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 March 31, 2024
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	
(Address of principal executive offices)	**92618 (Zip Code)**

(949) 418-1801
(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 May 2, 2024, the number of outstanding shares of the registrant's common stock, par value $0.0001 per share, was 37,781,693.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

We face risks and uncertainties associated with our business, many of which are beyond our control. Some of the more significant risks associated with our business include the following:

- We are a commercial-stage biopharmaceutical company with a limited operating history and a single product approved for commercial sale. We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.
- Due to the recently initiated commercialization of XDEMVY and our continued development of our pipeline of product candidates through clinical trials and other indications, our capital requirements are difficult to predict and may change. We may need to obtain substantial additional funding to achieve our goals and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.
- We have only recently obtained regulatory approval for XDEMVY in the U.S. and we have limited experience as a commercial company generating revenue from product sales. If the commercial launch of XDEMVY is unsuccessful or any future approved products are unsuccessful, we may never be profitable.
- We are heavily dependent on the successful commercialization of XDEMVY and the development, regulatory approval, and commercialization of our current and future product candidates. XDEMVY remains subject to ongoing post-marketing review and extensive regulation.
- We may not be successful in educating eye care providers ("ECPs"), and the market about the need for treatments specifically for *Demodex* blepharitis and other diseases or conditions targeted by XDEMVY or our product candidates. XDEMVY or other product candidates that we may develop may fail to achieve market acceptance by ECPs, other healthcare providers and patients, or adequate formulary coverage, pricing or reimbursement by third-party payers and others in the medical community, and the market opportunity for these products may be smaller than we estimate. XDEMVY and any product candidates for which we obtain marketing approval may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.
- The sizes of the market opportunity for XDEMVY for the treatment of *Demodex* blepharitis and TP-03 for the treatment of Meibomian Gland Disease ("MGD"), as well as our other product or product candidates, have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.
- The development and commercialization of our products, including XDEMVY, for the treatment of *Demodex* blepharitis, 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, is dependent on intellectual property we license from Elanco Tiergesundheit AG ("Elanco").
- We expect to expand our development, regulatory and operational capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We contract with third parties for the commercial manufacture of XDEMVY and for the manufacture of our product candidates for preclinical studies, clinical trials and for eventual commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of XDEMVY or our product candidates or compounds or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our commercialization or development efforts.
- Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates do not meet safety or efficacy endpoints or are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

- Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- If we are unable to obtain and maintain sufficient intellectual property protection for XDEMVY or our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- Patent terms may be inadequate to protect our competitive position on our product candidates and preclinical programs for an adequate amount of time.
- The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

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TARSUS PHARMACEUTICALS, INC.

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

	March 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 193,705	$ 224,947
Marketable securities	104,819	2,495
Accounts receivable, net	29,885	16,621
Inventory	4,036	3,107
Other receivables	1,476	1,093
Prepaid expenses	6,803	7,868
Total current assets	340,724	256,131
Property and equipment, net	1,338	1,468
Intangible assets, net	3,767	3,867
Operating lease right-of-use assets	2,132	1,880
Long-term investments	—	631
Other assets	1,317	1,514
Total assets	$ 349,278	$ 265,491
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 36,570	$ 23,691
Accrued payroll and benefits	5,958	13,245
Total current liabilities	42,528	36,936
Term loan, net	29,933	29,819
Other long-term liabilities	1,606	1,748
Total liabilities	74,067	68,503
Commitments and contingencies (*Note 7*)		
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; 37,749,468 shares issued and outstanding at March 31, 2024 (unaudited); 34,211,190 shares issued and outstanding at December 31, 2023	6	5
Additional paid-in capital	555,655	441,641
Accumulated other comprehensive loss	(63)	(2)
Accumulated deficit	(280,387)	(244,656)
Total stockholders' equity	275,211	196,988
Total liabilities and stockholders' equity	$ 349,278	$ 265,491

