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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

or

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

For the transition period from to Commission File Number: 001-39614

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 No.)**

> 92618 (Zip Code)

(949) 409-9820

(Registrant's telephone number, including area code)

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 smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. Large accelerated filer Accelerated filer X Non-accelerated filer Smaller reporting company

 \times X Emerging growth company

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

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

26,672,188 shares of common stock, \$0.0001 par value, outstanding as of November 7, 2022.

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PART I—FINANCIAL INFORMATION

Item I. Financial Statements (Unaudited)

TARSUS PHARMACEUTICALS, INC. INDEX TO THE FINANCIAL STATEMENTS

<u>Condensed Balance Sheets</u> <u>Condensed Statements of Operations and Comprehensive (Loss) Income</u> <u>Condensed Statements of Stockholders' Equity</u> <u>Condensed Statements of Cash Flows</u> <u>Notes to Condensed Financial Statements</u>

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CONDENSED BALANCE SHEETS

(In thousands, except share and par value amounts)

	Septe	ember 30, 2022	Dece	mber 31, 2021
	(1	unaudited)		
ASSETS				
Current assets:				
Cash and cash equivalents	\$	169,489	\$	171,332
Marketable securities		57,083		483
Accounts receivable		17		—
Other receivables		3,995		92
Prepaid expenses	_	3,494		4,045
Total current assets		234,078		175,952
Property and equipment, net		951		755
Operating lease right-of-use assets		696		1,074
Long-term investments		157		—
Other assets		583		1,126
Total assets	\$	236,465	\$	178,907
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable and other accrued liabilities	\$	10,181	\$	8,680
Accrued payroll and benefits		4,092		2,798
Total current liabilities		14,273		11,478
Term loan, net		19,356		_
Other long-term liabilities		209		699
Total liabilities		33,838		12,177
Commitments and contingencies (Note 8)				
Stockholders' equity:				
Preferred stock, \$0.0001 par value; 10,000,000 authorized; no shares issued and outstanding		—		_
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 26,671,812 shares issued and outstanding at September 30, 2022 (unaudited); 20,726,580 shares issued and 20,698,737 outstanding, which excludes 27,840 shares subject to repurchase at December 31, 2021		5		4
Additional paid-in capital		297,796		213,398
Accumulated other comprehensive loss		(10)		
Accumulated deficit		(95,164)		(46,672)
Total stockholders' equity		202,627		166,730
Total liabilities and stockholders' equity	\$	236,465	\$	178,907
	Φ	230,403	φ	1/0,907

See accompanying notes to these unaudited condensed financial statements.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,				nths Ended nber 30,		
		2022		2021	 2022		2021
Revenues:							
License fees	\$	—	\$	708	\$ 13,893	\$	53,067
Collaboration revenue		—		532	 1,923		3,622
Total revenues		_		1,240	 15,816		56,689
Operating expenses:							
Cost of license fees and collaboration revenue		_		65	555		2,099
Research and development		10,912		10,209	32,596		33,674
General and administrative		11,994		6,671	30,316		18,625
Total operating expenses		22,906		16,945	63,467		54,398
(Loss) income from operations before other income (expense) and income taxes		(22,906)		(15,705)	 (47,651)		2,291
Other income (expense):		i			 		
Interest income		1,061		8	1,372		24
Interest expense		(633)		_	(1,507)		—
Other (expense) income, net		(7)		5	136		(68)
Unrealized loss on equity investments		(13)			(326)		
Change in fair value of equity warrants issued by licensee		(18)		(346)	(520)		(1,222)
Total other income (expense), net		390		(333)	(845)		(1,266)
Benefit (provision) for income taxes		5		341	 4		(1)
Net (loss) income	\$	(22,511)	\$	(15,697)	\$ (48,492)	\$	1,024
Other comprehensive (loss) income:							
Unrealized loss on marketable securities and cash equivalents		(10)			(10)		_
Comprehensive (loss) income	\$	(22,521)	\$	(15,697)	\$ (48,502)	\$	1,024
Net (loss) income per share, basic	\$	(0.84)	\$	(0.76)	\$ (2.03)	\$	0.05
Net (loss) income per share, diluted	\$	(0.84)	\$	(0.76)	\$ (2.03)	\$	0.05
Weighted guarage shares outstanding heads		26 662 274		20 641 295	 22 022 512		20 511 072
Weighted-average shares outstanding, basic		26,662,374	_	20,641,285	 23,923,512	_	20,511,973
Weighted-average shares outstanding, diluted		26,662,374		20,641,285	 23,923,512		22,032,487

See accompanying notes to these unaudited condensed financial statements.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited) (In thousands, except share data)

_	Preferr	ed Stock		Common St	ock		Additional Paid-In	Accumulated Other Comprehensive	A	Accumulated	Ste	Total ockholders'
	Shares	Amo	unt	Shares	Ar	nount	 Capital	Loss		Deficit		Equity
Balance as of December 31, 2021	_	\$	—	20,698,737	\$	4	\$ 213,398	\$	\$	(46,672)	\$	166,730
Net loss	_		—	—		_	_	—		(20,238)		(20,238)
Recognition of stock-based compensation expense	_		_	_		_	2,674	_		_		2,674
Exercise of vested stock options	—		—	225		—		—		—		—
Issuance of common stock upon the vesting of restricted stock units	_		_	4,257		_	_	_		_		_
Lapse of repurchase obligation for stock option exercises, prior to vesting	_		_	15,309		_	31					31
Balance as of March 31, 2022	_	\$		20,718,528	\$	4	\$ 216,103	\$	\$	(66,910)	\$	149,197
Net loss			_			_	 			(5,743)	-	(5,743)
Recognition of stock-based compensation expense	_			_		_	3,532	_		_		3,532
Issuance of common stock upon follow- on public offering, net of issuance costs of \$5,246	_		_	5,889,832		1	74,266			_		74,267
Shares issued in connection with the employee stock purchase plan			_	17,874		_	222	_				222
Exercise of vested stock options	_		—	7,056		—	17	—		_		17
Issuance of common stock upon the vesting of restricted stock units	_		_	4,257		_	_	_		_		_
Lapse of repurchase obligation for stock option exercises, prior to vesting	_		_	6,705		—	13			—		13
Balance as of June 30, 2022	—	\$	—	26,644,252	\$	5	\$ 294,153	\$ —	\$	(72,653)	\$	221,505
Net loss						_	 			(22,511)		(22,511)
Recognition of stock-based compensation expense	_		_	_		_	3,583	_		_		3,583
Lapse of repurchase obligation for stock option exercises, prior to vesting	_		_	5,826		_	12	_		_		12
Exercise of vested stock options	_		—	21,734		—	82	—		—		82
Issuance costs related to follow-on public offering	_		_	_		_	(34)	_		_		(34)
Unrealized loss on marketable securities and cash equivalents	_		_			_	_	(10)		_		(10)
Balance as of September 30, 2022	_	\$	_	26,671,812	\$	5	\$ 297,796	\$ (10)	\$	(95,164)	\$	202,627

See accompanying notes to these unaudited condensed financial statements.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited) (In thousands, except share data)

	Preferred	Stock	Common	Common Stock		Common Stock						Total
_	Shares	Amount	Shares		Amount	Pa	Additional Paid-In Capital				Accumulated Deficit	Stockholders' Equity
Balance as of December 31, 2020	_	\$ —	20,323,201	\$	4	\$	198,821	\$	(32,845)	\$ 165,980		
Net income					_		_		10,376	 10,376		
Recognition of stock-based compensation expense		_	—				1,363		—	1,363		
Exercise of vested stock options	—	—	13,773				19		—	19		
Shares issued as consideration for in-license rights		_	187,500				5,494		—	5,494		
Balance as of March 31, 2021	_	\$ —	20,524,474	\$	4	\$	205,697		(22,469)	\$ 183,232		
Net income	_						_		6,345	 6,345		
Recognition of stock-based compensation expense		_	_				2,794		_	2,794		
Lapse of repurchase obligation for stock option exercises, prior to vesting	_	_	49,222		_		99		_	99		
Exercise of vested stock options	—	—	255				1		—	1		
Balance as of June 30, 2021	_	\$ —	20,573,951	\$	4	\$	208,591		(16,124)	\$ 192,471		
Net loss									(15,697)	 (15,697)		
Recognition of stock-based compensation expense		\$	_	\$		\$	2,119	\$	_	\$ 2,119		
Lapse of repurchase obligation for stock option exercises, prior to vesting			87,004				174			174		
Exercise of vested stock options		_	10,124		_		75		_	75		
Balance as of September 30, 2021		\$	20,671,079	\$	4	\$	210,959	\$	(31,821)	\$ 179,142		

See accompanying notes to these unaudited condensed financial statements.

