Table of Contents

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

FORM 10-Q

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

For the quarterly period ended September 30, 2023
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	**81-4717861**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
15440 Laguna Canyon Road, Suite 160 Irvine, California	**92618**
(Address of principal executive offices)	**(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 non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 3, 2023, the number of outstanding shares of the registrant's common stock, par value $0.0001 per share, was 33,104,612.

TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

Item I. Financial Statements (Unaudited)

TARSUS PHARMACEUTICALS, INC.
INDEX TO THE FINANCIAL STATEMENTS

TARSUS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(In thousands, except share and par value amounts)

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 226,672	$ 71,660
Marketable securities	20,213	145,366
Accounts receivable, net	5,362	—
Inventory	15	—
Other receivables	1,008	3,582
Prepaid expenses	6,007	4,767
Total current assets	259,277	225,375
Property and equipment, net	1,614	957
Intangible assets, net	3,967	—
Operating lease right-of-use assets	2,011	575
Long-term investments	210	371
Other assets	1,253	585
Total assets	$ 268,332	$ 227,863
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 15,351	$ 9,910
Accrued payroll and benefits	7,898	5,519
Total current liabilities	23,249	15,429
Term loan, net	29,708	19,434
Other long-term liabilities	1,711	100
Total liabilities	54,668	34,963
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; 33,104,087 shares issued and outstanding at September 30, 2023 (unaudited); 26,727,458 shares issued and outstanding at December 31, 2022	5	5
Additional paid-in capital	416,421	301,732
Accumulated other comprehensive loss	(8)	(74)
Accumulated deficit	(202,754)	(108,763)
Total stockholders' equity	213,664	192,900
Total liabilities and stockholders' equity	$ 268,332	$ 227,863

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product sales, net	$ 1,653	$ —	$ 1,653	$ —
License fees and collaboration revenue	218	—	2,718	15,816
Total revenues	1,871	—	4,371	15,816
Operating expenses:				
Cost of sales	377	—	377	—
Cost of license fees and collaboration revenue	—	—	—	555
Research and development	12,105	10,912	37,007	32,596
Selling, general and administrative	30,324	11,994	65,695	30,316
Total operating expenses	42,806	22,906	103,079	63,467
Loss from operations before other income (expense) and income taxes	(40,935)	(22,906)	(98,708)	(47,651)
Other income (expense):				
Interest income	2,840	1,061	7,359	1,372
Interest expense	(858)	(633)	(2,357)	(1,507)
Other (expense) income, net	(48)	(7)	(89)	136
Unrealized loss on equity investments	(111)	(13)	(161)	(326)
Change in fair value of equity warrants issued by licensee	(36)	(18)	(35)	(520)
Total other income (expense), net	1,787	390	4,717	(845)
Benefit from income taxes	—	5	—	4
Net loss	$ (39,148)	$ (22,511)	$ (93,991)	$ (48,492)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities and cash equivalents	15	(10)	66	(10)
Comprehensive loss	$ (39,133)	$ (22,521)	$ (93,925)	$ (48,502)
Net loss per share, basic and diluted	$ (1.28)	$ (0.84)	$ (3.35)	$ (2.03)
Weighted-average shares outstanding, basic and diluted	30,622,440	26,662,374	28,065,434	23,923,512

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

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

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2022	—	$ —	26,727,458	$ 5	$ 301,732	$ (74)	$ (108,763)	$ 192,900
Net loss	—	—	—	—	—	—	(23,419)	(23,419)
Recognition of stock-based compensation expense	—	—	—	—	3,906	—	—	3,906
Exercise of vested stock options	—	—	6,443	—	13	—	—	13
Issuance of common stock upon the vesting of restricted stock units	—	—	66,611	—	—	—	—	—
Other comprehensive gain	—	—	—	—	—	4	—	4
Balance as of March 31, 2023	—	$ —	26,800,512	$ 5	$ 305,651	$ (70)	$ (132,182)	$ 173,404
Net loss	—	—	—	—	—	—	(31,424)	(31,424)
Recognition of stock-based compensation expense	—	—	—	—	5,192	—	—	5,192
Exercise of vested stock options	—	—	16,118	—	45	—	—	45
Issuance of common stock upon the vesting of restricted stock units	—	—	45,653	—	—	—	—	—
Shares issued in connection with the employee stock purchase plan	—	—	37,289	—	465	—	—	465
Other comprehensive gain	—	—		—	—	47	—	47
Balance as of June 30, 2023	—	$ —	26,899,572	$ 5	$ 311,353	$ (23)	$ (163,606)	$ 147,729
Net loss	—	—	—	—	—	—	(39,148)	(39,148)
Recognition of stock-based compensation expense	—	—	—	—	5,250	—	—	5,250
Issuance of common stock upon follow-on public offering, net of issuance costs of $6,912	—	—	6,069,449	—	99,302	—	—	99,302
Exercise of vested stock options	—	—	109,627	—	516	—	—	516
Issuance of common stock upon the vesting of restricted stock units	—	—	25,439	—		—	—	—
Other comprehensive gain	—	—	—	—	—	15	—	15
Balance as of September 30, 2023	—	$ —	33,104,087	$ 5	$ 416,421	$ (8)	$ (202,754)	$ 213,664

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' 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)
Other comprehensive loss	—	—	—	—	—	(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.

TARSUS PHARMACEUTICALS, INC.

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash Flows From Operating Activities:		
Net loss	$ (93,991)	$ (48,492)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	497	227
Amortization of intangible assets	33	—
Accretion of term loan-related costs	274	231
Stock-based compensation	14,348	9,789
Non-cash lease expense	410	343
Unrealized loss on equity investments	161	326
Net amortization/accretion on marketable securities	(3,038)	(63)
Change in fair value of equity warrants issued by licensee	35	520
Unrealized gain from transactions denominated in a foreign currency	—	(1)
Changes in operating assets and liabilities:		
Accounts receivable, net	(5,362)	(17)
Inventory	(15)	—
Other receivables	2,574	(3,902)
Prepaid expenses	(1,028)	551
Other non-current assets	(608)	(75)
Accounts payable and other accrued liabilities	5,177	1,187
Accrued payroll and benefits	2,379	1,294
Other long-term liabilities	(4)	(74)
Net cash used in operating activities	(78,158)	(38,156)
Cash Flows From Investing Activities:		
Proceeds from maturities of marketable securities	156,920	—
Purchases of marketable securities	(28,664)	(57,031)
Intangible asset additions	(4,000)	—
Purchases of property and equipment	(1,502)	(379)
Net cash provided by (used in) investing activities	122,754	(57,410)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock upon follow-on public offerings, net of paid issuance costs	99,377	74,352
Proceeds from sale of common stock under employee stock purchase plan	465	222
Proceeds from exercise of equity awards	574	99
Proceeds from term loan	10,000	20,000
Payment of term loan issuance costs	—	(875)
Payment of deferred offering costs	—	(75)
Net cash provided by financing activities	110,416	93,723
Net increase (decrease) in cash and cash equivalents	155,012	(1,843)
Cash and cash equivalents — beginning of period	71,660	171,332
Cash and cash equivalents — end of period	$ 226,672	$ 169,489
Supplemental Disclosures Noncash Investing and Financing Activities:		
Operating lease right-of-use asset obtained in exchange for operating lease liability	$ 1,846	$ —
Interest expense paid in cash	$ 2,034	$ 1,094
Additions of property and equipment included within accounts payable and other accrued liabilities	$ 32	$ 44
Deferred offering costs included within accounts payable and accrued liabilities	$ 22	$ —

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

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

Description of Business

Tarsus Pharmaceuticals, Inc. (“Tarsus” or the “Company”) is a commercial stage biopharmaceutical company focused on the development and commercialization of therapeutics, starting with eye care. The Company launched XDEMVY® (lotilaner ophthalmic solution) 0.25%, formerly known as TP-03, for the treatment of *Demodex* blepharitis, on August 24, 2023, after receiving United States ("U.S.") Food and Drug Administration ("FDA") approval on July 24, 2023.

Follow-On Public Offerings

On August 4, 2023, the Company completed a follow-on public offering under its shelf registration statement on Form S-3 that was declared effective by the SEC on November 5, 2021 of 5,714,285 shares of common stock at a public offering price of $17.50 per share (the "August 2023 Public Offering"). The aggregate net proceeds received by the Company were approximately $93.5 million, after deducting underwriting discounts, commissions, and other estimated offering-related expenses. The Company also granted the underwriters a 30-day option to purchase up to 857,142 additional shares of its common stock at the public offering price. On September 6, 2023, the underwriters partially exercised this option resulting in the Company's issuance of an additional 355,164 shares of common stock at the public offering price of $17.50 per share. The aggregate net proceeds received by the Company from the partially exercised option was approximately $5.8 million, after deducting underwriting discounts, commissions, and other estimated offering-related expenses.

In connection with the August 2023 Public Offering, the Company terminated the prospectus (the “ATM Prospectus”) filed with Shelf Registration Statement, issuable pursuant to the terms of an Open Market Sale Agreement℠ (the "Sales Agreement") dated November 1, 2021 by and between the Company and Jefferies LLC. The Company has not made any sales pursuant to the ATM Prospectus. Further, the Company will not make any sales of our common stock pursuant to the Sales Agreement, unless and until a new prospectus, prospectus supplement or a new registration statement is filed. Other than the termination of the ATM Prospectus, the Sales Agreement remains in full force and effect.

In May 2022, the Company completed a follow-on public offering under its Shelf Registration Statement for an initial underwritten sale of 5,600,000 shares of its common stock at the public offering 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 an additional 289,832 shares at the public offering price of $13.50 per share was concurrently completed. Total aggregate net proceeds received by the Company were approximately $74.3 million, after deducting underwriting discounts, commissions, and other estimated offering-related expenses.

Liquidity

The Company has a limited operating history, limited history of product sales and has accumulated losses and negative cash flows from operations since inception. The Company has funded its inception-to-date operations through proceeds from product sales, net, proceeds from its out-license agreement, equity capital raises; including the Company's initial public offering in 2020 and the follow-on public offerings completed in May 2022 and August 2023, and draws from its credit facility. The Company estimates that 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, which have been prepared on a going-concern basis.

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 is unable to raise additional funds as required, it may need to delay, reduce, or terminate some or all of its commercialization efforts, development programs, and clinical trials. 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.

Operating Segment

The Company operates one reportable operating segment focused on the development and commercialization of therapeutics. To date, the Company has operated, managed and organized its business and financial information on an aggregate basis for the purposes of evaluating financial performance and the allocation of capital and personnel resources. The Company's chief operating decision-maker (CODM), its Chief Executive Officer, reviews its operating results for the purpose of allocating resources and evaluating financial performance.