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 March 31,	
	2024	**2023**
Revenues:		
Product sales, net	$ 24,720	$ —
License fees and collaboration revenue	2,894	2,500
Total revenues	27,614	2,500
Operating expenses:		
Cost of sales	1,654	—
Research and development	12,066	12,356
Selling, general and administrative	51,578	15,096
Total operating expenses	65,298	27,452
Loss from operations before other income (expense)	(37,684)	(24,952)
Other income (expense):		
Interest income	3,117	2,293
Interest expense	(983)	(684)
Other income, net	605	6
Unrealized loss on equity investments	(585)	(65)
Change in fair value of equity warrants issued by licensee	(201)	(17)
Total other income, net	1,953	1,533
Net loss	$ (35,731)	$ (23,419)
Other comprehensive loss:		
Unrealized (loss) gain on marketable securities and cash equivalents	(61)	4
Comprehensive loss	$ (35,792)	$ (23,415)
Net loss per share, basic and diluted	$ (1.01)	$ (0.88)
Weighted-average shares outstanding, basic and diluted	35,300,655	26,742,023

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	34,211,190	$ 5	$ 441,641	$ (2)	$ (244,656)	$ 196,988
Net loss	—	—	—	—	(35,731)	(35,731)
Recognition of stock-based compensation expense	—	—	5,519	—	—	5,519
Issuance of common stock, net of issuance costs of $6.7 million	3,281,250	1	98,328	—	—	98,329
Issuance of pre-funded warrants, net of issuance costs of $0.6 million	—	—	9,365	—	—	9,365
Exercise of vested stock options	49,310	—	802	—	—	802
Issuance of common stock upon the vesting of restricted stock units	207,718	—	—	—	—	—
Other comprehensive loss	—	—	—	(61)	—	(61)
Balance as of March 31, 2024	37,749,468	$ 6	$ 555,655	$ (63)	$ (280,387)	$ 275,211

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	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

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

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

	Three Months Ended March 31,	
	2024	**2023**
Cash Flows From Operating Activities:		
Net loss	$ (35,731)	$ (23,419)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	170	104
Amortization of intangible assets	100	—
Accretion of term loan-related costs	114	81
Stock-based compensation	5,519	3,906
Non-cash lease expense	132	151
Unrealized loss on equity investments	585	65
Net amortization/accretion on marketable securities	(290)	(1,484)
Change in fair value of equity warrants issued by licensee	201	17
Unrealized gain from transactions denominated in a foreign currency	—	16
Changes in operating assets and liabilities:		
Accounts receivable, net	(13,264)	(2,500)
Inventory	(929)	—
Other receivables	(383)	3,165
Prepaid expenses	1,065	257
Other non-current assets	106	38
Accounts payable and other accrued liabilities	12,335	(1,046)
Accrued payroll and benefits	(7,287)	(1,313)
Other long-term liabilities	(232)	(8)
Net cash used in operating activities	(37,789)	(21,970)
Cash Flows From Investing Activities:		
Proceeds from maturities of marketable securities	2,500	40,301
Purchases of marketable securities	(104,550)	(28,667)
Purchases of property and equipment	(174)	(340)
Net cash (used in) provided by investing activities	(102,224)	11,294
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock, net of paid issuance costs	98,604	—
Proceeds from issuance of pre-funded warrants, net of paid issuance costs	9,365	—
Proceeds from exercise of equity awards	802	13
Proceeds from term loan	—	5,000
Net cash provided by financing activities	108,771	5,013
Net decrease in cash and cash equivalents	(31,242)	(5,663)
Cash and cash equivalents — beginning of period	224,947	71,660
Cash and cash equivalents — end of period	$ 193,705	$ 65,997
Supplemental Disclosures Noncash Investing and Financing Activities:		
Operating lease right-of-use asset obtained in exchange for operating lease liability	$ 384	$ 116
Interest expense paid in cash	$ 868	$ 593
Offering costs included within accounts payable and accrued liabilities	$ 275	$ —

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, in August 2023, after receiving United States ("U.S.") Food and Drug Administration ("FDA") approval in July 2023.