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

	Nine Month Septemb			ed
		2022		2021
Cash Flows From Operating Activities:				
Net (loss) income	\$	(48,492)	\$	1,024
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:				
Depreciation and amortization		227		272
Accretion of term loan-related costs		231		
Stock-based compensation		9,789		6,276
Non-cash lease expense		343		178
Loss on disposal of property and equipment				70
Loss on lease termination		—		2
Unrealized loss on equity investment		326		
Amortization of discount on available-for-sale debt securities		(63)		—
Change in fair value of equity warrants issued by licensee		520		1,222
Unrealized gain from transactions denominated in a foreign currency		(1)		(4
Issuance of common stock upon in-license agreement milestone achievement				5,494
Changes in operating assets and liabilities:				
Accounts receivable		(17)		
Other receivables		(3,902)		(119
Prepaid expenses		551		(663
Other non-current assets		(75)		(2,762
Accounts payable and other accrued liabilities		1,187		3,523
Accrued payroll and benefits		1,294		1,206
Other long-term liabilities		(74)		150
Net cash (used in) provided by operating activities		(38,156)		15,869
Cash Flows From Investing Activities:				
Purchases of marketable securities		(57,031)		—
Purchases of property and equipment		(379)		(312)
Cash used in investing activities		(57,410)		(312
Cash Flows From Financing Activities:				
Proceeds from issuance of common stock upon follow-on public offering, net of paid issuance costs		74,352		
Proceeds from sale of common stock under employee stock purchase plan		222		
Proceeds from exercise of vested stock options		99		95
Payment of deferred offering costs		(75)		
Proceeds from term loan		20,000		—
Payment of term loan issuance costs		(875)		
Net cash provided by financing activities		93,723		95
Net (decrease) increase in cash and cash equivalents		(1,843)		15,652
Cash and cash equivalents — beginning of period		171,332		168,149
Cash and cash equivalents — end of period	\$	169,489	\$	183,801
Supplemental Disclosures Noncash Investing and Financing Activities:				
"Operating lease right-of-use asset" obtained in exchange for operating lease liability	\$	—	\$	741
"Interest expense" paid in cash	\$	1,094	\$	
Additions of "property and equipment, net" included within "accounts payable and other accrued liabilities"	\$	44	\$	_
Expensing of "operating lease right-of-use assets" upon lease termination	\$		\$	(38
	\$			
Stock issued for in-license agreements included within "research and development" expense	2		\$	5,494

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 focused on the development and commercialization of therapeutics, starting with eye care.

(b) Liquidity Risk Overview

The Company has no product sales and has accumulated losses and negative cash flows from operations since inception. The Company has funded its inception-to-date operations through equity capital raises, proceeds from its out-license agreement, and a draw on its credit facility. The Company estimates its existing capital resources will be sufficient to meet projected operating expense requirements for at least 12 months from the filing date of the accompanying Condensed Financial Statements in this Form 10-Q; accordingly, these financial statements have been prepared on a "going-concern" basis.

The Company's operations currently consist of its preclinical and clinical studies, corporate administration build-out to support its planned business growth, commercial leadership build-out in anticipation of the potential approval of TP-03 by the FDA in 2023 (see *Note 11*), and in/out-licensing activities. The Company faces the clinical, business, and liquidity risks that are typically associated with biopharma companies. It must significantly invest in and conduct research and development activities with inherently uncertain outcomes, recruit and retain skilled personnel (including executive management), and expand and defend its intellectual property rights.

Management expects the Company to continue to incur operating losses for the foreseeable future and may be required to raise additional capital to fund its ongoing operations. However, no assurance can be given as to whether financing will be available on terms acceptable to the Company, or at all. If the Company raises additional funds by issuing equity securities, its stockholders may experience significant dilution. The Company's credit facility imposes certain covenants that limit its ability to incur liens or secure additional debt financing, pay dividends, repurchase common stock, make certain investments, or engage in certain merger or asset sale transactions. Any new debt financing or additional equity raise may contain additional terms that are not favorable to the Company or its stockholders. The Company's potential inability to raise capital when needed could have a negative impact on its financial condition and ability to pursue planned business strategies. If the Company may also be required to sell or license its rights to product candidates in certain territories or indications that it would otherwise prefer to develop and commercialize on its own and/or enter into collaborations and other arrangements to address its liquidity needs which could materially and adversely affect its business and financial prospects, or even its ability to remain a going concern.

(c) Operating Segment

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

(d) 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 is required for other public companies that are not emerging growth companies.



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

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 generally accepted accounting principles ("GAAP") in the United States ("U.S.") for interim financial information and pursuant to Form 10-Q and with the rules and regulations 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 and should be read in conjunction with the audited financial statements and the related notes thereto in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 14, 2022.

The interim Condensed Balance Sheet as of September 30, 2022, the interim Condensed Statements of Operations and Comprehensive (Loss) Income, and the interim Condensed Statements of Stockholders' Equity for the three and nine months ended September 30, 2022 and 2021, and the interim Condensed Statements of Cash Flows for the nine months ended September 30, 2022 and 2021 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, 2021 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, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022 or any other interim or annual period.

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 estimates and assumptions involve judgments with respect to numerous factors that are difficult to forecast and may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption.

There have been no significant changes in the Company's significant accounting policies during the three and nine months ended September 30, 2022, as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 14, 2022, except as discussed below. 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, that are readily convertible into cash without penalty, with original maturities of three months or less from the purchase date.

(iii) Marketable Securities and Long-Term Investments

As of September 30, 2022, marketable securities consist of short term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities (see *Note 7*). Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities are classified as current assets on the accompanying Condensed Balance Sheets due to their highly liquid nature and availability for use in current operations.

Marketable securities are recorded at fair value with unrealized losses and gains reported as a component of "accumulated other comprehensive loss" within the Condensed Statements of Stockholders' Equity until realized. The Company periodically evaluates whether declines in fair values of its available-for-sale securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery



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

occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any available-forsale securities before recovery of its amortized cost basis. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, as well as interest and dividends, are included in interest income. Realized losses and gains as well as credit losses, if any, on marketable securities identified on a specific identification basis and are included in "other income (expense), net" on the accompanying Condensed Statement of Operations. The Company evaluated the underlying credit quality and credit ratings of the issuers during the period. To date, the Company has not identified any other than temporary declines in fair value of its investments and no credit losses have occurred or have been recorded. Interest earned on marketable securities is included in "interest income" within the accompanying Condensed Statement of Operations.

As of December 31, 2021, marketable securities consisted of holdings of LianBio common stock. These shares are reported within "long-term investments" on the accompanying Condensed Balance Sheet as of September 30, 2022, reflecting the intent to hold these shares for at least one year from the balance sheet date. These equity securities are designated as "available-for-sale" with associated gains or losses reported in "other income (expense), net" within the Condensed Statements of Operations and Comprehensive (Loss) Income for each reported period.

(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, cash equivalents and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

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, (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 the necessary approvals. If the Company is denied approval, approval is delayed, or the Company is unable to maintain approval for any product candidate, it could have a materially adverse impact on its business.

(v) Revenue Recognition for Out-License Arrangements

Overview

The Company currently has no product revenue. Reported revenue in the accompanying Statements of Operations and Comprehensive (Loss) Income is associated with one out-license agreement (the "China Out-License") that allows the third-party licensee to market the Company's TP-03 product candidate (representing "functional intellectual property") in the People's Republic of China, Hong Kong, Macau, and Taiwan (the "China territory") - 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 China Out-License was analyzed under GAAP to determine whether the promised goods or services are distinct, or in the alternative, 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.



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

The China Out-License includes the following forms of consideration: (i) non-refundable upfront license payments, (ii) equity securities and warrants, (iii) sales-based royalties, (iv) sales threshold milestones, (v) development milestone payments, and (vi) regulatory milestone payments. 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 respective 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, are as follows:

(1) *Upfront License Fees:* The Company determines whether non-refundable license fee consideration is recognized at the time of contract execution (i.e., when the license is transferred to the customer and the customer is able to use and benefit from the license) or over the actual (or implied) contractual period of the China 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. Upfront payments may require deferral of revenue recognition to a future period until the Company performs obligations under these arrangements.