Emerging Growth Company Status

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES

Basis of Presentation

The Company's Condensed Financial Statements have been prepared in accordance with generally accepted accounting principles ("GAAP") in the U.S. for interim financial information 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, 2022, as filed with the SEC on March 17, 2023.

The interim Condensed Balance Sheet as of September 30, 2023, the Condensed Statements of Operations and Comprehensive Loss, and the Condensed Statements of Stockholders' Equity for the three and nine months ended September 30, 2023 and 2022, and the Condensed Statements of Cash Flows for the nine months ended September 30, 2023 and 2022 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, 2022 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, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023 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 are based upon historical experience, knowledge of current events and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources and involve judgments with respect to numerous factors that are difficult to predict and may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption. Actual results could differ materially from those estimates.

The Company's financial statements as of and for the three and nine months ended September 30, 2023, reflect the Company's estimates of the impact of the macroeconomic and geopolitical environment, including the impact of inflation, higher interest rates, and foreign exchange rate fluctuations. The duration and the scope of these conditions cannot be predicted; therefore, the extent to which these conditions will directly or indirectly impact the Company's business, results of operations and financial condition, is uncertain. The Company is not aware of any specific event or circumstance that would require an

update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of the issuance date of the accompanying Condensed Financial Statements.

The accounting policies and estimates that most significantly impact the presented amounts within the accompanying Condensed Financial Statements are further described below.

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. The carrying amounts reported in the accompanying Condensed Balance Sheets for cash and cash equivalents are valued at cost, which approximate their fair value.

Marketable Securities and Long-Term Investments

Marketable securities consist primarily of short-term fixed income investments carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities (see *Note 3*). Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase, including those that have maturity dates beyond one year from the balance sheet date, are classified as current assets on the 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 accompanying 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 occurs. 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 and Comprehensive Loss. 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 associated with credit risk have occurred or have been recorded. Interest earned on marketable securities is included in interest income within the accompanying Condensed Statements of Operations and Comprehensive Loss.

Long-term investments consist of holdings of common stock in the publicly-traded parent company of LianBio Ophthalmology Limited ("LianBio"), 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 for each reported period.

Accounts Receivable, Net

Accounts receivable generally consists of amounts due from its customers, which includes pharmaceutical wholesalers and specialty pharmacy providers related to sales of XDEMVY in the U.S. Payment terms are typically 30-60 days following delivery to customers. Accounts receivable are recorded net of discounts, chargebacks, allowances and other adjustments. The Company monitors the financial performance and creditworthiness of its customers so it can properly assess and respond to changes in their credit profile. The Company estimates the allowance for credit losses based on existing contractual payment terms, actual payment patterns of customers and individual customer circumstances. Amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The Company did not record a reserve for estimated credit losses during the three months ended September 30, 2023.

Inventory

Inventory is valued at the lower-of-cost or net realizable value, with cost determined on a first-in, first-out (FIFO) basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and

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

adjusts the value for any excess and obsolete inventory to net realizable value in the period in which the impairment is first identified and such charges are recorded as a component of cost of sales in the Condensed Statements of Operations and Comprehensive Loss. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. The Company capitalizes inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. Product that may be used in clinical development programs are excluded from inventory and the costs are charged to research and development expense in the Condensed Statements of Operations and Comprehensive Loss as incurred, as long as they do not have an alternative use. Prior to FDA approval of XDEMVY on July 24, 2023, costs related to the production of inventory were recorded as research and development expense on the Condensed Statements of Operations and Comprehensive Loss in the period incurred. The inventory balance as of September 30, 2023 consisted of finished goods.

Intangible Assets, Net

Intangible assets are measured at fair value as of the acquisition date or, in the case of commercial milestone payments, the date they become due. The evaluation of intangible assets includes assessing the amortization period for which the asset is expected to contribute to the future cash flows of the Company. Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis when the Company is unable to reliably estimate the pattern of cash flow. The carrying value of intangible assets as a result of commercial milestones was $4.0 million as of September 30, 2023, and will be amortized to cost of sales over its useful life of 10 years from the date of first commercial sale. Amortization expense for the three and nine months ended September 30, 2023 was not material (see *Note 8*). The Company had no intangible assets as of December 31, 2022.

As of September 30, 2023, the expected future amortization expense for the Company's intangible assets is as follows:

	Amounts
2023 (remaining three months)	$ 100
2024	400
2025	400
2026	400
2027	400
Thereafter	2,267
Total future amortization	$ 3,967

Long-lived assets, including intangibles, are evaluated for impairment whenever events or changes in circumstance indicate that the carrying value of an asset might not be fully recoverable. To do so, the Company compares the carrying value of the intangible asset to the undiscounted net cash flows over its remaining useful life, and if not recoverable, will estimate the fair value of the asset. If the fair value is less than the carrying amount, an impairment loss is recognized in the Condensed Statements of Operations and Comprehensive Loss. There have been no impairments of intangible assets for the periods presented.

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, cash equivalents, accounts receivable, net, accounts payable and accrued liabilities approximate fair value due to the short maturities for each. The Company's equity warrant holdings disclosed as other assets are carried at fair value based on unobservable market inputs (see *Note 3*).

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

Property and Equipment, Net

Property and equipment, net are stated at historical cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets that range from three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of the remaining lease term or the estimated useful lives of related improvements. The Company evaluates the recoverability of its property and equipment, net whenever events or changes in circumstances of the business indicate that the asset’s carrying amount may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the sum of the future undiscounted cash flows the assets are expected to generate over the remaining useful lives of the assets. If a long-lived asset fails a recoverability test, the Company measures the amount by which the carrying value of the asset exceeds its fair value. There were no impairments recognized during the three and nine months ended September 30, 2023 and 2022.

Leases

The Company determines if an arrangement is or contains a lease at inception. Right-of-Use assets (“ROU assets”) represent the Company’s right to control an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the initial non-cancelable lease term, unless there is a renewal option that is reasonably certain to be exercised. The Company uses its incremental borrowing rate at the lease commencement date in determining the discount rate utilized to present value the future minimum lease payments since an implicit interest rate in each at-market lease agreement was not determinable. The Company has lease agreements with both lease and non-lease components, which are accounted for as a single component for all asset classes. Lease expense for the Company's operating leases are recognized on a straight-line basis over the lease term.

The Company's variable lease costs, consisting primarily of real estate taxes, insurance costs, and common area maintenance, are expensed as incurred and excluded from the reported ROU asset and lease liability amounts presented in the accompanying Condensed Balance Sheets. Rent expense is allocated to research and development and general and administrative expenses in the accompanying Condensed Statements of Operations and Comprehensive Loss.

Concentration Risk

Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities and accounts receivable. The Company maintains cash held on deposit at financial institutions in the U.S., including Silicon Valley Bank ("SVB"), a division of First Citizens Bank. These

deposits are insured by the Federal Deposit Insurance Corporation ("FDIC") in an amount up to $250,000 for any depositor. To the extent the Company holds cash deposits in amounts that exceed the FDIC insurance limitation, it may incur a loss in the event of a failure of any of the financial institutions where it maintains deposits. The Company invests its excess cash in highly liquid investments, including money market fund accounts, that are readily convertible into cash without penalty.

Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institution, but will continue to monitor regularly and adjust, if needed, to mitigate risk, including any ongoing or new events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions. The Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. To date, the Company has not experienced any losses associated with this credit risk and continues to assess that this exposure is not significant.

Major Customers

The Company entered into agreements with certain limited specialty pharmacies and specialty distributors for the sale of XDEMVY in the U.S. For the three months ended September 30, 2023, the Company's three largest customers accounted for 55%, 21% and 13% of product sales, respectively. As of September 30, 2023, amounts due from these three customers each exceeded 10% of gross accounts receivable and accounted for approximately 89% of the accounts receivable balance on a combined basis.

Major Suppliers

The Company does not currently own manufacturing facilities and depends on an outsourced manufacturing strategy for the production of XDEMVY for commercial use and for the production of its other product candidates for clinical trials. The Company entered into agreements with third-party manufacturers that are approved for the commercial production of XDEMVY and third-party suppliers that are approved for XDEMVY's active pharmaceutical ingredient. Although there are potential sources of supply other than our existing manufacturers and suppliers, any new supplier would be required to qualify under applicable regulatory requirements. The loss of certain manufacturers and third-party suppliers could result in a temporary disruption of the Company’s commercialization efforts.

Revenue Recognition

(i) Product Sales, Net

The Company recognizes product sales, net of XDEMVY when a customer obtains control of promised goods or services, which occurs at a point in time, typically upon delivery of the Company's product to the customer. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods in the contract; (ii) determination of whether the promised goods are performance obligations, including whether they are capable of being distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue as each performance obligation is satisfied.

The Company sells XDEMVY to customers in the U.S., which became available for commercial sale during the third quarter of 2023. The Company sells XDEMVY to a limited number of specialty pharmacies and distributors (i.e., its customers) who in turn sell it directly to clinics, hospitals, pharmacies and federal healthcare programs. Revenue from product sales is primarily recognized upon physical delivery of the product (when the customer obtains control of the product), in return for agreed-upon consideration. Shipping and handling activities are considered to be fulfillment activities rather than a separate performance obligation and are recorded within selling, general and administrative expenses in the accompanying Condensed Statements of Operations and Comprehensive Loss.

Revenues from product sales are recorded at the net sales price, or the transaction price, which may include fixed or variable consideration for (i) invoice discounts for prompt payment and distribution service fees, (ii) government and private payer rebates, chargebacks, discounts and fees, (iii) product returns and (iv) costs of co-pay assistance programs for patients, as well as other incentives. Estimates of variable consideration are calculated based on the actual product sales each reporting period and the nature of the variable consideration related to those sales. Where appropriate, the Company utilizes the expected

value method to determine the appropriate amount for estimates of variable consideration based on factors such as the current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in product sales, net only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Overall, these estimates reflect the Company's best estimate of the amount of consideration to which the Company expects to be entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ materially from estimates. If actual results in the future vary from estimates, the Company will adjust these estimates, which would affect product sales, net and earnings in the period such variances are adjusted. The Company categorizes product sales deduction estimates as follows:

Distribution Service Fees: The Company engages with wholesalers and specialty pharmacies to distribute its products to end customers. The Company pays the wholesalers and certain specialty pharmacies a fee for services such as: inventory management, chargeback administration, and service level commitments. The Company estimates the amount of distribution services fees to be paid to the customers and adjusts the transaction price with the amount of such estimate at the time of sale to the customer. An accrued liability is recorded for unpaid distribution service fees.

Prompt Pay Discounts: The Company provides its customers with a percentage discount on their invoice if the customers pay within the agreed upon timeframe. The Company expects that its customers will earn prompt pay discounts. The Company estimates the probability of customers paying promptly based on the percentage of discount outlined in the purchase agreement between the two parties, and deducts the full amount of these discounts from gross product sales and accounts receivable at the time revenue is recognized.