Follow-On Public Offerings

In August 2023, the Company completed a follow-on public offering under its shelf registration statement on Form S-3 (the "2021 Shelf Registration Statement") of 5,714,285 shares of common stock at a public offering price of $17.50 per share. In September 2023, the underwriters partially exercised the underwriters option to purchase additional shares 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 were $99.3 million, after deducting underwriting discounts, commissions, and other offering-related expenses.

In November 2023, the Company filed a shelf registration statement on Form S-3 that was declared effective by the Securities and Exchange Commission ("SEC") on November 21, 2023, (the "2023 Shelf Registration Statement"), which replaced the 2021 Shelf Registration Statement, and permits the Company 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.

In February 2024, the Company filed an automatic shelf registration on Form S-3 ASR (the "2024 Shelf Registration Statement"). On March 5, 2024 the Company completed an underwritten follow-on public offering under the 2024 Shelf Registration Statement of 2,812,500 shares of the Company’s common stock, par value $0.0001 per share, and, in lieu of common stock to a certain investor, pre-funded warrants to purchase 312,500 shares of its common stock (the “March 2024 Public Offering”). The price to the public was $32.00 per share and $31.9999 per pre-funded warrant, which was the price to the public of each share of common stock sold in the March 2024 Public Offering, minus the $0.0001 exercise price per pre-funded warrant. The pre-funded warrants are exercisable, subject to certain beneficial ownership restrictions, at any time after their original issuance and will not expire; as of March 31, 2024, 312,500 of pre-funded warrants are exercisable. The Company also granted the underwriters a 30-day option to purchase up to 468,750 additional shares of its common stock at the public offering price of $32.00 per share, which the underwriters exercised in full and was completed on March 5, 2024. The aggregate net proceeds received by the Company were $107.7 million, after deducting underwriting discounts, commissions, and other estimated offering-related expenses.

Open Market Sales Agreement

As part of the 2023 Shelf Registration Statement, the Company concurrently filed a sales agreement prospectus covering the sale of up to $100.0 million of common stock pursuant to an Open Market Sale Agreement (the "2023 ATM Prospectus") with Jefferies LLC ("Jefferies"), which replaced the November 1, 2021 Open Market Sale Agreement™ (the "2021 ATM Prospectus"). Under the terms of the 2023 ATM Prospectus, Jefferies will act as the Company's sales agent and is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold.

During the three months ended March 31, 2024, there were no sales of the Company's common stock pursuant to the 2023 ATM Prospectus. During the year ended December 31, 2023, the Company sold 1,000,000 shares of common stock under the 2023 ATM Prospectus for net proceeds of $19.2 million, after deducting broker commissions and 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 its Initial Public Offering ("IPO"), subsequent follow-on public offerings, and the 2023 ATM Prospectus, as well as from proceeds from product sales, the development and license agreement (the "China Out-License") with LianBio Ophthalmology Limited ("LianBio"), and draws on the loan and security agreements with Hercules Capital, Inc. ("Hercules") and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("SVB") (the "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 issuance date of the accompanying Condensed Financial Statements that have been prepared on a going-concern basis.

The Company plans to fund its operations, capital funding and other liquidity needs using existing cash and investments and, to the extent available, cash generated from commercial operations. 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 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 purpose of evaluating financial performance and the allocation of capital and personnel resources. The Company's chief operating decision-maker, 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 accompanying 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 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, 2023, as filed with the SEC on February 27, 2024.

The interim Condensed Balance Sheet as of March 31, 2024, the Condensed Statements of Operations and Comprehensive Loss, and the Condensed Statements of Stockholders' Equity for the three months ended March 31, 2024 and 2023, and the Condensed Statements of Cash Flows for the three months ended March 31, 2024 and 2023 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-month periods are also unaudited. The Condensed Balance Sheet as of December 31, 2023 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 months ended March 31, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024 or any other interim or annual period.