(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 as these represent variable consideration. 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. Given the high degree of uncertainty around the occurrence of these events, the Company determines the milestone and other contingent amounts to be "constrained" until the uncertainty associated with these payments is resolved. 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, and 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) as these represent variable consideration. 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 deemed constrained for revenue recognition until achievement.

(4) *Royalties:* Under the "sales-or-usage-based royalty exception" the Company recognizes revenue based on the contractual percentage of the licensee's sale of products to its customers at the later of (i) the occurrence of the related product 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 arrangement.

(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 the out-licensing arrangement.

The Company re-evaluates the measure of progress to each performance obligation in each reporting period as uncertain events are resolved and other changes in circumstances occur. A "performance obligation" is a promise in a contract

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

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.

(vi) 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, preclinical and clinical trial expenses, manufacturing costs for drug products before FDA approval, and the costs of various research and development contractors. Expenses for pre-clinical studies and clinical trial activities that are performed by third parties on behalf of the Company are 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. These costs are in accordance with the agreements established with the contracted clinical research organizations and associated trial 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* $\delta(b)$) were evaluated and determined to represent "asset" acquisitions. Because these assets have not yet received regulatory approval and have no alternative future use, the purchase price for each was immediately recognized as "research and development" expense in the accompanying financial statements. 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 it becomes payable, provided there is no alternative future use in other research and development projects for its capitalization.

(vii) 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 for unvested awards in the same period of forfeiture.

The measurement of the fair value of stock option 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.

Management estimates the expected term of awarded stock options utilizing the "simplified method" for awards since the Company does not yet have sufficient exercise history since its November 2016 corporate formation and also lacks specific historical and implied stock volatility information. Accordingly, management estimates this expected volatility based on a designated peer-group of publicly-traded companies for a look-back period (from the date of grant) that corresponds 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 period that corresponds 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. 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.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

All stock-based compensation expense is reported in the accompanying Condensed 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.

(viii) Net (Loss) Income per Share

Basic net (loss) income per share is calculated by dividing the net (loss) income by the weighted-average number of shares of common stock outstanding for the period, without 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.

Due to a net loss for the three and nine months ended September 30, 2022, 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 this period.

(ix) 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 the short maturities for each. The Company's equity warrant holdings are carried at fair value based on unobservable market inputs (see *Note 7*).

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

The Company did not have any transfers of assets and liabilities between the levels of the fair value hierarchy during the years presented.

(x) Comprehensive (Loss) Income

Comprehensive (loss) income represents (i) net loss or income for the periods presented, and (ii) unrealized gains or losses on our reported available-for-sale debt securities.

(xi) Recently Issued or Effective Accounting Standards

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) Prepaid Expenses

"Prepaid expenses" consists of the following:

	September 30, 2022	December 31, 2021
Other prepaid expenses	\$ 3,430	\$ 2,832
Prepaid insurance	64	1,213
Prepaid expenses	\$ 3,494	\$ 4,045

(b) Other Receivables

"Other receivables" consists of the following:

	Septen	nber 30, 2022	I	December 31, 2021
PDUFA Fee reimbursement ⁽¹⁾	\$	3,117	\$	_
R&D payroll tax receivable		340		90
Clinical receivables		292		—
Interest receivable		198		2
Income tax receivable		48		—
Other receivables	\$	3,995	\$	92

(1) This amount represents the required FDA filing fee upon the Company's submission of its New Drug Application ("NDA") for TP-03 in the third quarter of 2022. This fee is expected to be refunded in full, based on the Company's status as a qualified "Small Business" as defined in the relevant Federal statute.

(c) Property and Equipment, Net

"Property and equipment, net" 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, 2022	December 31, 2021
Furniture and fixtures	\$ 632	\$ 596
Office equipment	197	84
Laboratory equipment	167	167
Leasehold improvements	403	129
Property and equipment, at cost	1,399	976
(Less): Accumulated depreciation and amortization	448	221
Property and equipment, net	\$ 951	\$ 755

Depreciation expense (included within "total operating expenses" in the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income) for the three months ended September 30, 2022 and 2021 was \$0.1 million and \$0.1 million, respectively, and for the nine months ended September 30, 2022 and 2021 was \$0.2 million and \$0.3 million, respectively.

(d) Other Assets

"Other assets" consists of the following:

	September	r 30, 2022	December	31, 2021
Deposits	\$	71	\$	71
Equity warrants issued by licensee (Note 7)		246		663
Other non-current assets		266		392
Other assets	\$	583	\$	1,126

(e) Accounts Payable and Other Accrued Liabilities

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

	September 30, 2022	December 31, 2021
Trade accounts payable and other	\$ 5,592	\$ 2,856
Operating lease liability, current	572	609
Accrued clinical studies	3,821	4,407
Contract liability	—	697
Accrued interest, current	182	—
Income taxes payable	14	55
Employee stock option pre-vesting exercise liability	—	56
Accounts payable and other accrued liabilities	\$ 10,181	\$ 8,680

(f) Other Long-Term Liabilities

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

	September 30, 2022	December 31, 2021
Operating lease liability, non-current	5 169	\$ 585
Lotilaner licensor liability	40	114
Other long-term liabilities	\$ 209	\$ 699



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

4. STOCKHOLDERS' EQUITY AND EQUITY INCENTIVE PLANS

Common Stock Outstanding and Reserves for Future Issuance

As of September 30, 2022, the Company had 26.7 million common shares issued and outstanding. As of December 31, 2021, the Company had both issued and outstanding shares of 20.7 million. Each share of common stock is entitled to one vote.

The Company's outstanding equity awards and shares reserved for future issuance under its 2020 and 2016 Equity Incentive Plans and 2020 Employee Stock Purchase Plan is summarized below:

	September 30, 2022	December 31, 2021
Common stock awards reserved for future issuance under 2020 and 2016 Equity Incentive Plans	8,482,877	9,266,200
Common stock awards reserved for future issuance under the 2020 Employee Stock Purchase Plan	2,682,601	2,493,488
Stock options issued and outstanding (unvested and vested) under 2020 and 2016 Equity Incentive Plans	3,839,077	2,759,830
Restricted stock units issued and outstanding (unvested) under 2020 Equity Incentive Plan	516,005	17,251
Total shares of common stock reserved	15,520,560	14,536,769

Follow-On Public Offering

In May 2022, the Company completed a follow-on public offering under its Shelf Registration Statement for an initial underwritten sale of 5.6 million shares of its common stock at a price of \$13.50 per share. The Company also granted the underwriters a 30-day option to purchase up to 840,000 additional shares of its common stock at the public offering price. In June 2022, the underwriters partially exercised this option and the Company's sale of additional 289,832 shares at \$13.50 per share was concurrently completed.

Total gross proceeds from this offering were \$79.5 million (before underwriting discounts, commissions and other estimated offering expenses), resulting in net proceeds of \$74.3 million.

5. STOCK-BASED COMPENSATION

Stock-Based Compensation Summary

Stock-based compensation expense for the three and nine months ended September 30, 2022 and 2021 was reported in the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income as follows:

	Three Months E	nded September 30,	Nine Months En	ded September 30,
	2022	2021	2022	2021
Research and development	\$ 1,015	\$ 544	\$ 2,677	\$ 1,315
General and administrative	2,568	1,575	7,112	4,961
Total stock-based compensation	\$ 3,583	\$ 2,119	\$ 9,789	\$ 6,276

6. NET (LOSS) INCOME PER SHARE

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

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

	Three Months Ended September 30,					Nine Months End	led S	ed September 30,		
		2022		2021		2022		2021		
Basic EPS										
Net (loss) income	\$	(22,511)	\$	(15,697)	\$	(48,492)	\$	1,024		
Less: undistributed income allocated to participating securities		—		—		—		7		
Net (loss) income available to common shareholders	\$	(22,511)	\$	(15,697)	\$	(48,492)	\$	1,017		
Basic weighted average shares outstanding		26,662,374		20,641,285		23,923,512		20,511,973		
Net (loss) income per share—basic	\$	(0.84)	\$	(0.76)	\$	(2.03)	\$	0.05		
Diluted EPS										
Net (loss) income	\$	(22,511)	\$	(15,697)	\$	(48,492)	\$	1,024		
Less: undistributed income reallocated to participating securities		—		—		—		7		
Net (loss) income available to common shareholders	\$	(22,511)	\$	(15,697)	\$	(48,492)	\$	1,017		
De la collecte de la construction l'activité de la construction de la		26 662 274		20 (41 205		22 022 512		20 511 072		
Basic weighted average shares outstanding		26,662,374		20,641,285		23,923,512		20,511,973		
Effect of dilutive securities:										
Common stock options								1,520,514		
Diluted weighted average shares outstanding		26,662,374		20,641,285		23,923,512		22,032,487		
Net (loss) income per share—diluted	\$	(0.84)	\$	(0.76)	\$	(2.03)	\$	0.05		