Product Returns: The Company's customers are contractually permitted to return the product within the contractual allowable time before and after the applicable expiration date. In the initial sales period, the Company estimates its provision for returns based on industry data and adjusts the transaction price at the time of the product sale to the customer. Once sufficient history has been collected for product returns, the Company will utilize that history to inform its returns estimate. Once the product is returned, it is destroyed since it can not be resold.

Chargebacks: A chargeback is the difference between the Company's invoice price to the wholesaler and the wholesaler's customer's contract price. The wholesaler tracks these sales and charges back the Company for the difference between the negotiated prices paid between the wholesaler's customers and wholesaler's acquisition cost. The Company estimates the percentage of goods sold that are eligible for chargeback and adjusts the transaction price and accounts receivable at the time of sale of the product to the customer.

Co-payment Assistance: Patients who meet certain eligibility requirements may receive co-payment assistance. The Company records contra-revenue for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators. An accrued liability is recorded on unredeemed co-payment assistance related to products for which control has been transferred to the customer.

Rebates and Discounts: The Company accrues rebates for contractually agreed-upon discounts with commercial insurance companies and mandated discounts under government programs such as the Medicaid Drug Rebate Program. Medicare Part D Prescription Drug Program, and other government health care programs in the U.S. The Company's estimates for expected utilization of commercial insurance rebates are based on data received from its customers. The Company's estimates for rebates under government programs are based on statutory discount rates and expected utilization as well as historical data it has accumulated since product launch. The Company's rebate calculations may require estimates, including estimates of customer mix, to determine which product sales will be subject to rebates and the amount of such rebates. The Company updates its estimates and assumptions on a quarterly basis and records any necessary adjustments to revenue in the period identified. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual rebates vary from estimates, the Company may need to adjust accruals, which would affect product sales, net in the period of adjustment. An accrued liability is recorded for unpaid rebates related to product for which control has transferred to the customer.

(ii) License Fees and Collaboration Revenue

China Out-License

License fees and collaboration revenue in the accompanying Condensed Statements of Operations and Comprehensive Loss has historically primarily related to 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 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 not distinct, the license is combined with other promised goods or services as a combined performance obligation for revenue recognition.

The China Out-License arrangement included the following forms of consideration: (i) non-refundable upfront license payment; (ii) equity-based consideration; (iii) sales-based royalties; (iv) sales-based threshold milestones; (v) one-time payments for executing drug supply agreements; (vi) development milestone payments; and (vii) 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, adjusts the probability of achievement and related revenue recognition. The measure of progress, and thereby periods over which revenue is recognized, is subject to estimates by management and may change over the course of the agreement.

Contractual Terms for Receipt of Payments

A performance obligation is a promise in a contract to transfer a distinct good or service and is the unit of accounting. A contract's transaction price is allocated among each distinct performance obligation based on relative standalone selling price and recognized when, or as, the applicable performance obligation is satisfied.

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:

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.

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.

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.

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 the China Out-License.

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 China Out-License.

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.

Other License Fees and Collaboration Revenue

License fees and collaboration revenue also includes revenue recognized from satisfaction of performance obligations under an existing clinical supply agreement. The Company recognizes revenue when a customer obtains control of the promised good or service. Revenue recognized for the three and nine months ended September 30, 2023 was $0.2 million. No revenue was recognized under such arrangements for the three and nine months ended September 30, 2022.

Cost of Sales

Cost of sales consists of direct and indirect costs related to the manufacturing and distribution of XDEMVY, including raw materials, third-party manufacturing costs, packaging services, freight, third-party royalties payable on the Company's product sales, net and amortization of capitalized intangible assets associated with XDEMVY. Cost of sales may also include period costs related to certain inventory warehouse and distribution operations and inventory adjustment charges. The Company began capitalizing inventory costs upon FDA approval of XDEMVY on July 24, 2023. Prior to FDA approval of XDEMVY, manufacturing and other inventory costs were recorded to research and development expenses in the Condensed Statements of Operations and Comprehensive Loss.

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. Research and development expenses include internal costs directly attributable to in-development programs, including the costs of salaries, payroll taxes, employee benefit and other employee-related costs (including stock-based compensation expense), license fees, materials, supplies and the cost of services provided by outside contractors to conduct nonclinical studies, clinical trials and contract manufacturing activities. All costs associated with research and development are expensed as incurred. The Company accrues these costs based on factors such as estimates of the work completed and in accordance with agreements established with third-party service providers under the service agreements. As it relates to clinical trials, the financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized. The Company's objective is to reflect the appropriate expense in its financial statements by matching those expenses with the period in which the services and efforts are expended. The

Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial taking into consideration discussions with applicable personnel and outside service providers. The clinical trial accrual is dependent in part upon the timely and accurate reporting of progress and efforts incurred from contract research organizations ("CROs"), contract manufacturers and other third-party vendors. Although estimates are expected to be materially consistent with actual amounts incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed can vary and may result in changes in estimates in any particular period. The Company makes significant judgments and estimates in determining the accrued liabilities balance at each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

The Company has entered into, and may continue to enter into, license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date, none of the Company's license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expense in the Condensed Statements of Operations and Comprehensive Loss when paid or become payable, provided there is no alternative future use of rights in other research and development projects.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for equity awards granted to employees, consultants, and members of its Board of Directors. Stock option awards are at an exercise price of not less than 100% of the fair market value of common stock on the respective date of grant. The grant date is the date the terms of the award are formally approved by the Company's Board of Directors or its designee. The Company uses the Black-Scholes option pricing model 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 market price of the Company's stock on the date preceding the award grant date.

Stock awards granted typically have one to four-year service conditions and a contractual term of 10 years. Any performance conditions for vesting are explicitly stated in each award agreement and are associated with clinical, business development, or operational milestones. 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. At each reporting period, the Company reassesses the probability of the achievement of the performance vesting conditions. As applicable, the Company reverses previously recognized expense for unvested awards in the same period of forfeiture.

All stock-based compensation expense is reported in the accompanying Condensed Statements of Operations and Comprehensive Loss within cost of sales, research and development expense or selling, general and administrative expense, based upon the assigned department of the award recipient. 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:

Fair Value of Common Stock — 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 the option grant.

Expected Term — The Company's expected term represents the period that the Company's stock option awards are expected to be outstanding. Management estimates the expected term of awarded stock options utilizing the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term since the Company does not yet have sufficient exercise history.

Expected Volatility — Prior to 2023, the Company did not have sufficient trading history for its common stock to use its own historical volatility. Management estimated the expected volatility based on a designated peer-group of publicly-traded companies for a look-back period (from the date of grant) that corresponded with the expected term of the awarded stock option. Beginning in January 2023, the Company began using its own historical stock price for expected volatility.

Risk-Free Interest Rate — The Company estimates the risk-free interest rate based upon the U.S. Department of Treasury yield curve in effect at award grant date for the time period that corresponds with the expected term of the awarded stock option.

Dividend Yield — The Company's expected dividend yield is zero because it has never paid cash dividends and does not expect to for the foreseeable future.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss 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 per share is computed by dividing the net loss 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.

Due to a net loss for the three and nine months ended September 30, 2023 and 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 each period presented.

Comprehensive Loss

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

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 financial position, results of operations, or cash flows.

3. FAIR VALUE MEASUREMENTS

The table below summarizes certain financial instruments measured at fair value that are included within the accompanying Condensed Balance Sheets, and their designation among the three fair value measurement categories (see *Note 2 - Fair Value Measurements*):

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

	September 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 226,672	$ —	$ —	$ 226,672
U.S. Treasury securities	7,494	—	—	7,494
Commercial paper	—	6,964	—	6,964
Corporate debt securities	—	314	—	314
Government-related debt securities	—	5,441	—	5,441
Common stock in LianBio	210	—	—	210
Equity warrants (for LianBio shares)	—	—	73	73
Total assets measured at fair value	$ 234,376	$ 12,719	$ 73	$ 247,168

[1] This balance includes cash requirements settled on a nightly basis.

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 64,685	$ —	$ —	$ 64,685
U.S. Treasury securities	69,644	—	—	69,644
Commercial paper	—	60,355	—	60,355
Corporate debt securities	—	11,521	—	11,521
Government-related debt securities	—	10,821	—	10,821
Common stock in LianBio	371	—	—	371
Equity warrants (for LianBio shares)	—	—	108	108
Total assets measured at fair value	$ 134,700	$ 82,697	$ 108	$ 217,505

[1] This balance includes cash requirements settled on a nightly basis.

Money Market Funds and U.S. Treasury Securities

Money market funds and U.S. Treasury securities are highly liquid investments and are actively traded with readily-available market prices that are publicly observable and independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

Commercial Paper, Corporate Debt Securities and Government-related Debt Securities

Commercial paper, corporate debt securities and government-related debt securities were valued using Level 2 inputs that utilized 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. The Company reviews trading activity and pricing for these investments as of each measurement date.

LianBio Common Stock and Equity Warrants

In March 2021, contemporaneous with the China Out-License transaction (see *Note 9*), the Company and LianBio, executed a warrant agreement for the Company to purchase, in three tranches, common shares in LianBio at an exercise price equal to common stock par value, which converted into warrants of the parent company of LianBio (LianBio, a pharmaceutical company focused on the Greater China and other Asian markets; Nasdaq: LIAN; any references to common stock or warrants of LianBio shall refer to common stock or warrants of the publicly-traded parent of LianBio) in connection with LianBio's previous Initial Public Offering. The first two tranches were vested and exercised as of December 31, 2022 and converted into 156,746 shares of LianBio common stock and were recognized at fair value within long-term investments in the Condensed Balance Sheets as of September 30, 2023 and December 31, 2022. LianBio common stock is classified within Level 1 of the fair value hierarchy, given its publicly reported price on the Nasdaq Global Market.

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

The third warrant tranche will vest upon the achievement of a regulatory event and is presented within other assets in the accompanying Condensed Balance Sheets as of September 30, 2023 and December 31, 2022. This warrant tranche remains classified as Level 3 in the fair value hierarchy. The most significant assumptions used in the option pricing valuation model as of each balance sheet date to determine its fair value included observable and unobservable inputs: 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.

The estimated fair value of the equity warrants are reported within other assets on the accompanying Condensed Balance Sheets and will be remeasured each reporting period with adjustments reported within other income (expense), net on the accompanying Condensed Statements of Operations and Comprehensive Loss, until exercised or expired. These equity warrants are valued in the accompanying Condensed Financial Statements as follows:

	Value of equity warrants
Fair value as of December 31, 2022	$ 108
Remeasurement of equity warrants	(17)
Fair value as of March 31, 2023	$ 91
Remeasurement of equity warrants	18
Fair value as of June 30, 2023	$ 109
Remeasurement of equity warrants	(36)
Fair value as of September 30, 2023	$ 73

	Value of equity warrants
Fair value as of December 31, 2021	$ 663
Remeasurement of equity warrants	(245)
Fair value as of March 31, 2022	$ 418
Recognition of equity warrants	103
Remeasurement of equity warrants	(257)
Fair value as of June 30, 2022	$ 264
Remeasurement of equity warrants	(18)
Fair value as of September 30, 2022	$ 246

TARSUS PHARMACEUTICALS, INC.