Use of Estimates

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 Condensed Financial Statements and 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. On an ongoing basis, management evaluates its estimates, including those related to recognition of revenue, clinical trial accruals, contract manufacturing accruals, expected demand for inventory, fair value of assets and liabilities, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ materially from those estimates and assumptions used in the preparation of the accompanying Condensed Financial Statements under different assumptions and conditions.

The Company’s Condensed Financial Statements as of and for the three months ended March 31, 2024, 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 these 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 accompanying Condensed Balance Sheets due to their highly liquid nature and availability for use in current operations.

Marketable securities are recorded at fair value with unrealized gains and losses 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 gains and losses as well as credit losses, if any, on marketable securities identified on a specific identification basis are included in other income (expense) on the accompanying Condensed Statements 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.

As of March 31, 2024, the Company's holdings of common stock in the parent company of LianBio was included as marketable securities. As of December 31, 2023, this LianBio common stock was classified as long-term investments due to the Company's intent at that time to hold these shares for longer than one year. These equity securities are designated as available-for-sale with associated unrealized gains or losses reported in other income (expense) within the Condensed Statements of Operations and Comprehensive Loss for each reported period.

Accounts Receivable, Net

Accounts receivable generally consists of amounts due from the Company's customers, which includes pharmaceutical wholesalers and specialty pharmacy providers related to product 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 March 31, 2024.

Inventory

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

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 achieving certain commercial milestones was $4.0 million as of March 31, 2024, and are amortized to cost of sales over their useful life of 10 years from the date of first commercial sale (see *Note 7*). Amortization expense for the three months ended March 31, 2024 was $0.1 million; no amortization expense was recorded for the three months ended March 31, 2023.

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

As of March 31, 2024, the expected future amortization expense for the Company's intangible assets is as follows:

	Amounts
2024 (remaining nine months)	$ 300
2025	400
2026	400
2027	400
2028	400
Thereafter	1,867
Total future amortization	$ 3,767

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 three months ended March 31, 2024 and 2023.

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 months ended March 31, 2024 and 2023.

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 assets and lease liabilities amounts presented in the accompanying Condensed Balance Sheets. The current and noncurrent portion of the operating lease liability are included in accounts payable and other accrued liabilities and other long-term liabilities, respectively, 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 SVB. 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. The following table summarizes the percentage of the Company's product sales from its largest customers:

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

	Three Months Ended March 31, 2024
Customer A	27 %
Customer B	25 %
Customer C	24 %
Customer D	14 %
Customer E	11 %

As of March 31, 2024, amounts due from these five customers each exceeded 10% of gross accounts receivable and accounted for approximately 100% 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 enters 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 the Company's 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. 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 cannot 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 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 8*. 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 payment for executing a drug supply agreement; (vi) development milestone payments; (vii) regulatory milestone payments; and (viii) a one-time termination payment to transition the rights to develop and commercialize TP-03 in China for the treatment of *Demodex* blepharitis to Xi An Grand Chang An Pharmaceutical Co., Ltd ("GrandPharma"). 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. There was no revenue recognized under this arrangement for the three months ended March 31, 2024 and 2023, respectively.

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 in July 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. Therefore, cost of sales of XDEMVY will reflect a lower average per unit cost until the related inventory is sold.

Selling, General and Administrative

Selling, general and administrative costs consist of salaries, benefits, stock-based compensation and other personnel-related costs for the Company's executive, finance, sales and marketing, and other administrative functions. Selling, general and administrative expenses also include sales and marketing costs to support our commercial launch, consulting fees, legal services, rent and other facilities costs, patient assistance donations, and other general operating expenses not otherwise classified as research and development expenses. Advertising costs are expensed as incurred.

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 common 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.

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

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.

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carry forwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain due to the Company's historical operating performance and recorded cumulative net losses in prior fiscal periods. A valuation allowance is recorded to reduce deferred tax assets, because based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized. If/when the Company were to determine that deferred tax assets are realizable, an adjustment to the corresponding valuation allowance would increase the net income in the period that such determination was made.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Interest and penalties related to unrecognized tax benefits, if any, are recorded as a component of income tax expense.