The following outstanding and potentially dilutive securities were excluded from the calculation of diluted net loss per share because their impact under the "treasury stock method" and "if-converted method" would have been anti-dilutive for each period presented:

	Three Months Ende	d September 30,	Nine Months Ende	led September 30,		
	2022	2021	2022	2021		
Stock options, unexercised-vested and unvested	3,839,077	2,663,356	3,839,077	902,981		
Stock options exercised prior to vesting- remaining unvested	_	43,149	—	43,149		
Restricted stock units-unvested	516,005	4,257	516,005	4,257		
Total	4,355,082	2,710,762	4,355,082	950,387		

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(ix)):



NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

	September 30, 2022 Fair Value Measurements								
		Level 1		Level 2		Level 3		Total	
ssets:									
Money market funds	\$	159,552	\$	—	\$	—	\$	159,552	
U.S. Treasury securities		34,482		_		—		34,482	
Commercial paper		_		27,377		—		27,377	
Corporate debt securities		_		5,161		—		5,161	
Common stock (LianBio shares included in "long-term investments")		157		—		—		157	
Equity warrants (for LianBio shares included in "other assets")		_		—		246		246	
Total assets measured at fair value	\$	194,191	\$	32,538	\$	246	\$	226,975	
			_		_				

	December 31, 2021 Fair Value Measurements									
	Level 1		Level 2		Level 3			Total		
Assets:										
Money market funds	\$	171,332	\$	_	\$	_	\$	171,332		
Common stock (LianBio shares included in "marketable securities")		483		_		_		483		
Equity warrants (for LianBio shares included in "other assets")		_		_		663		663		
Total assets measured at fair value	\$	171,815	\$	_	\$	663	\$	172,478		

Money Market Funds and U.S. Treasury Securities

Money market funds and U.S. Treasury securities have readily-available market prices in active markets that are publicly observable at the measurement date.

Commercial Paper and Corporate Debt Securities

Commercial paper and corporate debt securities were valued using third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value.

LianBio Common Stock and Equity Warrants

In March 2021, contemporaneous with the China Out-License transaction (see *Note 9*), the Company and LianBio (a pharmaceutical company focused on the Greater China and other Asian markets; NASDAQ: LIAN), executed a warrant agreement for the Company to purchase, in three tranches, a stated number of common shares in LianBio. The first two tranches are vested as of September 30, 2022 and the third warrant tranche will vest upon the achievement of a certain regulatory event; each has an exercise price at common stock par value.

In June 2021, one of these three warrant tranches was vested and then-converted to 78,373 shares of LianBio common stock, reported within "marketable securities" as of December 31, 2021, and within "long-term investments" as of September 30, 2022. LianBio common stock is classified within *Level 1* of the fair value hierarchy, given its publicly reported price on the NASDAQ Global Market.

In May 2022, the second warrant tranche vested, but has not yet been exercised. The second and third warrant tranche remain classified as *Level 3* in the fair value hierarchy as of September 30, 2022 and December 31, 2021 and are presented within "other assets" in the accompanying Condensed Balance Sheets (see *Note 3(d)*). The most significant assumptions used in the option pricing valuation model as of each balance sheet date to determine its fair value included: LianBio common stock volatility (based on the historical volatility of similar companies), the probability of regulatory milestone achievement for vesting, and the application of an assumed discount rate.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

The estimated fair value of these equity warrants will be remeasured each reporting period with adjustments reported within "other income (expense), net" on the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income, until exercised or expired, and is presented in these accompanying financial statements as follows:

	equity warrants Note 3(d))
Fair value as of December 31, 2021	\$ 663
Revaluation of equity warrant value in "other income (expense), net" within the Condensed Statement of Operations	(245)
Fair value as of March 31, 2022	\$ 418
Recognition of equity warrant value in "total revenues" within the Condensed Statement of Operations	 103
Revaluation of equity warrant value in "other income (expense), net" within the Condensed Statement of Operations	(257)
Fair value as of June 30, 2022	\$ 264
Revaluation of equity warrant value in "other income (expense), net" within the Condensed Statement of Operations for the three months ended September 30, 2022	(18)
Fair value as of September 30, 2022	\$ 246

	equity warrants <i>Note 3(d)</i>)
Fair value as of December 31, 2020	\$ _
Initial fair value estimate of equity warrant value in "total revenues"	1,233
Fair value as of March 31, 2021	\$ 1,233
Recognition of equity warrant value in "total revenues" within the Condensed Statement of Operations	719
Revaluation of equity warrant value in "other income (expense), net" within the Condensed Statement of Operations	(876)
Fair value as of June 30, 2021	\$ 1,076
Recognition of equity warrant value in "total revenues" within the Condensed Statement of Operations for the three months ended September 30, 2021	 771
Revaluation of equity warrant value in "other income (expense), 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

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

The following table summarizes the estimated value of the Company's cash, cash equivalents, marketable securities, and equity securities, including the gross unrealized holding gains and losses:

	September 30, 2022								
		Amortized cost		Unrealized gains		Unrealized losses		Estimated fair value	
Cash and cash equivalents:									
Money market funds	\$	159,552	\$	—	\$	_	\$	159,552	
U.S. Treasury securities		3,978		1		—		3,979	
Commercial paper		5,958		—		_		5,958	
Total cash and cash equivalents	\$	169,488	\$	1	\$	—	\$	169,489	
			_				_		
Marketable securities:									
U.S. Treasury securities	\$	30,511	\$	7	\$	(15)	\$	30,503	
Commercial paper		21,419		—		—		21,419	
Corporate debt securities		5,164		—		(3)		5,161	
Total marketable securities	\$	57,094	\$	7	\$	(18)	\$	57,083	
Long-term investments:									
Common stock in LianBio	\$	483	\$	_	\$	(326)	\$	157	
Total long-term investments	\$	483	\$		\$	(326)	\$	157	

	December 31, 2021								
	 Amortized cost		Unrealized gains		Unrealized losses	E	stimated fair value		
Cash and cash equivalents:									
Money market funds	\$ 171,332	\$	_	\$	_	\$	171,332		
Total cash and cash equivalents	\$ 171,332	\$	_	\$	_	\$	171,332		
Marketable securities:									
Common stock in LianBio	\$ 1.074	\$	_	\$	(591)	\$	483		

1,074 \$

(591) \$

483

S

As of September 30, 2022, all available-for-sale debt securities have a maturity of 12 months or less with gross unrealized losses in a continuous loss position for less than one year.

\$

8. COMMITMENTS & CONTINGENCIES

Total marketable securities

(a) Facility Leases

Overview

In the ordinary course of business, the Company enters into lease agreements with unaffiliated third parties for its facilities and office equipment. As of September 30, 2022 and December 31, 2021, the Company had four active leases in Irvine, California for adjacent office and laboratory suites that each expire on January 31, 2024.

The Company's operating leases have fixed annual rent amounts, payable monthly (operating lease costs), and our facility leases require payments for real estate taxes, insurance costs, and common area maintenance (variable lease costs). The variable lease costs are expensed as incurred and excluded from the reported lease asset and liability amounts presented in the accompanying Condensed Balance Sheets, as summarized in the below table. During the year ended December 31, 2021, and the nine months ended September 30, 2022, the Company had no sublease arrangements with it as lessor.

