/ Leo M. Greenstein

Leo M. Greenstein Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)