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

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

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 net losses in all periods presented, all otherwise potentially dilutive securities are antidilutive, and accordingly, the reported basic net loss per share equals diluted net loss per share.

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. Outside of the pronouncement below, 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.

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosure* ("ASU 2023-09"). ASU 2023-09 requires annual disclosures of specific categories in the rate reconciliation, additional information for reconciling items that meet a quantitative threshold and a disaggregation of income taxes paid, net of refunds. The standard also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities and is effective for the Company beginning with the 2025 Annual Report on Form 10-K. Early adoption is permitted. ASU 2023-09 should be applied prospectively. Retrospective adoption is permitted. The Company is currently assessing the impact this standard will have on the Company's financial statements.

3. FAIR VALUE MEASUREMENTS

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type are presented in the following table:

	March 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 186,744	$ —	$ —	$ 186,744
U.S. Treasury securities	31,812	—	—	31,812
Commercial paper	—	30,828	—	30,828
Corporate debt securities	—	25,490	—	25,490
Government-related debt securities	—	23,604	—	23,604
Common stock in LianBio	46	—	—	46
Total assets measured at fair value	$ 218,602	$ 79,922	$ —	$ 298,524

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

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

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 224,947	$ —	$ —	$ 224,947
Government-related debt securities	—	2,495	—	2,495
Common stock in LianBio	631	—	—	631
Equity warrants (for LianBio shares)	—	—	225	225
Total assets measured at fair value	$ 225,578	$ 2,495	$ 225	$ 228,298

[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, 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 (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 exercised, and converted into 156,746 shares of LianBio common stock as of December 31, 2022 and are recognized at fair value within long-term investments in the Condensed Balance Sheets as of March 31, 2024 and December 31, 2023.

On February 13, 2024, LianBio announced its plan to wind down its operations. On March 14, 2024, LianBio's Board of Directors made a special cash dividend payment to the Company for $0.7 million (equivalent to $4.80 per share), which was recorded to other income (expense) in the Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2024, and cash and cash equivalents in the Condensed Balance Sheets as of March 31, 2024. LianBio was delisted from NASDAQ in March 2024 and now trades on the over-the-counter markets. As of March 31, 2024 and December 31, 2023, LianBio common stock is classified within Level 1 of the fair value hierarchy, given its publicly reported price.

On March 26, 2024, the Company executed an agreement with LianBio to terminate the unvested third warrant tranche (the "Warrant Termination Agreement") for a cancellation payment of $0.4 million (see *Note 8*). Upon execution of the Warrant Termination Agreement the Company recorded the final change in fair value of the equity warrant to other income (expense) in the Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2024, and removed the equity warrant from other assets in the Condensed Balance Sheet as of March 31, 2024. The third tranche of the equity warrant was classified as Level 3 in the fair value hierarchy and presented within other assets in the accompanying Condensed Balance Sheets as of December 31, 2023. 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.

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

	Value of equity warrants
Fair value as of December 31, 2023	$ 225
Remeasurement of equity warrants prior to termination	(201)
Termination of equity warrants	(24)
Fair value as of March 31, 2024	$ —

	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

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

	March 31, 2024			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash equivalents:				
Money market funds[1]	$ 186,744	$ —	$ —	$ 186,744
U.S. Treasury securities	3,484	—	—	3,484
Commercial paper	3,478	—	(1)	3,477
Total cash equivalents	$ 193,706	$ —	$ (1)	$ 193,705
Marketable securities:				
U.S. Treasury securities	$ 28,341	$ —	$ (13)	$ 28,328
Commercial paper	27,374	—	(23)	27,351
Corporate debt securities	25,509	—	(19)	25,490
Government-related debt securities	23,613	4	(13)	23,604
Common stock in LianBio	1,108	—	(1,062)	46
Total marketable securities	$ 105,945	$ 4	$ (1,130)	$ 104,819

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

	December 31, 2023			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash equivalents:				
Money market funds[1]	$ 224,947	$ —	$ —	$ 224,947
Total cash equivalents	$ 224,947	$ —	$ —	$ 224,947
Marketable securities:				
Government-related debt securities	$ 2,496	$ —	$ (1)	$ 2,495
Total marketable securities	$ 2,496	$ —	$ (1)	$ 2,495
Long-term investments:				
Common stock in LianBio	$ 1,108	$ —	$ (477)	$ 631
Total long-term investments	$ 1,108	$ —	$ (477)	$ 631

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

(1) This balance includes cash requirements settled on a nightly basis.