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

Financial Reporting Captions

The below table summarizes the lease asset and liability accounts presented on the accompanying Condensed Balance Sheets:

Operating Leases	Condensed Balance Sheet Caption September 30, 2022		Decem	ber 31, 2021	
Operating lease right-of-use assets- non-current	Operating lease right-of-use assets	\$	696	\$	1,074
Operating lease liability— current	Accounts payable and other accrued liabilities	\$	572	\$	609
Operating lease liability-non-current	Other long-term liabilities		169		585
Total lease liabilities		\$	741	\$	1,194

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 "operating lease right-of-use assets" are amortized over each lease term on a straight-line basis and is allocated to "research and development" and "general and administrative" expenses in the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income. The below table summarizes the components of total lease expense:

	Т	Three Months Ended September 30,			Nine Months Ended September 30,			
		2022		2021		2022		2021
Operating lease cost	\$	142	\$	118	\$	427	\$	238
Variable lease cost		67		33		168		104
Short-term lease cost (lease with 12 month term or less)				21				116
Total lease expense	\$	209	\$	172	\$	595	\$	458

Weighted-Average Remaining Lease Term and Applied Discount Rate

As of September 30, 2022, the Company's facility leases had a weighted average remaining lease term of 1 year, 4 months. The weightedaverage estimated incremental borrowing rate of 10% was utilized to present value future minimum lease payments since an implicit interest rate in each at-market lease agreement was not 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	S	eptember 30, 2022
2022 (remaining three months, net of landlord credits)	\$	—
2023		736
2024		66
2025		—
2026		—
Total future lease payments, undiscounted	\$	802
(Less): Imputed interest		(61)
Present value of operating lease payments	\$	741

(b) In-License Agreements for Lotilaner

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

January 2019 Agreement for Skin and Eye Disease or Conditions in Humans

In January 2019, the Company entered into a 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, as amended in June 2022 (the "Eye and Derm Elanco 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 Eye and Derm Elanco Agreement in January 2019, and also made a required \$1.0 million clinical milestone payment in September 2020, associated with the first 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 in "research and development" expense in the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income for the three months ended June 30, 2021. As part of the China Out-License discussed in *Note 9*, the Company made a contractual payment in the amount of \$2.5 million to Elanco following the receipt of \$25 million of initial proceeds from LianBio during the second quarter of 2021. In June 2022, the Company made a contractual prepayment of \$1.5 million that can be applied towards any milestones that become due under the Eye and Derm Elanco Agreement and/or the Company's in-license agreement with Elanco, granting it 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), as amended in June 2022 (the "All Human Uses Elanco Agreement"). This prepayment is included within "prepaid expenses" on the accompanying Condensed Balance Sheet as of September 30, 2022.

The Company may make further cash payments to Elanco under the Eye and Derm Elanco Agreement upon 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, 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 be obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which it achieved applicable regulatory approval prior to sublicense execution.

September 2020 Agreement for All Other Diseases or Conditions in Humans

In September 2020, the Company executed the All Human Uses Elanco Agreement with Elanco. In September 2020, the Company issued Elanco 222,460 shares of its common stock at the execution of the All Human Uses Elanco Agreement with an estimated fair value of \$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 cash payments to Elanco under the All Human Uses Elanco 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 product 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 it achieved applicable regulatory approval prior to sublicense execution.

In March 2021, the Company entered into the China Out-License with LianBio (see *Note 9*) that required it to grant Elanco an additional fixed 187,500 shares of its common stock that otherwise would have been issuable no later than the 18-month anniversary of the All Human Uses Elanco Agreement for its continued license exclusivity. These issued shares were valued at \$5.5 million, based on the Company's stock closing price of \$29.30 per share on the date this 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 eight of its 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.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years) (Unaudited)

(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 vary, and in certain cases, are indefinite and do 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.

9. OUT-LICENSE AGREEMENT

Out-License of TP-03 Commercial Rights in the China Territory in March 2021

On March 26, 2021, the Company entered into The China Out-License with LianBio for its exclusive development and commercialization rights of TP-03 (lotilaner ophthalmic solution, 0.25%) in the China Territory for the treatment of Demodex blepharitis and Meibomian Gland Disease. LianBio is contractually responsible for all clinical development and commercialization activities and costs within the China Territory.

Through September 30, 2022, the Company received payments from LianBio totaling \$70.0 million, comprised of initial consideration of \$25.0 million and \$45.0 million for the achievement of three clinical development milestones.

The Company is eligible to receive further consideration from LianBio upon the achievement of additional events, including: (i) TP-03 clinical development and regulatory milestones (China-based) of up to \$30.0 million (\$10 million of which was achieved in November 2022 - see *Note 11*), (ii) TP-03 drug supply agreement milestone of \$5.0 million, (iii) TP-03 sales-based milestones for the China Territory of up to \$100 million, (iv) tiered mid-to-high-teen royalties for China Territory TP-03 product sales, and (v) vesting of a LianBio equity warrant upon China regulatory milestone achievement.

For the nine months ended September 30, 2022 and the three and nine months ended 2021, the Company reported "license fees" and "collaboration revenue" in the accompanying Condensed Statements of Operations and Comprehensive (Loss) Income, in accordance with the revenue recognition accounting policy described in *Note 2(vii)*. Reported revenue in each presented period relates to the satisfaction performance obligations relating to (i) the transfer of TP-03 license rights in the China Territory to LianBio and (ii) the completion of U.S. clinical activities and then providing LianBio with the related data to supplement its local pivotal trial package for TP-03 in the treatment of Demodex blepharitis.

10. CREDIT FACILITY AGREEMENT

On February 2, 2022, the Company executed the Credit Facility with Hercules and SVB that expires on February 2, 2027. The Credit Facility provides an aggregate principal amount of up to \$175.0 million with tranched availability as follows: \$40.0 million at its execution (to-date, \$20.0 million drawn February 2022), \$25.0 million upon submission of the NDA with the FDA for TP-03 (available with NDA submission announced in September 2022), \$35.0 million upon FDA approval of TP-03, \$50.0 million upon achievement of product net revenue thresholds, and \$25.0 million upon lender approval.

Each of these tranches may be drawn down in \$5.0 million increments at the Company's election. The Credit Facility requires interest-only payments through February 1, 2026, followed by 12 months of principal amortization, unless extended for one year to its maturity, upon meeting certain contractual conditions. All unpaid amounts under the Credit Facility become due on its February 2, 2027 expiry.

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

Principal draws accrue interest on the outstanding principal balance at a floating interest rate per annum equal to the *greater of* either (i) The Wall Street Journal ("WSJ") prime rate *plus* 5.20% or (ii) 8.45%. At the execution date of the Credit Facility, the WSJ prime rate was 3.25% and further increased during 2022, reaching 6.25% as of September 30, 2022.

The Company is required to pay a specified fee upon the *earlier of* (i) February 2, 2027 or (ii) the date the Company prepays, in full or in part, the outstanding principal balance of the Credit Facility ("End of Term Charge"). The current End of Term Charge of \$1.0 million was derived at the execution of the Credit Facility by *multiplying* 4.75% by the \$20.0 million drawn at closing and is accreted to "interest expense" through maturity.

As of September 30, 2022, the carrying value of the Credit Facility (reported as "term loan, net" on the accompanying Condensed Balance Sheets) consisted of \$20.0 million principal outstanding *less* legal and administrative issuance costs of approximately \$0.9 million that were recorded as a "contra-liability" to "term loan, net" and will continue to be accreted to "interest expense" using the *effective interest method* during its term. As of December 31, 2021 the Company had no outstanding debt.

The effective interest rate (i.e., coupon rate and other applicable fees) for the full term of the Credit Facility was 12.37%, as calculated September 30, 2022 with the latest coupon interest rate. During the three and nine months ended September 30, 2022, the Company recognized "interest expense" on its Condensed Statement of Operations and Comprehensive (Loss) Income in connection with the Credit Facility as follows:

	Three Months Ended September 30, 2022			Nine Months Ended September 30, 2022	
Interest expense for term loan	\$	539	\$	1,275	
Accretion of end of term charge		48		127	
Amortization of debt issuance costs		46		105	
Total interest expense related to term loan	\$	633	\$	1,507	

The principal balance of this Credit Facility and related accretion and amortization as of September 30, 2022 is reported on a combined basis as "term loan, net" on the accompanying Condensed Balance Sheet as follows:

	September 30, 2022	
Term loan, gross (amount drawn)	\$ 20,000	
Debt issuance costs (legal and other administrative fees)	(875)	
Accretion of end of term charge	127	
Accumulated amortization of debt issuance costs	104	
Term loan, net	\$ 19,356	



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

11. SUBSEQUENT EVENTS

China Out-License Milestone Achievement

On November 1, 2022, LianBio announced the dosing of their first patient in the Phase 3 LIBRA clinical trial of TP-03 in Chinese patients with Demodex blepharitis; the Company is entitled to receive a contractual milestone payment of \$10 million from this licensee.

TP-03 PDUFA Date: August 25, 2023

On November 9, 2022, the Company announced the acceptance of its NDA by the FDA for TP-03 for the treatment of Demodex blepharitis with a Prescription Drug User Fee Act (PDUFA) decision date of August 25, 2023.

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, 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. Factors that may cause actual results to differ from expected results, include, among others:

- 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;
- 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 ("U.S.") 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;
- 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 U.S. 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;



- 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 Initial Public Offering ("IPO") and Follow-on Public Offering (defined below).