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

The fair value and amortized cost of cash equivalents and available-for-sale investments by major security type are presented in the following table:

	September 30, 2023			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash equivalents:				
Money market funds[1]	$ 226,672	$ —	$ —	$ 226,672
Total cash equivalents	$ 226,672	$ —	$ —	$ 226,672
Marketable securities:				
U.S. Treasury securities	$ 7,481	$ 17	$ (4)	$ 7,494
Commercial paper	6,966	—	(2)	6,964
Corporate debt securities	312	2	—	314
Government-related debt securities	5,446	—	(5)	5,441
Total marketable securities	$ 20,205	$ 19	$ (11)	$ 20,213
Long-term investments:				
Common stock in LianBio	$ 1,108	$ —	$ (898)	$ 210
Total long-term investments	$ 1,108	$ —	$ (898)	$ 210

[1] This balance includes cash requirements settled on a nightly basis.

	December 31, 2022			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash equivalents:				
Money market funds[1]	$ 64,685	$ —	$ —	$ 64,685
Government-related debt securities	4,978	—	—	4,978
Commercial paper	1,997	—	—	1,997
Total cash equivalents	$ 71,660	$ —	$ —	$ 71,660
Marketable securities:				
U.S. Treasury securities	$ 69,720	$ 5	$ (81)	$ 69,644
Commercial paper	58,358	—	—	58,358
Corporate debt securities	11,524	8	(11)	11,521
Government-related debt securities	5,838	5	—	5,843
Total marketable securities	$ 145,440	$ 18	$ (92)	$ 145,366
Long-term investments:				
Common stock in LianBio	$ 1,231	$ —	$ (860)	$ 371
Total long-term investments	$ 1,231	$ —	$ (860)	$ 371

[1] This balance includes cash requirements settled on a nightly basis.

As of September 30, 2023, substantially all available-for-sale debt securities had a maturity of 12 months or less. Two securities have a contractual maturity between one and two years, with an estimated fair market value of $0.3 million and amortized cost of $0.3 million. As of December 31, 2022, substantially all available-for-sale debt securities had a maturity of 12 months or less. Three securities had a contractual maturity between one and five years, with an estimated fair market value of $4.6 million and amortized cost of $4.6 million. As of September 30, 2023 and December 31, 2022, all available-for-sale debt

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

securities have gross unrealized losses in a continuous loss position for less than one year. As of September 30, 2023 and December 31, 2022, unrealized credit losses on these securities were not material, and accordingly, the Company did not recognize any other-than-temporary impairment losses.

4. BALANCE SHEET ACCOUNT DETAIL

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

Property and Equipment, Net

Property and equipment, net consists of the following:

	September 30, 2023	December 31, 2022
Furniture and fixtures	$ 1,149	$ 714
Office equipment	660	197
Laboratory equipment	167	167
Leasehold improvements	680	425
Property and equipment, at cost	2,656	1,503
(Less): Accumulated depreciation and amortization	1,042	546
Property and equipment, net	$ 1,614	$ 957

Depreciation expense for the three months ended September 30, 2023 and 2022 was $0.2 million and $0.1 million, respectively, and for the nine months ended September 30, 2023 and 2022 was $0.5 million and $0.2 million, respectively.

Accounts Payable and Other Accrued Liabilities

Accounts payable and other accrued liabilities consists of the following:

	September 30, 2023	December 31, 2022
Trade accounts payable and other	$ 10,382	$ 5,498
Accrued product sales deductions	3,778	—
Accrued clinical studies	768	3,691
Operating lease liability, current	423	721
Accounts payable and other accrued liabilities	$ 15,351	$ 9,910

5. STOCKHOLDERS' EQUITY

Common Stock Outstanding and Reserves for Future Issuance

As of September 30, 2023 and December 31, 2022, the Company had 33.1 million and 26.7 million, respectively, of common stock issued and outstanding. 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 are summarized below:

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

	September 30, 2023	December 31, 2022
Common stock awards reserved for future issuance under 2020 and 2016 Equity Incentive Plans	7,119,277	8,346,738
Common stock awards reserved for future issuance under the 2020 Employee Stock Purchase Plan	2,893,305	2,663,319
Stock options issued and outstanding (unvested and vested) under 2020 and 2016 Equity Incentive Plans	4,737,575	3,899,342
Restricted stock units issued and outstanding (unvested) under 2020 Equity Incentive Plan	1,739,693	551,258
Total shares of common stock reserved	16,489,850	15,460,657

6. STOCK-BASED COMPENSATION

Stock-based compensation expense was recognized in the accompanying Condensed Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2023 and 2022 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of sales	$ 31	$ —	$ 31	$ —
Research and development	1,663	1,015	4,317	2,677
Selling, general and administrative	3,556	2,568	10,000	7,112
Total stock-based compensation	$ 5,250	$ 3,583	$ 14,348	$ 9,789

The fair value of granted stock options was estimated as of the date of grant using the Black-Scholes option-pricing model, based on the following inputs:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Weighted average risk-free interest rate	4.28 %	3.20 %	4.07 %	2.22 %
Weighted average volatility	72.6 %	80.4 %	71.7 %	78.2 %
Expected term (in years)	6.25	6.25	6.25	6.25
Dividend yield rate	— %	— %	— %	— %
Weighted-average grant-date fair value per stock option	$ 17.23	$ 15.81	$ 15.43	$ 18.43

Stock Option Activity

Stock option activity during the nine months ended September 30, 2023 was as follows:

TARSUS PHARMACEUTICALS, INC.

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

	Number of Shares	Weighted-Average Exercise Price/Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[(1)]
Outstanding - December 31, 2022	3,899,342	$ 16.69	8.07	$ 19,196
Granted	728,169	$ 15.07		
Exercised	(6,443)	$ 2.01		
Forfeited	(24,654)	$ 21.19		
Outstanding— March 31, 2023	4,596,414	$ 16.43	8.16	$ 15,316
Granted	283,367	$ 15.55		
Exercised	(16,118)	$ 2.78		
Forfeited	(144,514)	$ 20.36		
Outstanding— June 30, 2023	4,719,149	$ 16.31	7.93	$ 28,319
Granted	130,266	$ 17.23		
Exercised	(109,627)	$ 4.71		
Forfeited	(2,213)	$ 19.09		
Outstanding—September 30, 2023	4,737,575	$ 16.60	7.77	$ 26,084
Exercisable— September 30, 2023	2,471,190	$ 15.01	6.89	$ 20,742
Unvested—September 30, 2023	2,266,385	$ 18.33	8.74	$ 5,342

[(1)] The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of September 30, 2023.

As of September 30, 2023, there was approximately $25.9 million of unrecognized compensation expense related to unvested stock options, which the Company expects to recognize over a weighted average period of 2.2 years.

Restricted Stock Unit Activity

Restricted stock unit activity during the nine months ended September 30, 2023 was as follows:

	Number of Shares	Weighted-Average Exercise Price/Share
Outstanding - December 31, 2022	551,258	$ 17.78
Granted	647,768	$ 15.24
Vested	(66,611)	$ 19.15
Forfeited	(4,042)	$ 19.40
Outstanding— March 31, 2023	1,128,373	$ 16.24
Granted	380,196	$ 15.67
Vested	(45,653)	$ 14.04
Forfeited	(71,028)	$ 15.84
Outstanding— June 30, 2023	1,391,888	$ 16.17
Granted	373,244	$ 17.34
Vested	(25,439)	$ 16.36
Forfeited	—	$ —
Outstanding— September 30, 2023	1,739,693	$ 16.42

As of September 30, 2023, there was approximately $24.7 million of unrecognized compensation expense related to unvested restricted stock units, which the Company expects to recognize over a weighted average period of 3.4 years.

7. NET LOSS PER SHARE

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (39,148)	$ (22,511)	$ (93,991)	$ (48,492)
Weighted-average shares outstanding—basic and diluted	30,622,440	26,662,374	28,065,434	23,923,512
Net loss per share—basic and diluted	$ (1.28)	$ (0.84)	$ (3.35)	$ (2.03)

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:

	As of September 30,	
	2023	2022
Stock options, unexercised—vested and unvested	4,737,575	3,839,077
Restricted stock units—unvested	1,739,693	516,005
Total	6,477,268	4,355,082

8. COMMITMENTS & CONTINGENCIES

Lease Agreements

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, 2023, the Company had five active leases for adjacent office and laboratory suites in Irvine, California. On May 1, 2023 the Company amended the existing facilities lease, extending the term for three years through January 31, 2027.

The below table summarizes the components of total lease expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease expense	$ 179	$ 142	$ 525	$ 427
Variable lease expense	125	67	296	168
Total lease expense	$ 304	$ 209	$ 821	$ 595

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

As of September 30, 2023, the Company's facility leases had a remaining lease term of 3.3 years and a weighted-average incremental borrowing rate of 10%.

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	September 30, 2023
2023 (remaining three months)	$ 226
2024	701
2025	789
2026	816
2027	68
Total future lease payments, undiscounted	$ 2,600
(Less): Imputed interest	(381)
(Less): Tenant improvement allowance	(129)
Present value of operating lease payments	$ 2,090
Operating lease liability, current	423
Operating lease liability, noncurrent	1,667
Total operating lease liability	$ 2,090

In-License Agreements for Lotilaner

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

In January 2019, the Company executed 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.

In March 2023, a clinical milestone was triggered to Elanco under the Eye and Derm Agreement upon enrollment of the first patient in the Phase 2a Galatea trial, evaluating the potential treatment of rosacea. The related milestone payment of $1.0 million was included in research and development expense in the accompanying Condensed Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2023.

The Company has made cash payments to Elanco under the Eye and Derm Agreement comprised of $1.0 million upfront upon contract execution in January 2019 and a total of $4.0 million for three specified clinical milestone achievements in September 2020, April 2021, and March 2023, which were all recorded in research and development expense in the Condensed Statements of Operations and Comprehensive Loss. During the three months ended September 30, 2023 a milestone of $4.0 million was achieved and paid to Elanco upon the first commercial sale of XDEMVY in the U.S., which was recorded as an intangible asset in the accompanying Condensed Balance Sheet as of September 30, 2023. The Company is amortizing the intangible asset to cost of sales over its useful life of 10 years from the date of the first commercial sale.