As of March 31, 2024, substantially all available-for-sale debt securities had a maturity of 12 months or less. Four securities have a contractual maturity between one and two years, with an estimated fair market value of $20.6 million and amortized cost of $20.6 million. As of December 31, 2023, all available-for-sale debt securities had a maturity of 12 months or less. As of March 31, 2024 and December 31, 2023, the Company had twenty-six available-for-sale debt securities and one available-for-sale debt security, respectively, in a continuous gross unrealized loss position for less than one year. As of March 31, 2024 and December 31, 2023, unrealized credit losses on these securities were not material. Further, the Company does not intend to sell these investments prior to maturity and it is not more likely than not that the Company will be required to sell these investments before recovery of their amortized cost basis. 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:

Inventory

Inventory consists of the following:

	March 31, 2024	December 31, 2023
Raw materials	$ 2,533	$ 2,533
Work in process	677	392
Finished goods	826	182
Inventory	$ 4,036	$ 3,107

Property and Equipment, Net

Property and equipment, net consists of the following:

	March 31, 2024	December 31, 2023
Furniture and fixtures	$ 1,269	$ 1,251
Office equipment	681	660
Laboratory equipment	168	167
Leasehold improvements	680	680
Property and equipment, at cost	2,798	2,758
(Less): Accumulated depreciation and amortization	(1,460)	(1,290)
Property and equipment, net	$ 1,338	$ 1,468

Depreciation expense for the three months ended March 31, 2024 and 2023 was $0.2 million and $0.1 million, respectively.

Accounts Payable and Other Accrued Liabilities

Accounts payable and other accrued liabilities consists of the following:

	March 31, 2024	December 31, 2023
Trade accounts payable and other	$ 19,142	$ 18,149
Accrued product sales deductions	16,382	4,867
Accrued clinical studies	461	277
Operating lease liability, current	585	398
Accounts payable and other accrued liabilities	$ 36,570	$ 23,691

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

5. STOCK-BASED COMPENSATION

Common Stock Outstanding and Reserves for Future Issuance

As of March 31, 2024, the Company had 37,749,468 shares of common stock issued and outstanding, which excludes 312,500 of pre-funded warrants that remain exercisable at period end and are reserved for future issuance. As of December 31, 2023 the Company had 34,211,190 shares of common stock issued and outstanding, respectively. 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:

	March 31, 2024	December 31, 2023
Common stock awards reserved for future issuance under 2020 and 2016 Equity Incentive Plans	7,435,442	7,054,222
Common stock awards reserved for future issuance under the 2020 Employee Stock Purchase Plan	2,859,434	2,859,434
Stock options issued and outstanding (unvested and vested) under 2020 and 2016 Equity Incentive Plans	5,217,617	4,760,366
Restricted stock units issued and outstanding (unvested) under 2020 Equity Incentive Plan	1,981,673	1,708,725
Total shares of common stock reserved	17,494,166	16,382,747

Stock-Based Compensation Expense

Stock-based compensation expense was recognized in the accompanying Condensed Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended March 31,	
	2024	2023
Cost of sales	$ 135	$ —
Research and development	1,465	1,163
Selling, general and administrative	3,919	2,743
Total stock-based compensation	$ 5,519	$ 3,906

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 March 31,	
	2024	2023
Expected term (in years)	6.25	6.25
Weighted average risk-free interest rate	4.08 %	4.20 %
Weighted average volatility	71.23 %	71.9 %
Dividend yield rate	— %	— %
Weighted-average grant-date fair value per stock option	$ 35.09	$ 15.07