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and growth prospects, and these forward-looking statements are not guarantees of future performance or development. 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 focused on the development and commercialization of therapeutics, starting with eye care. Our lead product candidate, TP-03 (lotilaner ophthalmic solution, 0.25%), is a novel investigational eye drop to treat 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 an ophthalmic lid margin disease characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes, which are pathognomonic for Demodex blepharitis. Poorly controlled and progressive blepharitis can lead to corneal damage over time and, in extreme cases, blindness. There are an estimated 25 million people in the U.S. who suffer from Demodex blepharitis.

We designed TP-03 to target and eradicate the root cause of Demodex blepharitis — Demodex mite infestation. The active pharmaceutical ingredient ("API") of TP-03, lotilaner, paralyzes and eradicates mites and other parasites through the inhibition of parasite-specific gamma-aminobutyric acid-gated chloride ("GABA-Cl") channels.

To date, we have completed six clinical trials that include four Phase 2 trials, the Phase 2b/3 Saturn-1 trial, and the Phase 3 Saturn-2 trial for TP-03 in Demodex blepharitis. Each of these trials for TP-03 met their primary, secondary and/or exploratory endpoints, with the drug well tolerated. On November 9, 2022, we announced the New Drug Application ("NDA") for TP-03 for the treatment of Demodex blepharitis was accepted by the U.S. Food and Drug Administration ("FDA"). We believe TP-03 has the potential to be the first therapeutic approved by the FDA and become the definitive standard of care for the treatment of Demodex blepharitis.

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. We are developing product candidates to address targeted diseases with high unmet medical needs, which currently include TP-03 for the potential treatment of MGD, TP-04 for the potential treatment of rosacea, and TP-05 for potential Lyme disease prophylaxis and community malaria reduction.

Recent Business and Clinical Highlights

TP-03 Demodex Blepharitis, NDA Filing and PDUFA date: On November 9, 2022, we announced the acceptance of our NDA by the FDA for TP-03 for the treatment of Demodex blepharitis, with a stated Prescription Drug User Fee Act (PDUFA) decision date of August 25, 2023.

In May 2022, we announced positive topline results of Saturn-2, our second and final TP-03 pivotal trial. Saturn-2 enrolled 412 adults having, among other things, more than 10 collarettes per lid and at least mild lid erythema. All pre-specified primary and secondary endpoints were met, TP-03 was well tolerated and complete resolution of Demodex blepharitis was demonstrated in patients treated with TP-03 (lotilaner ophthalmic solution, 0.25%).

Primary Endpoint:

- 56% of patients on TP-03 achieved complete collarette cure, defined as 0-2 collarettes per lid at day 43, compared to 13% on vehicle (p<0.0001).
 - 89% of patients on TP-03 achieved a clinically meaningful collarette cure, defined as 0-10 collarettes per lid at day 43 compared to 33% of those on vehicle (p<0.0001).

Secondary Endpoints:

- 52% of patients on TP-03 achieved mite eradication defined as zero mites per lash at day 43, compared to 15% on vehicle (p<0.0001).
- 31% of patients on TP-03 compared to 9% of patients on vehicle (p<0.0001) achieved complete lid erythema cure at day 43.
- 19% of patients on TP-03 achieved a complete composite cure, based on achieving both complete collarette cure and complete lid erythema cure, compared to 4% on vehicle (p<0.0001) at day 43.

Safety Profile:

- Consistent with Saturn-1, Saturn-2 demonstrated that TP-03 was well tolerated with a safety profile similar to the vehicle group.
 - 91% 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.

<u>TP-03 Meibomian Gland Disease, Phase 2a Trial, Ersa</u>: On August 5, 2022, we announced the enrollment of our first patient in the Phase 2a Ersa clinical trial studying TP-03 for the treatment of MGD.

<u>TP-05 Lyme Disease Phase 1 Trial, Callisto</u>: We advanced 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 second half of 2022. The Callisto trial is 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. We also expect to initiate a Phase 2a study in Lyme disease prevention in the coming weeks.

We believe TP-05 is currently the only non-vaccine, oral tablet, 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.

TP-03 China Territory Out-License: In March 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"). In November 2022, LianBio announced that they initiated dosing of their first patient in the TP-03 Phase 3 LIBRA pivotal trial in Chinese patients for the treatment of Demodex blepharitis to support regulatory approval in China.

To date, we have received contractual cash proceeds from LianBio of \$70.0 million, representing initial consideration of \$25.0 million and \$45.0 million for the achievement of three clinical development milestones. We also received equity in LianBio as part of this China Out-License, a portion of which remains subject to a China-based regulatory vesting provision.

We are further eligible to receive:

- Drug supply agreement execution milestone of \$5.0 million (expected by the first quarter of 2023)
- China-based clinical and regulatory milestones totaling \$30.0 million (\$10.0 million achieved in November 2022 with the initiation of a Phase 3 pivotal trial in China and expected cash receipt in December 2022)
- Sales threshold milestones in the China Territory totaling \$100.0 million; and
- Tiered mid-to-high teen royalties on the net product sales of TP-03 within the China Territory

<u>Credit Facility with Hercules Capital and Silicon Valley Bank</u>: On February 2, 2022, we executed a loan and security agreement with Hercules Capital and Silicon Valley Bank (the "Credit Facility). This \$175.0 million Credit Facility has tranched availability as follows:

- \$40.0 million at closing (\$20 million drawn in February 2022 and \$20 million remaining available);
- \$25.0 million upon NDA submission of TP-03 (available with our NDA submission announced in September 2022);
- \$35.0 million upon FDA approval of TP-03;
- \$50.0 million upon achievement of certain quarterly revenue thresholds; and
- \$25.0 million available with lender approval.

Capital draws are at our election and are in \$5.0 million increments. This Credit Facility includes a four-year interest only period and is extendable to five years upon meeting certain conditions that we expect to achieve.

Follow-On Public Offering: In May 2022, we completed a follow-on public offering under our effective Form S-3 shelf registration statement through an initial underwritten sale of 5.6 million shares of common stock at a price of \$13.50 per share (the "Follow-On Public Offering"). We also granted the underwritters a 30-day option to purchase up to 840,000 additional shares of common stock at the public offering price, less discounts and commissions. In June 2022, the underwritters partially exercised this option by purchasing an additional 289,832 shares of common stock at \$13.50 per share.

After giving effect to the exercise of the underwriters' option, the total number of shares of our common stock sold in the Follow-On Public Offering was 5,889,832 shares which resulted in total gross proceeds of \$79.5 million before underwriting discounts, commissions and other estimated offering expenses for total net proceeds of \$74.3 million.

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 issuance of common stock in our IPO and Follow-On Public Offering, cash proceeds from our China Out-License, and draw downs on our Credit Facility.

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, increasing operating losses for the foreseeable future. Our net loss was \$22.5 million and \$15.7 million for the three months ended September 30, 2022 and 2021, respectively. 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. We anticipate that our operating expenses will increase significantly as we:

- seek regulatory approvals for TP-03 and other product candidates that successfully complete clinical development, if any;
- advance the clinical development of TP-03 for the potential treatment of MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction;
- establish our own sales force in the U.S. to commercialize TP-03 upon regulatory approval and our other products for which we obtain such approvals;
- 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 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 and achieve profitability, 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 forecast 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.

We do not yet have revenue from product sales. Our reported revenue within "license fees" and "collaboration revenue" is from our China Out-License; we expect to report additional revenue under these captions in future periods (see *Note 9*).

As of September 30, 2022, our aggregate cash, cash equivalents and marketable securities was \$226.6 million – see the section below titled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources" for our liquidity discussion.

Impact of the COVID-19 Pandemic on our Operations

Efforts to contain the spread of COVID-19 in the U.S. (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. Various of these orders and restrictions have expired, but there is no assurance they will not be reinstated.