As of September 30, 2023, the Company is obligated to make further cash payments to Elanco of $2.0 million under the Eye and Derm Elanco Agreement upon achievement of the last clinical milestone in the treatment of human skin diseases using lotilaner and a maximum of $75.0 million for various commercial and sales threshold milestones for the treatment of human skin diseases and the treatment of blepharitis in humans using lotilaner.

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, until achievement of the first applicable regulatory approval of a product covered under the license. As a result of the commercialization of XDEMVY, the Company

began accruing royalties payable to Elanco during the third quarter of 2023, which are recorded to cost of sales in the accompanying Condensed Statement of Operations and Comprehensive Loss for the three and nine months ended September 30, 2023 and accounts payable and other accrued liabilities in the accompanying Condensed Balance Sheet as of September 30, 2023. Royalty expense during the three and nine months ended September 30, 2023 was $0.1 million.

September 2020 Agreement for All Other Diseases or Conditions in Humans

In September 2020, the Company executed a 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"). In September 2020, the Company issued Elanco 222,460 shares of its common stock 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 made cash payments under the All Human Uses Elanco Agreement of $0.5 million related to a clinical milestone that was triggered in December 2022 upon enrollment of the first patient in the Phase 2a Carpo trial, for the treatment of Lyme disease. The Company is required to make further cash payments under this agreement upon the achievement of various clinical milestones for an aggregate maximum of $4.0 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 product sales, net. 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, until achievement of the first applicable regulatory approval of a product covered under the license.

Employment Agreements

The Company has entered into employment agreements with seven 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.

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.

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

In March 2021, the Company entered into the China Out-License agreement with LianBio for its exclusive development and commercialization rights of TP-03 (lotilaner ophthalmic solution, 0.25%) in the China Territory, as defined in the agreement, 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.

The Company assessed this arrangement and identified the following material promises under the arrangement: (i) the exclusive license to research, develop, manufacture, commercialize, make, offer for sale, sell, and import TP-03 in the China Territory; and (ii) the research and development services in the form of clinical study materials for the respective Phase 2b/3 trial (Saturn-1) and Phase 3 (Saturn-2) TP-03 trials. The promises to provide research and development services for

Saturn-1 and Saturn-2 clinical trials were evaluated and determined to be distinct promises in the contract and each of the two clinical trials are separate performance obligations apart from the promise to provide the license.

The assessment of the initial transaction price for the China Out-License agreement included an analysis of amounts the Company expected to receive, which at contract inception consisted of: (i) the upfront cash payment of $15.0 million; (ii) a second cash payment of $10.0 million; (iii) a $10.0 million milestone that was determined to be within the control of the Company; and (iv) $1.2 million representing the initial fair value of the equity warrant.

The Company accounted for each performance obligation as follows:

Out-License

The Company determined that this license was distinct based on an evaluation of the delivery of the functional license that was in the later stages of development, and it met the criteria for being distinct from the research and development services required under the China Out-License agreement. The Company determined the standalone selling price of this license using a discounted projected sales model and recognized as license fees and collaboration revenue the total allocated transaction price at contract inception, upon delivery of the license.

Research and Development Services

The standalone selling price of these performance obligations was determined using the adjusted market assessment approach. The Company analyzed costs expected to be incurred for each of the clinical trials through completion to estimate the price that a customer would be willing to pay for these services in order to benefit from the clinical trials. The Company determined that LianBio simultaneously benefited from the research and development services that are satisfied over time, as they were able to request and access the clinical trial data at any point through the trial completion. Therefore, the Company recognized the amounts allocated to the respective research and development performance obligations for Saturn-1 and Saturn-2 within license fees and collaboration revenue as the research and development services were provided using an input method, based on the costs incurred for each clinical trial and the total costs expected to be incurred to satisfy each performance obligation. The Company believes this method most faithfully depicted its performance in transferring the promised services during the expected period of time that each clinical trial was ongoing. The Company monitored the expected completion dates for each clinical trial and updated its estimated time to completion at each reporting period, as necessary.

In February 2023, a specified milestone event was triggered resulting in $2.5 million recognized as license fees and collaboration revenue in the accompanying Condensed Statements of Operations for the nine months ended September 30, 2023. This cash payment was received in the second quarter of 2023. Through September 30, 2023, the Company received aggregate payments from LianBio totaling $82.5 million, comprised of initial consideration of $15.0 million and $67.5 million for the achievement of specified milestones.

As of September 30, 2023 the Company is eligible to receive further consideration from LianBio upon the achievement of additional TP-03 events, including: (i) additional regulatory milestones and one-time payments of up to an aggregate of $22.5 million; (ii) China-Based TP-03 sales threshold milestone payments of up to an aggregate of $100.0 million; (iii) tiered low-to-high-teen royalties for China Territory TP-03 product sales; and (iv) vesting of a LianBio equity warrant upon certain regulatory milestones.

As part of the China Out-License with LianBio the Company granted Elanco an additional 187,500 shares of the Company's 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 closing stock price of $29.30 per share on the date this issuance became contractually required.

The Company made a contractual payment in the amount of $2.5 million to Elanco following the receipt of $25 million of proceeds from LianBio during the second quarter of 2021. During the fourth quarter of 2022, the Company recognized $0.4 million of cost of license fees and collaboration revenue upon receipt of $10 million of cash proceeds from LianBio for the achievement of a clinical development milestone.

The expenses recognized under the China-Out License were not material for the three and nine months ended September 30, 2023 and 2022.

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

10. CREDIT FACILITY AGREEMENT

On February 2, 2022, the Company executed the Credit Facility with Hercules Capital, Inc. ("Hercules") and SVB that expires on February 2, 2027. Concurrent with the execution of the Credit Facility, the Company made a $20.0 million draw.

On January 5, 2023, the Company entered into an amendment to the loan and security agreement (the "First Amendment"). The First Amendment set a maximum interest rate, and updated the terms of prepayment under the Credit Facility and other certain specific conditions, including an extended period for the Company to draw down the $25.0 million tranche associated with the New Drug Application ("NDA") submission, from March 15, 2023 to March 15, 2024, provided at least $5.0 million was drawn on or before March 15, 2023 and at least an additional $5.0 million is drawn on or before September 15, 2023. The Company did not incur any lender fees as part of this First Amendment.

On March 15, 2023 and September 15, 2023, respectively, the Company made separate draws of $5.0 million (including SVB's commitment of $1.25 million) from the $25.0 million tranche that became available upon submission of the NDA. As of September 30, 2023, the Credit Facility provides for a remaining aggregate principal amount of up to $125.0 million with tranched availability as follows: $15.0 million currently available related to the Company's NDA submission with the FDA for TP-03 in September 2022; $35.0 million currently available due to the FDA approval of XDEMVY on July 24, 2023; $50.0 million available upon achievement of product sales, net thresholds; and $25.0 million available 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.

Under the First Amendment, the outstanding principal draws accrue interest at a floating interest rate per annum equal to the greater of either (i) The Wall Street Journal ("WSJ") prime rate plus 4.45% with an aggregate cap of 11.45%, or (ii) 8.45%. At the execution date of the Credit Facility, the WSJ prime rate was 3.25% and increased to 8.50% as of September 30, 2023.

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 $1.4 million was derived by multiplying 4.75% by the $30.0 million outstanding principal balance as of September 30, 2023 and is accreted to interest expense through maturity.

As of September 30, 2023 and 2022, the effective interest rate for the full term of the Credit Facility was 11.96% and 12.37%, respectively.

During the three and nine months ended September 30, 2023 and 2022, the Company recognized interest expense on the accompanying Condensed Statements of Operations and Comprehensive Loss in connection with the Credit Facility as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Interest expense for term loan	$ 757	$ 539	$ 2,083	$ 1,275
Accretion of end of term charge	68	48	184	127
Amortization of debt issuance costs	33	46	90	105
Total interest expense related to term loan	$ 858	$ 633	$ 2,357	$ 1,507

The carrying value of the Credit Facility consists of principal outstanding less legal and administrative issuance costs that were recorded as a debt discount to the term loan, net and will continue to be accreted to interest expense using the effective interest method during its term. The principal balance of this Credit Facility and related accretion and amortization are reported on a combined basis as term loan, net on the accompanying Condensed Balance Sheets as follows:

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

	September 30, 2023	December 31, 2022
Term loan, gross	$ 30,000	$ 20,000
Debt issuance costs	(875)	(875)
Accretion of end of term charge	358	174
Accumulated amortization of debt issuance costs	225	135
Term loan, net	$ 29,708	$ 19,434

11. RELATED PARTY TRANSACTIONS

Consulting Agreements

The Company has a preexisting consulting agreement with a board member who was appointed in December 2021. This Consulting Agreement provides for annual cash compensation of approximately $0.2 million and option grants to purchase 45,134 shares of the Company’s common stock, with exercise prices ranging from $2.01 to $34.72 per share. This Consulting Agreement may be terminated by either party with ten days' notice and contains standard confidentiality, indemnification, and intellectual property assignment provisions in favor of the Company.

Sponsorship Activities

In May 2023, a board member of the Company was appointed president of the American Society of Cataract and Refractive Surgery ("ASCRS"), a society dedicated to meeting the needs of anterior segment ophthalmic surgeons.

During the three and nine months ended September 30, 2023, the Company recorded $0.2 million and $0.4 million, respectively, of selling, general and administrative expenses in the accompanying Condensed Statement of Operations and Comprehensive Loss for sponsorship and event-related activities associated with ASCRS.

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:

- our ability to successfully commercialize XDEMVY®, formerly known as TP-03, for the treatment of *Demodex* blepharitis;
- the prevalence of *Demodex* blepharitis and the size of the market opportunity for XDEMVY;
- our plans relating to commercializing XDEMVY and our product candidates, if approved, including commercialization timelines and sales strategy;
- any statements regarding our ability to achieve distribution and patient access for our products including XDEMVY and timing and breadth of payer coverage; our expectations of the potential market size, pricing, gross-to-net yields, eye care provider and patient acceptance of our product candidates, opportunity and patient populations for our product candidates, including XDEMVY; our sales force size and hiring plans;
- the rate and degree of market acceptance and clinical utility of XDEMVY and our product candidates;
- 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;
- the timing or likelihood of regulatory filings and approval for our product candidates and our ability to meet existing or future regulatory standards or comply with post-approval requirements;
- 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 impact of health epidemics on our business and operations;
- the impact of unfavorable global and geopolitical economic conditions 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 ability to obtain and maintain regulatory approval of our product candidates and our product candidates to meet existing or future regulatory standards;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the expected potential benefits of strategic collaborations with third parties (including, for example, the receipt of payments, achievement and timing of milestones under license agreements, and the ability of our third-party collaborators to commercialize our product candidates in the territories under license) and our ability to attract collaborators with development, regulatory and commercialization expertise;
- existing regulations and regulatory developments in the 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 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”), our subsequent follow-on public offerings in May 2022 (the "May 2022 Public Offering") and August 2023 (the "August 2023 Public Offering", together with the May 2022 Public Offering, the “Follow-On Public Offerings”), and draw-downs from our loan and security agreement with Hercules Capital, Inc. ("Hercules") and Silicon Valley Bank ("SVB") (the "Credit Facility").