We have been 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. 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. While the pandemic has begun to subside, the ultimate effect from this pandemic on our development timelines for TP-03 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, 2021, filed with the SEC on March 14, 2022 and in this Quarterly Report, for a further discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations:

	2022 2021 (in thousands)			Change	
Revenues:					
License fees	\$	—	\$ 708	\$ (708)	
Collaboration revenue			532	(532)	
Total revenues		_	1,240	(1,240)	
Operating expenses:					
Cost of license fees and collaboration revenue		—	65	(65)	
Research and development		10,912	10,209	703	
General and administrative		11,994	6,671	5,323	
Total operating expenses		22,906	16,945	5,961	
Loss from operations before other income (expense) and income taxes		(22,906)	(15,705)	(7,201)	
Other income (expense):					
Interest income		1,061	8	1,053	
Interest expense		(633)	_	(633)	
Other (expense) income, net		(7)	5	(12)	
Unrealized loss on equity investments		(13)	—	(13)	
Change in fair value of equity warrants issued by licensee		(18)	(346)	328	
Total other income (expense), net		390	(333)	723	
Benefit for income taxes		5	341	(336)	
Net loss	\$	(22,511)	\$ (15,697)	\$ (6,814)	

License Fees and Collaboration Revenue

For the three months ended September 30, 2022, we had no reported license fees and collaboration revenue under the China Out-License (see *Note 9*), as there were no contractual milestones achieved or allocated in the current year period. In the prior year period, license fees and collaboration revenue was \$1.2 million, which was attributable to the portion of the contractual milestones that were fully or partially complete by September 30, 2021. These allocated amounts respectively represent the satisfaction of the transfer of license rights to LianBio and the partial completion of clinical-related "performance obligations".

We will recognize additional "license fees" and "collaboration revenue" to the extent other events occur, specifically related to (i) milestone achievement of a drug supply agreement execution, (ii) milestone achievement of clinical and regulatory events in the China Territory (see *Note 11*), and (iii) royalties and milestones from our licensee's product sales 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. This amount relates to our contractual payment obligations to our lotilaner licensor, in proportion to our recognized "license fee" and "collaboration revenue" in the same period.

Research and Development Expenses

Research and development expenses increased by \$0.7 million for the three months ended September 30, 2022, as compared to the prior year period. This increase was primarily due to (i) \$2.1 million of increased payroll and personnel-related costs (including stock-based compensation) for 23 employee additions period over period to drive our product development initiatives and (ii) \$1.3 million of increased regulatory and consulting costs to prepare for potential TP-03 drug commercialization. These increases were partially offset by \$2.6 million of decreased clinical and preclinical study costs, primarily related to the completion of our Saturn-2 clinical trial in the first half of 2022.

General and Administrative Expenses

General and administrative expenses increased by \$5.3 million for the three months ended September 30, 2022, as compared to the prior year period. The increase was primarily due to (i) \$3.1 million of increased payroll and personnel-related costs (including stock-based compensation) for 19 corporate employee additions, period over period, to support our business growth and commercial leadership hires for readiness of our anticipated commercial launch of TP-03 in the second half of 2023, and (ii) \$2.3 million of increased marketing-related costs associated with the preparation of our potential TP-03 commercial launch. We expect sales and marketing headcount and associated vendor spend to meaningfully ramp during 2023 as part of our TP-03 commercial launch-related activities.

Other Income (Expense), Net

Other income (expense), net increased by \$0.7 million primarily due to (i) \$1.1 million of interest income earned on our cash, cash equivalents and marketable securities, (ii) \$0.6 million of interest expense on the Credit Facility executed in February 2022, and (iii) \$0.3 million change in estimated fair value of the LianBio equity warrants we received as part of our China Out-License in March 2021.

Benefit for Income Taxes

We maintain a valuation allowance against our net deferred tax assets as of September 30, 2022 and 2021 due to the uncertainty that such assets will be realized. We evaluate the recoverability of our deferred tax assets on at least an annual basis. For the three months ended September 30, 2022, we recorded a nominal income tax benefit due to the losses we incurred in that period.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations:

	Nine Months End			
	2022 2021		Change	
		(in thousands)		
Revenues:				
License fees	\$ 13,893	\$ 53,067	\$ (39,174)	
Collaboration revenue	1,923	3,622	(1,699)	
Total revenues	15,816	56,689	(40,873)	
Operating expenses:				
Cost of license fees and collaboration revenue	555	2,099	(1,544)	
Research and development	32,596	33,674	(1,078)	
General and administrative	30,316	18,625	11,691	
Total operating expenses	63,467	54,398	9,069	
(Loss) income from operations before other (expense) income and income taxes	(47,651)	2,291	(49,942)	
Other (expense) income:				
Interest income	1,372	24	1,348	
Interest expense	(1,507)	_	(1,507)	
Other income (expense), net	136	(68)	204	
Unrealized loss on equity investments	(326)	—	(326)	
Change in fair value of equity warrants issued by licensee	(520)	(1,222)	702	
Total other expense, net	(845)	(1,266)	421	
Benefit (provision) for income taxes	4	(1)	5	
Net (loss) income	\$ (48,492)	\$ 1,024	\$ (49,516)	

License Fees and Collaboration Revenue

License fees and collaboration revenue was \$15.8 million for the nine months ended September 30, 2022, attributable to contractual milestones under the China Out-License (see *Note 9*), to the extent achieved by September 30, 2022. These allocated amounts respectively represent the satisfaction of the transfer of license rights to LianBio and the completion of clinical-related "performance obligations".

Prior year period revenue was \$56.7 million, attributable to the portion of the contractual milestones that were fully or partially complete by September 30, 2021. These allocated amounts represent the satisfaction of the transfer of license rights to LianBio and the partial completion of clinical-related "performance obligations".

We will recognize additional "license fees" and "collaboration revenue" to the extent other events occur, specifically related to (i) milestone achievement of a drug supply agreement execution, (ii) milestone achievement of clinical and regulatory events in the China Territory (see *Note 11*), and (iii) royalties and milestones from our licensee's product sales of TP-03 in the China Territory.

Cost of License Fees and Collaboration Revenue

Cost of license fees and collaboration revenue decreased by \$1.5 million for the nine months ended September 30, 2022, as compared to the prior year period. These amounts relate to our contractual payment obligations to our Lotilaner licensor, in proportion to our recognized "license fee" and "collaboration revenue" in the same period.

Research and Development Expenses

Research and development expenses decreased by \$1.1 million for the nine months ended September 30, 2022, as compared to the prior year period. The decrease was primarily due to non-recurring costs in the prior year period including (i) a contractual payment in March 2021 through the issuance of 187,500 shares of our common stock (then valued at \$5.5 million to extend the period of our September 2020 in-license agreement), and (ii) a contractual payment of \$2 million under our January 2019 in-license for the commencement of our Saturn-2 trial. Additionally, clinical trial costs decreased \$1.5 million, primarily related to the completion of our Saturn-2 trial during the first half of 2022.

These decreases were partially offset by (i) \$4.7 million of increased payroll and personnel-related costs (including stock-based compensation), for 23 employee additions period-over-period to drive our product development initiatives, (ii) \$0.6 million of increased preclinical study costs, (iii) \$2.3 million of increased regulatory and consulting costs in preparation of our NDA filing for TP-03, and (iv) \$0.2 million of increased product manufacturing and formulation costs.

General and Administrative Expenses

General and administrative expenses increased by \$11.7 million for the nine months ended September 30, 2022, as compared to the prior year period. The increase was primarily due to (i) \$7.4 million of increased payroll and personnel-related costs (including stock-based compensation) for 19 corporate employee additions period-over-period to support our business growth and commercial leadership hires for readiness of our anticipated commercial launch of TP-03 in the second half of 2023, and (ii) \$4.4 million of increased marketing-related costs for TP-03. We expect sales and marketing headcount and associated vendor spend to meaningfully ramp during 2023 as part of our TP-03 commercial launch-related activities.

Other Expense, Net

Other expense, net decreased by \$0.4 million primarily due to (i) \$1.3 million of increased interest income earned on our cash, cash equivalents and marketable securities, (ii) \$0.7 million change in estimated fair value of the LianBio equity warrants we received as part of our China Out-License in March 2021, and (iii) \$0.2 million increase related to miscellaneous items. These decreases to "other expense, net" were partially offset by (i) \$1.5 million of interest expense on the Credit Facility executed in February 2022, and (ii) \$0.3 million of unrealized losses reported on our LianBio common stock.

Benefit (Provision) for Income Taxes

We maintain a valuation allowance against our net deferred tax assets as of September 30, 2022 and 2021 due to the uncertainty that such assets will be realized. We evaluate the recoverability of our deferred tax assets on at least an annual basis. For the nine months ended September 30, 2022, we recorded a nominal income tax benefit due to the losses we incurred in that period.

Liquidity and Capital Resources

Sources of Liquidity

Overview

As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$226.6 million. Since our inception, our operations have been substantially financed by cash proceeds of private placements of preferred stock, IPO proceeds, China Out-License consideration, Credit Facility draw, and the Follow-On Public Offering.

IPO - October 2020

In connection with our October 2020 IPO, we sold 6,325,000 shares of our common stock (inclusive of the full exercise of the underwriters' option to purchase 825,000 shares of common stock). After deducting underwriting discounts, commissions and other related expenses, our IPO proceeds were \$91.7 million.

Follow-On Public Offering - completed May 2022

In May 2022, we completed the Follow-On Public Offering. We also granted the underwriters a 30-day option to purchase up to 840,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions. In June 2022, the underwriters partially exercised their option to purchase an additional 289,832 shares of common stock at the offering price of \$13.50 per share, before underwriting discounts and commissions. After giving effect to the exercise of the underwriters' option, we sold 5,889,832 shares for total gross proceeds of \$79.5 million, before underwriting discounts, commissions and other estimated offering expenses for total net proceeds received in the second quarter of 2022 of \$74.3 million.

China Out-License - executed March 2021

As of September 30, 2022, we have received \$70.0 million of total proceeds in connection with our China Out-License, inclusive of 2022 milestone receipts of \$15.0 million in June for the achievement of the Saturn-2 topline primary endpoint (see *Note 9*). We expect to receive an additional \$10.0 million from the achievement of a China-based clinical development milestone (achieved in November 2022) and \$5.0 million from a supply agreement milestone (expected during the first quarter of 2023), resulting in expected aggregate milestone receipts through the first quarter of 2023 of \$85.0 million. The remaining \$120.0 million of available milestones under this arrangement will potentially be received upon future regulatory and sales achievements all within the China Territory.

Credit Facility - executed February 2022

In February 2022, we drew \$20.0 million from our Credit Facility with Hercules Capital and Silicon Valley Bank. This \$175.0 million Credit Facility has tranched availability as follows:

- \$40.0 million at closing (\$20 million drawn and \$20.0 million available);
- \$25.0 million upon NDA submission of TP-03 (available with NDA submission announced in September 2022);
- \$35.0 million upon FDA approval of TP-03;
- \$50.0 million upon achievement of certain quarterly revenue thresholds; and
- \$25.0 million available with lender approval.

Capital draws are at our election and are in \$5.0 million increments. The Credit Facility includes four-year period of interest-only payments and is extendable for a fifth year to February 2027 maturity, upon our expected achievement of required conditions. We currently have no other financing commitments, such as lines of credit or guarantees.

Funding Requirements

Cash Runway

Our operating expenditures currently consist of research and development costs (including activities within our preclinical, clinical, regulatory, and drug manufacturing initiatives) and general and administrative costs. 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, cash equivalents and marketable securities of \$226.6 million as of September 30, 2022 is sufficient to fund our current and planned operations for at least the next twelve months from the date of this filing on Form 10-Q. These funds in combination with additional expected milestone proceeds from our China Out-License of \$30.0 million through 2024 (\$10.0 million of which is expected to be received in December 2022 and \$5.0 million during the first quarter of



2023), are expected to provide sufficient capital resources to fund our planned pipeline development, operating expenses, and capital expenditure requirements at least into 2026.

Our cash runway estimate on revenue and expense assumptions may require future adjustments. Accordingly, we may require additional capital resources earlier than we currently expect. We also anticipate having at least \$80.0 million of available capital from our Credit Facility through December 2023 (excluding our \$20.0 million draw in February 2022) and an additional \$75.0 million of availability through maturity in February 2027.

Shelf Registration Statement

On November 1, 2021, we filed a shelf registration statement on Form S-3 that was declared effective by the SEC on November 5, 2021 (the "Shelf Registration Statement"), which permitted 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. We have approximately \$220 million remaining under our Shelf Registration Statement, after giving effect to the Follow-On Public Offering (but inclusive of the sales agreement prospectus described below). 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. We completed the Follow-On Public Offering under this Shelf Registration Statement.

Also, as part of this Shelf Registration Statement, we concurrently filed a sales agreement prospectus covering the sale of up to \$100.0 million of our common stock pursuant to an Open Market Sale AgreementTM (the "ATM Agreement") with Jefferies LLC. Through the date of this Form 10-Q filing, we have not sold any shares of our common stock under the ATM Agreement.

Other Liquidity Risks

To date, we have not generated any product sales, though we have recognized revenue and cash receipts from our China Out-License. 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 our product candidates 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 as we prepare for the potential launch of TP-03. We may also encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business.

We may 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 and timing 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 and availability under our Credit Facility;
- the extent to which we acquire or in-license other product candidates and technologies;

- the costs of preparing, filing and prosecuting patent 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 Statements of Cash Flows

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

	Nine Months Ended September 30,			
	 2022	2021		
	 (in thousands)			
Net cash (used in) provided by:				
Operating activities	\$ (38,156)	\$ 15,869		
Investing activities	(57,410)	(312)		
Financing activities	93,723	95		
Net (decrease) increase in cash and cash equivalents	\$ (1,843)	\$ 15,652		

Net Cash (Used in) Provided by Operating Activities

Net cash used in operating activities was \$38.2 million for the nine months ended September 30, 2022. In this period, we recognized \$15.8 million of "license fees" and "collaboration revenue" in connection with our China Out-License, of which we received \$15.0 million in June 2022. Our cash payments to vendors totaled \$38.4 million and payroll-related cash payments (inclusive of 2021 bonus payouts) totaled \$14.0 million. In addition, we made contractual payments of \$1.8 million to our lotilaner licensor as required by our in-license agreements.

Net cash provided by operating activities was \$15.9 million for the nine months ended September 30, 2021. In this period we recognized \$56.7 million of "license fees" and "collaboration revenue" from the China Out-License transaction, of which we received \$55.0 million during that period. Our cash payments to vendors totaled \$32.6 million and payroll-related cash payments (inclusive of 2021 bonus payouts) totaled \$6.9 million. We also made \$4.5 million of payments to our lotilaner licensor as required by our in-license agreements.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$57.4 million for the nine months ended September 30, 2022, and primarily relates to \$57.0 million of purchases of investment securities and \$0.4 million of purchases of leasehold improvements for our laboratory and administrative offices and various purchases of office equipment.

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 Provided by Financing Activities

Net cash provided by financing activities was \$93.7 million for the nine months ended September 30, 2022, and includes (i) \$74.4 million of net proceeds from the issuance of common stock upon our Follow-On Public Offering, (ii) \$20.0 million of proceeds from our Credit Facility, partially offset by \$0.9 million of issuance costs, and (iii) \$0.2 million of proceeds from our employee stock purchase plan.

Net cash provided by financing activities was \$0.1 million for the nine months ended September 30, 2021 associated with the proceeds from stock option exercises.

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, 2021.

There were no material changes to our previously reported "Critical Accounting Policies" during the nine months ended September 30, 2022.

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.

Indemnification Agreements

As permitted under Delaware law and in accordance with our 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, 2022.

JOBS Act Accounting Election



The Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") permits an "emerging growth company" such as us 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 1.235 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.

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, 2022, we had cash, cash equivalents, and marketable securities of \$226.6 million, consisting of interest-bearing money market accounts, U.S. Treasury securities, commercial paper and corporate debt securities, 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, cash equivalents and marketable securities.

As of September 30, 2022, we had \$20.0 million of debt principal outstanding. Our Credit Facility bears interest at an annual rate equal to the *greater of* (i) the Wall Street Journal prime rate *plus* 5.20% or (ii) 8.45%. As of September 30, 2022, the resulting coupon interest rate was 11.45% (and further increased to 12.20% in November 2022). A hypothetical interest rate of 20% would have resulted in reported interest expense of \$1.0 million and \$3.0 million for the three and nine months ended September 30, 2022, respectively.

Inflation, interest rate changes, and foreign currency exchange rate fluctuations did not have a significant impact on our results of operations for any periods presented herein. However, with further inflationary pressures, certain significant increased costs could have an adverse impact on the results of our operations.

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, 2021, as filed with the SEC on March 14, 2022, as updated by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed on May 11, 2022.

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

Use of Proceeds from Initial Public Offering

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 of 1933, as amended.

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
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	<u>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.</u>					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*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					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.

SIGNATURES

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

TARSUS PHARMACEUTICALS, INC.

Date:

November 9, 2022

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

Date:

November 9, 2022

/s/ Leonard M. Greenstein

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

Exhibit 31.1

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2022

By:

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

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

Exhibit 31.2

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2022

By:

/s/ Leo M. Greenstein

Leo M. Greenstein Chief Financial Officer (Principal Financial Officer and Principal Accounting 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, 2022 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 results of operations of the Company.

Date: November 9, 2022

By:

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

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

Exhibit 32.2

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, 2022 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 results of operations of the Company.

Date: November 9, 2022

By:

/s/ Leo M. Greenstein

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