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

Our Business

We are a commercial stage biopharmaceutical company focused on the development and commercialization of therapeutics, starting with eye care. Our lead product, XDEMVY (lotilaner ophthalmic solution) 0.25% was approved by the U.S. Food and Drug Administration ("FDA") on July 24, 2023 for the treatment of blepharitis caused by the infestation of *Demodex* mites, which is referred to as *Demodex* blepharitis. Blepharitis ("Blephar" is a reference to eyelid and “itis” is a reference to inflammation) is 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. XDEMVY is the first and only therapeutic approved by the FDA and we believe is the definitive standard of care for the treatment of *Demodex* blepharitis.

We designed XDEMVY to target and eradicate the root cause of *Demodex* blepharitis — *Demodex* mite infestation. The active pharmaceutical ingredient ("API") of XDEMVY, 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 seven clinical trials that include a Phase 3 Saturn-2 trial, a Phase 2b/3 Saturn-1 trial, four Phase 2 trials, and a Phase 1 trial for XDEMVY in *Demodex* blepharitis, all of which met their primary, secondary and/or certain exploratory endpoints, with the drug well tolerated throughout each trial.

We intend to further advance our pipeline with the lotilaner API to address several diseases across therapeutic and/or prophylactic categories in human medicine, including eye care, dermatology, and other diseases. We are investigating the development of 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

XDEMVY was approved by the FDA on July 24, 2023, as the first and only approved therapeutic for *Demodex* blepharitis, a highly prevalent eyelid disease that impacts approximately 25 million eye care patients in the U.S. XDEMVY targets the root cause of *Demodex* blepharitis and in pivotal trials demonstrated significant improvement in eyelids (reduction of collarettes, the pathognomonic sign of the disease, to no more than two collarettes per upper lid), mite eradication (mite density of zero mites per lash) and erythema cure (grade zero).

- We launched XDEMVY on August 24, 2023 with our targeted sales force and recognized $1.7 million in product sales, net during the third quarter of 2023
- Active disease education is continuing to drive awareness and encouraging eye care providers ("ECPs") to proactively diagnose *Demodex* blepharitis
- We actively engaged in contracting discussions with all the key commercial and Medicare accounts and we are on track to potentially secure commercial coverage sequentially throughout 2024 and Medicare coverage in 2025
- We presented additional Saturn-2 pivotal data at the American Academy of Optometry and the American Academy of Ophthalmology further demonstrating XDEMVY as the standard of care for *Demodex* blepharitis
- The American Academy of Ophthalmology added XDEMVY as the first and only FDA-approved therapeutic for the treatment of *Demodex* blepharitis in their Preferred Practice Patterns (PPP) guidelines

TP-03 Meibomian Gland Disease, Ersa Trial: In August 2022, we announced the enrollment of our first patient in the Phase 2a Ersa clinical trial studying TP-03 for the treatment of MGD. We expect topline availability during the fourth quarter of 2023.

TP-04 Rosacea, Galatea Trial: In March 2023, we initiated the Galatea trial, a Phase 2a trial evaluating TP-04, a novel gel formulation of lotilaner, for the treatment of rosacea. We expect topline availability in the first quarter of 2024.

TP-05 Lyme Disease, Callisto and Carpo Trials: In December 2022, we announced positive topline results from the completed Phase 1 Callisto trial and enrollment of the first patient in the Phase 2a Carpo trial. The Carpo trial is designed to evaluate TP-05, a novel investigative oral, non-vaccine pharmacological prophylactic for the potential prevention of Lyme disease. The Carpo trial, evaluating TP-05 for the potential prevention of Lyme disease in humans, is a randomized, double-blind trial that will evaluate the efficacy of TP-05 in killing lab grown, non-disease carrying ticks after they have attached to the skin of healthy volunteers, as well as confirm the safety, tolerability, and blood concentration of TP-05. Given enrollment delays, we now expect topline availability from the Phase 2a Carpo trial during the first quarter of 2024.

We believe TP-05 is currently the only non-vaccine, drug-based prophylaxis in development that targets ticks, and potentially prevents Lyme disease transmission. It is designed to rapidly and durably 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 February 2023, a specified milestone was triggered resulting in $2.5 million recognized as license fees and collaboration revenue in the accompanying Condensed Statements of Operations for the nine months ended September 30, 2023. This cash payment was received during the second quarter of 2023. As of the date of this filing, we have received aggregate contractual cash proceeds from LianBio of $82.5 million, representing initial consideration of $15.0 million and $67.5 million for the achievement of specified milestone events. 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.

Corporate and Financial Overview

We were incorporated as a Delaware corporation in November 2016, and our headquarters are 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, net proceeds from issuance of common stock in our IPO and our Follow-On Public Offerings, proceeds from product sales, net proceeds from our China Out-License, and draw-downs from the Credit Facility.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant operating expenses as we commercialize XDEMVY for *Demodex* blepharitis and as we advance our other product candidates through clinical trials, regulatory submissions, and potential commercialization. Our net loss was $39.1 million and $22.5 million for the three months ended September 30, 2023 and 2022, respectively, and $94.0 million and $48.5 million for the nine months ended September 30, 2023 and 2022, respectively. Our net losses 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:

- commercialize XDEMVY and our other products for which we obtain regulatory approvals;
- maintain regulatory approval for XDEMVY and seek regulatory approval for our 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;
- engage with contract manufacturers to ensure a sufficient supply chain capacity to provide commercial quantities of XDEMVY and any other 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 commercialization efforts, and to enable us to operate as a public company.

We began generating product sales, net during the three months ended September 30, 2023 following the FDA approval of XDEMVY in July 2023 and our subsequent commercial launch in August 2023. Our reported revenue within license fees and collaboration revenue is from our China Out-License and clinical supply agreement; we expect to report additional revenue under this caption in future periods.

Until such time as we can generate significant revenue from product sales, net 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 and commercialization, 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 significant revenue from product sales, net we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels.

As of September 30, 2023, our aggregate cash, cash equivalents and marketable securities was $246.9 million – see the section below titled *"Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources."*

Impact of the Macroeconomic Environment

Recently, the economy has experienced downward pressure, and together with high rates of inflation and energy supply issues experienced in certain regions, war and geopolitical conflicts, have led to regional and/or global macroeconomic challenges, the effects of which may be of an extended duration.

In addition, we may be exposed to credit risk on deposits at financial institutions to the extent our account balances exceed the amount insured by the Federal Deposit Insurance Corporation ("FDIC"). We maintain cash held in deposit at financial institutions in the U.S., including SVB, a division of First Citizens Bank. While these deposits are insured by the FDIC in an amount up to $250,000 for any depositor, to the extent we hold cash deposits in amounts that exceed the FDIC insurance limitation, we may incur a loss in the event of a failure of any of the financial institutions where we maintain deposits. We invest our excess cash in highly liquid investments, including money market fund accounts, that are readily convertible into cash without penalty. We believe the Company is not exposed to significant credit risk due to the financial position of the depository institution, but will continue to monitor regularly and adjust, if needed, to mitigate risk, including any ongoing or new events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions.

See the section titled *Risk Factors* in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 17, 2023 and in this Quarterly Report, for a further discussion of the potential adverse impact of unfavorable global and geopolitical economic conditions on our business, results of operations and financial condition.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations:

	Three Months Ended September 30,		
	2023	2022	Change
	(in thousands)		
Revenues:			
Product sales, net	$ 1,653	$ —	*
License fees and collaboration revenue	218	—	*
Total revenues	1,871	—	*
Operating expenses:			
Cost of sales	377	—	*
Research and development	12,105	10,912	1,193
Selling, general and administrative	30,324	11,994	18,330
Total operating expenses	42,806	22,906	19,900
Loss from operations before other income (expense) and income taxes	(40,935)	(22,906)	(18,029)
Other income (expense):			
Interest income	2,840	1,061	1,779
Interest expense	(858)	(633)	(225)
Other expense, net	(48)	(7)	(41)
Unrealized loss on equity investments	(111)	(13)	(98)
Change in fair value of equity warrants issued by licensee	(36)	(18)	(18)
Total other income, net	1,787	390	1,397
Benefit from income taxes	—	5	(5)
Net loss	$ (39,148)	$ (22,511)	$ (16,637)

* Not meaningful for further disclosure.

Product Sales, Net

During the three months ended September 30, 2023, in conjunction with the launch of our first FDA approved product, XDEMVY, we recognized revenue of $1.7 million from product sales, net of rebates, chargebacks, discounts, and other adjustments. During the three months ended September 30, 2022, there were no product sales, net recognized.

License Fees and Collaboration Revenue

For the three months ended September 30, 2023, we recognized $0.2 million of license fees and collaboration revenue from the satisfaction of performance obligations under an existing clinical supply agreement. No revenue was recognized under such arrangements for the three months ended September 30, 2022.

No revenue was recognized under the China Out-License arrangement for the three months ended September 30, 2023 and 2022. We will recognize additional license fees and collaboration revenue under the China Out-License to the extent other events occur, specifically related to (i) milestone achievement of an additional drug supply agreement execution, (ii) milestone achievement of certain regulatory events in the China Territory, and (iii) royalties and milestones from our licensee's product sales of TP-03 in the China Territory.

Cost of Sales

For the three months ended September 30, 2023, we recognized $0.4 million in cost of sales for XDEMVY. Cost of sales consists of direct and indirect costs related to the manufacturing and distribution of XDEMVY, including raw materials, third-party manufacturing costs, packaging services, and freight-in, as well as third-party royalties payable on our product sales, net and amortization of capitalized intangible assets associated with XDEMVY. Cost of sales may also include period costs related to certain inventory warehouse and distribution operations and inventory adjustment charges. Prior to FDA approval of XDEMVY, manufacturing and other inventory costs were recorded to research and development expenses. Therefore, cost of sales of XDEMVY will reflect a lower average per unit cost until the related inventory is sold. During the three months ended September 30, 2022, there were no cost of sales recognized.

Cost of License Fees and Collaboration Revenue

For the three months ended September 30, 2023 and 2022, we did not recognize any cost of license fees and collaboration revenue.

Research and Development Expenses

	Three Months Ended September 30,		
	2023	2022	Change
Direct external expenses:			
TP-03 program	$ 3,070	$ 4,937	$ (1,867)
TP-04 program	590	759	(169)
TP-05 program	1,001	972	29
Other early-stage programs	199	—	199
Indirect expenses:			
Compensation and personnel-related	6,549	3,736	2,813
Other	696	508	188
Total research and development expenses	$ 12,105	$ 10,912	$ 1,193

Research and development expenses increased by $1.2 million for the three months ended September 30, 2023, as compared to the prior year period. This increase was primarily due to $2.8 million of increased payroll and personnel-related costs (including increased stock-based compensation expense of $0.6 million) and $0.2 million of other indirect expenses related to 25 employee additions period over period to drive our product development initiatives. These increases were partially offset by $1.9 million of decreased program spend for TP-03 primarily due to a reduction in clinical trial expenses of $1.4 million given the completion of our Saturn-2 trial in the first half of 2022 and reduced preclinical expenses of $0.2 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $18.3 million for the three months ended September 30, 2023, as compared to the prior year period. The increase was primarily due to (i) $7.9 million of increased payroll and personnel-related costs (including increased stock-based compensation expense of $1.0 million) for 130 corporate employee additions, period over period, to support our business growth and commercial leadership hires for our recent commercial launch of XDEMVY, (ii) $8.1 million of increased commercial and market research costs as we continued our commercial expansion and prepared for the recent commercial launch of XDEMVY, (iii) $1.5 million of increased IT applications, legal and other professional expenses to support the continued growth and expansion of our corporate infrastructure, and (iv) $0.8 million of increased facilities and office and administrative expenses. We expect sales and marketing headcount and associated vendor expenses to meaningfully increase during 2023 due to our commercial launch and related activities for XDEMVY.

Other Income, Net

Other income, net increased by $1.4 million primarily due to $1.8 million of increased interest income earned on our cash, cash equivalents and marketable securities, partially offset by (i) $0.1 million change in fair value of the LianBio common stock and (ii) increased interest expense of $0.2 million on the Credit Facility.

Benefit from Income Taxes

We maintain a valuation allowance against our net deferred tax assets as of September 30, 2023 and 2022 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.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations:

	Nine Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Revenues:			
Product sales, net	$ 1,653	$ —	*
License fees and collaboration revenue	2,718	15,816	(13,098)
Total revenues	4,371	15,816	(11,445)
Operating expenses:			
Cost of sales	377	—	*
Cost of license fees and collaboration revenue	—	555	(555)
Research and development	37,007	32,596	4,411
Selling, general and administrative	65,695	30,316	35,379
Total operating expenses	103,079	63,467	39,612
Loss from operations before other income (expense) and income taxes	(98,708)	(47,651)	(51,057)
Other income (expense):			
Interest income	7,359	1,372	5,987
Interest expense	(2,357)	(1,507)	(850)
Other (expense) income, net	(89)	136	(225)
Unrealized loss on equity investments	(161)	(326)	165
Change in fair value of equity warrants issued by licensee	(35)	(520)	485
Total other income (expense), net	4,717	(845)	5,562
Benefit from income taxes	—	4	(4)
Net loss	$ (93,991)	$ (48,492)	$ (45,499)

* Not meaningful for further disclosure.

Product Sales, Net

During the nine months ended September 30, 2023, due to the launch of our first FDA approved product, XDEMVY, we recognized revenue of $1.7 million from product sales, net of rebates, chargebacks, discounts, and other adjustments. During the nine months ended September 30, 2022, there were no product sales, net recognized.

License Fees and Collaboration Revenue

For the nine months ended September 30, 2023 and 2022, we recognized $2.5 million and $15.8 million, respectively, of license fees and collaboration revenue primarily attributable to contractual milestones under the China Out-License. These amounts represent the contractual milestones achieved or allocated under the China Out-License that have been fully or partially completed by the period end. These allocated amounts represented the satisfaction of the transfer of license rights to LianBio and the completion of related performance obligations.

We will recognize additional license fees and collaboration revenue under the China Out-License to the extent other events occur, specifically related to (i) milestone achievement of an additional drug supply agreement execution, (ii) milestone achievement of certain regulatory events in the China Territory, and (iii) royalties and milestones from our licensee's product sales of TP-03 in the China Territory.

For the nine months ended September 30, 2023, we recognized $0.2 million of other license fees and collaboration revenue from the satisfaction of performance obligations under an existing clinical supply agreement. No revenue was recognized under such arrangement for the nine months ended September 30, 2022.

Cost of Sales

For the nine months ended September 30, 2023, we recognized $0.4 million in cost of sales of XDEMVY. Cost of sales consists of direct and indirect costs related to the manufacturing and distribution of XDEMVY, including raw materials, third-party manufacturing costs, packaging services, and freight-in, as well as third-party royalties payable on our product sales, net and amortization of capitalized intangible assets associated with XDEMVY. Prior to FDA approval of XDEMVY, manufacturing and other inventory costs were recorded to research and development expenses. Therefore, cost of sales of

XDEMVY will reflect a lower average per unit cost until the related inventory is sold. For the nine months ended September 30, 2022, there were no cost of sales recognized.

Cost of License Fees and Collaboration Revenue

For the nine months ended September 30, 2023, we did not recognize any cost of license fees and collaboration revenue. Cost of license fees and collaboration revenue for the nine months ended September 30, 2022 was $0.6 million. This amount relates to our contractual payment obligations to Elanco, in proportion to our recognized license fees and collaboration revenue under the China Out-License arrangement in the same period.

Research and Development Expenses

	Nine Months Ended September 30,		
	2023	2022	Change
Direct external expenses:			
TP-03 program	$ 10,423	$ 17,130	$ (6,707)
TP-04 program	1,986	2,912	(926)
TP-05 program	4,159	2,032	2,127
Other early-stage programs	379	88	291
Indirect expenses:			
Compensation and personnel-related	17,656	9,257	8,399
Other	1,404	1,177	227
Elanco milestone expenses	1,000	—	1,000
Total research and development expenses	$ 37,007	$ 32,596	$ 4,411

Research and development expenses increased by $4.4 million for the nine months ended September 30, 2023, as compared to the prior year period. The increase was primarily due to (i) $8.4 million of increased indirect expenses related to payroll and personnel-related costs (including increased stock-based compensation expense of $1.6 million) for 25 employee additions period over period to drive our product development initiatives, (ii) $1.0 million of milestone expense related to our in-license agreement with Elanco, (iii) $2.1 million of increased TP-05 program expenses primarily related to the Phase 2a Carpo trial initiated in December 2022 and the new food effect study initiated during the first quarter of 2023, and (iv) $0.3 million of increased spend related to other early-stage programs. These increases were partially offset by decreases in direct external spend for the TP-03 and TP-04 programs of $6.7 million and $0.9 million, respectively. The decrease in our TP-03 program expenses was primarily due to significantly reduced clinical trial costs of $7.0 million given the completion of our Saturn-2 trial in the first half of 2022, partially offset by $0.6 million of clinical trial expenses related to the Phase 2a Ersa clinical trial studying TP-03 for the treatment of MGD. The decrease in our TP-04 program expenses were primarily due to $1.4 million of decreased preclinical expenses, partially offset by $0.7 million of increased clinical trial expenses related to the Galatea trial.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $35.4 million for the nine months ended September 30, 2023, as compared to the prior year period. The increase was primarily due to (i) $16.0 million of increased payroll and personnel-related costs (including increased stock-based compensation expense of $2.9 million) for 130 corporate employee additions period-over-period to support our business growth and commercial leadership hires for our recent commercial launch of XDEMVY, (ii) $0.9 million of severance costs related to our former Chief Financial Officer's separation from the Company in June 2023, (iii) $14.6 million of increased commercial and market research costs as we continued our commercial expansion and prepared for the recent commercial launch of XDEMVY, (iv) $2.6 million of increased IT applications, legal and other professional expenses to support the continued growth and expansion of our corporate infrastructure, and (v) $1.3 million of increased facilities and office and administrative expenses. We expect sales and marketing headcount and associated vendor spend to meaningfully ramp during 2023 due to our commercial launch and related activities for XDEMVY.

Other Income (Expense), Net

Other income (expense), net increased by $5.6 million primarily due to (i) $6.0 million of increased interest income earned on our cash, cash equivalents and marketable securities, (ii) $0.5 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 change in fair value of the

LianBio common stock. These increases to other income were partially offset by increased interest expense of $0.9 million on the Credit Facility.

Benefit from Income Taxes

We maintain a valuation allowance against our net deferred tax assets as of September 30, 2023 and 2022 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.

Liquidity and Capital Resources

Sources of Liquidity

Overview

Since our inception, we have financed our operations substantially through private placements of preferred stock, net proceeds from issuance of common stock through our IPO and Follow-on Public Offerings, proceeds from product sales, net, proceeds from our China Out-License, and draw-downs from our Credit Facility. As of September 30, 2023, we had cash, cash equivalents and marketable securities of $246.9 million.

IPO and Follow-On Public Offerings

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.

In May 2022, we completed a 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 net proceeds received of $74.3 million, after deducting underwriting discounts, commissions, and other estimated offering-related expenses.

On August 4, 2023, we completed a Follow-On Public Offering of 5,714,285 shares of common stock at an offering price of $17.50 per share. The aggregate net proceeds received were approximately $93.5 million, after deducting underwriting discounts, commissions, and other estimated offering-related expenses. We also granted the underwriters a 30-day option to purchase up to 857,142 additional shares of our common stock at the public offering price. On September 6, 2023, the underwriters partially exercised this option and the sale of an additional 355,164 shares at the public offering price of $17.50 per share was concurrently completed. We received $5.8 million of aggregate net proceeds, after deducting underwriting discounts, commissions, and other estimated offering-related expenses.

China Out-License

As of the date of this filing, we have received $82.5 million of total proceeds in connection with our China Out-License. We expect to receive an additional $2.5 million during the first half of 2024 for the achievement of a specific milestone, for expected cumulative milestone receipts of $85.0 million through December 2024. 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

In February 2022, we executed the Credit Facility with Hercules and SVB. Capital draws are at our election and are in $5.0 million increments. Concurrent with the execution of the Credit Facility we drew $20.0 million. This Credit Facility was amended in January 2023. The Credit Facility, as amended, set a maximum interest rate, updated the terms of prepayment under the Credit Facility and includes an extended period to draw down the tranche associated with the NDA submission, from March 15, 2023 to March 15, 2024 provided at least $5.0 million was drawn on or before March 15, 2023 and at least an additional $5.0 million was drawn on or before September 15, 2023. On March 15, 2023 and September 15, 2023, respectively, we made draws of $5.0 million (including SVB's commitment of $1.25 million) from the $25.0 million tranche associated with the NDA submission of TP-03. 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.

As of the date of this filing, we have $125.0 million of tranched availability as follows:

- $15.0 million, which became available in September 2022 upon our NDA submission of TP-03 to the FDA;
- $35.0 million, which became available in July 2023 upon FDA approval of XDEMVY;
- $50.0 million available upon achievement of certain quarterly revenue thresholds; and
- $25.0 million available with lender approval.

Funding Requirements

Liquidity

Our operating expenditures currently consist of cost of sales, research and development costs (including activities within our preclinical, clinical, regulatory, and drug manufacturing initiatives) and selling, 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 have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $202.8 million as of September 30, 2023.

As of September 30, 2023, we had cash, cash equivalents and marketable securities of $246.9 million. We received aggregate net proceeds of approximately $99.4 million from the August 2023 Public Offering. We anticipate having at least $50.0 million of available capital from our Credit Facility through March 2024 and an additional $75.0 million of additional tranched availability through December 2024. The Credit Facility requires interest-only debt service payments that are expected to remain through its maturity in February 2027 and its remaining tranches are subject to undrawn expiry in either March 2024 or December 2024 (see *Note 10*).

We believe that our existing cash, cash equivalents and marketable securities will be 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. Our cash runway estimate is predicated on current assumptions for future revenue, operating expenses, and debt availability and may require future adjustments. Accordingly, we may be required to raise additional capital earlier than we currently expect based on our cash requirements and market dynamics.

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 $120 million remaining under our Shelf Registration Statement, after giving effect to the Follow-On Public Offerings (and exclusive 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 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 Agreement™ (the "ATM Agreement") with Jefferies LLC. Through the date of this filing, we have not sold any shares of our common stock under the ATM Agreement. On July 31, 2023, in connection with the August 2023 Public Offering, we terminated the sales agreement prospectus relating to the ATM.

Other Liquidity Risks

We expect to incur significant operating losses for the foreseeable future, and expect these losses to further increase, as we expand our clinical development programs for our other product candidates and given the recent commercial launch of XDEMVY. 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 amount of revenue, if any, received from commercial sales of XDEMVY or our product candidates, should any of our product candidates receive marketing approval;
- the cost and timing associated with commercializing XDEMVY or our product candidates, if they receive marketing approval;
- 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 achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time and availability of 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 health epidemics 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,	
	2023	2022
	(in thousands)	
Net cash provided by (used in) provided by:		
Operating activities	$ (78,158)	$ (38,156)
Investing activities	122,754	(57,410)
Financing activities	110,416	93,723
Net increase (decrease) in cash and cash equivalents	$ 155,012	$ (1,843)

Net Cash Used in Operating Activities

Net cash used in operating activities was $78.2 million for the nine months ended September 30, 2023, which primarily consisted of our net loss of $94.0 million partially offset by stock-based compensation of $14.3 million. For the nine months ended September 30, 2023, our cash payments for operating activities primarily consisted of $54.9 million related to vendors and $30.8 million for payroll-related activities (inclusive of 2022 bonus payouts).

Net cash used in operating activities was $38.2 million for the nine months ended September 30, 2022. 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. In the prior year period, our cash payments for operating activities included: (i) $38.4 million related to vendors (ii) $14.0 million for payroll-related activities (inclusive of 2021 bonus payouts), and (iii) $1.8 million to our lotilaner licensor as required by our in-license agreements.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $122.8 million for the nine months ended September 30, 2023, and primarily relates to $156.9 million of proceeds from maturities of investments, partially offset by $28.7 million of purchased investments and $1.5 million of purchased furniture, fixtures, office equipment and leasehold improvements for our laboratory and administrative offices.

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $110.4 million for the nine months ended September 30, 2023 which primarily relates to (i) $99.4 million of net proceeds from the issuance of common stock related to the August 2023 Public Offering, (ii) $10.0 million of proceeds from our Credit Facility, (iii) $0.5 million of proceeds from our employee stock purchase plan, and (iv) $0.6 million of proceeds from employee option exercises.

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

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our Condensed Financial Statements, which have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of these condensed financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or 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, 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, 2023.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012 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) December 31, 2025, which is the last day of our first fiscal year following the fifth anniversary of the completion of our IPO, (2) the last day of our first fiscal year (a) in which we have total annual gross revenues of at least $1.235 billion or (b) 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, as of the prior June 30th and (3) 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, 2023, we had cash, cash equivalents, and marketable securities of $246.9 million, consisting of interest-bearing money market accounts, U.S. Treasury securities, commercial paper, corporate debt securities and government-related 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, 2023, we had $30.0 million of debt principal outstanding. Our Credit Facility bears interest at an annual rate equal to the greater of (i) the prime rate as reported in the Wall Street Journal plus 4.45% with an aggregate cap of 11.45% or (ii) 8.45%. Assuming our interest rate is the aggregate cap of 11.45% our reported interest expense would aggregate $0.9 million and $2.6 million, respectively, for the three and nine months ended September 30, 2023.

We do not believe inflation, interest rate changes, and foreign currency exchange rate fluctuations had 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, 2022, as filed with the SEC on March 17, 2023, as updated by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed on August 10, 2023.

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
10.1	Second Amendment to Loan and Security Agreement, dated as of August 28, 2023, by and among Registrant, Hercules Capital, Inc. and First-Citizens Bank & Trust Company.					X
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.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
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.					X
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.					X
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.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					X

* 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, 2023

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

Date: November 9, 2023

/s/ Jeffrey Farrow
Jeffrey Farrow
Chief Financial Officer and Chief Strategy Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.1

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of August 28, 2023 (the "**Amendment Effective Date**"), is entered into by and among TARSUS PHARMACEUTICALS, INC., a Delaware corporation, and each of its Subsidiaries joined hereafter from time to time pursuant to Section 7.13 of the Loan and Security Agreement (hereinafter collectively referred to as the "**Borrower**"), the several banks and other financial institutions or entities from time to time parties to this Agreement (each, a "**Lender**", and collectively, referred to as the "**Lenders**"), and HERCULES CAPITAL, INC., a Maryland corporation **(**"**Hercules**"), in its capacity as administrative agent and collateral agent for itself and the Lender (in such capacity, together with its successors and assigns in such capacity, "**Agent**").

The Borrower, the Lenders and Agent are parties to a Loan and Security Agreement dated as of February 2, 2022 (as amended by the First Amendment, dated as of January 5, 2023, and as further amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "**Loan and Security Agreement**"). The Borrower has requested that Agent and Lenders agree to certain amendments to the Loan and Security Agreement. Agent and Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1. Definitions; Interpretation.

(a) Terms Defined in Loan and Security Agreement. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) Interpretation. The rules of interpretation set forth in Section 1.3 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendments to the Loan and Security Agreement.

(a) **The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:**

(i) Section 7.12 is hereby amended and restated in its entirety as follows:

"7.12 Deposit Accounts. Borrower shall maintain at all times in Deposit Accounts (including cash sweep accounts) or securities accounts with SVB or SVB's Affiliates an aggregate balance not less than the greater of (a) $40,000,000 and (b) twenty-five percent (25%) of the aggregate Cash of Borrower; provided, notwithstanding the foregoing, that if Borrower's aggregate Cash, wherever located, is less than $40,000,000 at any time, Borrower shall maintain not less than seventy-five percent (75%) of the aggregate Cash of Borrower in Deposit Accounts (including cash sweep accounts) or securities accounts with SVB or

SVB's Affiliates. To the extent any of Borrower's Cash is not required to be maintained with SVB or SVB's Affiliates pursuant to the terms of this Section 7.12, Borrower

is permitted to maintain such Cash in Deposit Accounts (including cash sweep accounts) or securities accounts with other financial institutions, subject, in each case, to an Account Control Agreement in favor of Agent. In addition to the foregoing, except as permitted pursuant to clause (iv) or (vii) of the definition of Permitted Indebtedness, Borrower and any Subsidiary of Borrower, shall obtain any business credit card and any letter of credit exclusively from SVB. Notwithstanding anything herein to contrary, in no event shall Borrower be obligated to deliver any Account Control Agreement with respect to an Excluded Account."

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3. Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) This Amendment. Agent shall have received this Amendment, executed by Agent, the Lenders and Borrower.

(b) Representations and Warranties; No Default. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 5 of the Loan and Security Agreement shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date, after giving effect in all cases to any standard(s) of materiality contained in the Agreement as to such representations and warranties; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4. Representations and Warranties. To induce Agent and Lender to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided, however,* that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that there has not been and there does not exist a Material Adverse Change; and (c) that the information included in the Perfection Certificate delivered to Agent on the Amendment Effective Date is true and correct in all material respects. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete as of such earlier date).

SECTION 5. Miscellaneous.

(a) Loan Documents Otherwise Not Affected; Reaffirmation. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. Borrower hereby reaffirms the grant of security under Section 4.1 of the Loan and Security Agreement, and hereby reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement and the other Loan Documents.

(b) Conditions. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) [Reserved].

(d) No Reliance. Each Borrower hereby acknowledges and confirms to Agent and the Lender that such Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) Costs and Expenses. Each Borrower agrees to pay to Agent on the Amendment Effective Date the out-of-pocket costs and expenses of Agent and the Lenders party hereto, and the reasonable and documented fees and disbursements of counsel to Agent and the Lenders party hereto, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(f) Binding Effect. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) Governing Law. This Amendment and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

(h) Complete Agreement; Amendments. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(i) Severability of Provisions. Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) Counterparts. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf)

or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) Loan Documents. This Amendment shall constitute a Loan Document.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

TARSUS PHARMACEUTICALS, INC.

By: /s/ Jeffrey S. Farrow

Name: Jeffrey S. Farrow

Title: Chief Financial Officer and Chief Strategy Officer

AGENT:
HERCULES CAPITAL, INC.

By /s/ Seth Meyer
Name: Seth Meyer
Title: Chief Financial Officer

LENDER:
HERCULES CAPITAL FUNDING TRUST 2022-1
By: Hercules Capital, Inc., its Administrator

By /s/ Seth Meyer
Name: Seth Meyer
Title: Chief Financial Officer

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC,
its Investment Advisor

By: /s/ Seth Meyer
Name: Seth Meyer
Title: Authorized Signatory

HERCULES PRIVATE CREDIT FUND I L.P.

By: Hercules Adviser LLC,
its Investment Advisor

By: /s/ Seth Meyer
Name: Seth Meyer
Title: Authorized Signatory

FIRST-CITIZENS BANK & TRUST COMPANY

By: /s/ Kristine Rohmer
Name: Kristine Rohmer
Title: Director

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, 2023

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

Bobak Azamian, M.D., Ph.D.
President, Chief Executive Officer and Board Chairman
(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, Jeffrey Farrow, 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, 2023

By: /s/ Jeffrey Farrow

Jeffrey Farrow
Chief Financial Officer and Chief Strategy Officer
(*Principal Financial Officer and Principal Accounting Officer*)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Tarsus Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 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, 2023

By: /s/ Bobak Azamian, M.D., Ph.D.
Bobak Azamian, M.D., Ph.D.
President, Chief Executive Officer and Board Chairman
(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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey Farrow, 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, 2023

By: /s/ Jeffrey Farrow
Jeffrey Farrow
Chief Financial Officer and Chief Strategy Officer
(Principal Financial Officer and Principal Accounting Officer)