Stock Option Activity

Stock option activity during the three months ended March 31, 2024 was as follows:

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	Number of Shares	Weighted-Average Exercise Price/Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[1]
Outstanding - December 31, 2023	4,760,366	$ 16.62	7.53	$ 34,128
Granted	633,887	$ 35.09		
Exercised	(49,310)	$ 16.21		
Forfeited	(127,326)	$ 18.03		
Expired	—	—		
Outstanding— March 31, 2024	5,217,617	$ 18.83	7.46	$ 96,254
Exercisable— March 31, 2024	2,972,207	$ 15.51	6.41	$ 65,826
Unvested—March 31, 2024	2,245,410	$ 23.22	8.86	$ 30,428

[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 March 31, 2024.

As of March 31, 2024, there was approximately $33.0 million of unrecognized compensation expense related to unvested stock options, which the Company expects to recognize over a weighted average period of 2.6 years.

Restricted Stock Unit Activity

Restricted stock unit activity during the three months ended March 31, 2024 was as follows:

	Number of Shares	Weighted-Average Exercise Price/Share
Outstanding - December 31, 2023	1,708,725	$ 16.31
Granted	596,726	$ 36.03
Vested	(207,718)	$ 16.11
Forfeited	(116,060)	$ 17.62
Outstanding— March 31, 2024	1,981,673	$ 22.19

As of March 31, 2024, there was approximately $41.0 million of unrecognized compensation expense related to unvested restricted stock units, which the Company expects to recognize over a weighted average period of 3.5 years.

Employee Stock Purchase Plan ("ESPP")

Stock-based compensation expense related to the ESPP was $0.2 million and $0.1 million, respectively, for the three months ended March 31, 2024 and 2023.

6. NET LOSS PER SHARE

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

	Three Months Ended March 31,	
	2024	2023
Net loss	$ (35,731)	$ (23,419)
Weighted-average shares outstanding—basic and diluted[1]	35,300,655	26,742,023
Net loss per share—basic and diluted	$ (1.01)	$ (0.88)

[1] Weighted-average shares outstanding includes pre-funded warrants issued on March 5, 2024.

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

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 March 31,	
	2024	2023
Stock options, unexercised—vested and unvested	5,217,617	4,596,414
Restricted stock units—unvested	1,981,673	1,128,373
Total	7,199,290	5,724,787

7. 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. On March 20, 2024, the Company executed an amendment for an additional office suite. This amendment was accounted for as a lease modification and resulted in the recognition of an operating lease right-of-use asset valued at $0.4 million as of the execution date. As of March 31, 2024, the Company had six active leases for adjacent office and laboratory suites in Irvine, California with a lease term through January 2027.

The below table summarizes the components of total lease expense:

	Three Months Ended March 31,	
	2024	2023
Operating lease expense	$ 179	$ 170
Variable lease expense	103	81
Total lease expense	$ 282	$ 251

As of March 31, 2024, the Company's facility leases had a remaining lease term of 2.8 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:

	March 31, 2024
2024 (remaining nine months)	$ 660
2025	961
2026	994
2027	83
2028	—
Total future lease payments, undiscounted	2,698
(Less): Imputed interest	(343)
(Less): Tenant improvement allowance	(164)
Present value of operating lease payments	$ 2,191
Operating lease liability, current	585
Operating lease liability, noncurrent	1,606
Total operating lease liability	$ 2,191

In-License Agreements for Lotilaner

Elanco In-License 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 Elanco 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 three months ended March 31, 2023.

The Company has made cash payments to Elanco under the Eye and Derm Elanco 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 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 Balance Sheet as of December 31, 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.

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 is obligated to pay tiered contractual royalties to Elanco in the mid to high single digits of its net sales. If the Company received certain types of payments from its sublicensees, it was 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, which occurred in July 2023 with FDA approval of XDEMVY. 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 months ended March 31, 2024, and accounts payable and other accrued liabilities in the accompanying Condensed Balance Sheets as of March 31, 2024. Royalty expense during the three months ended March 31, 2024 was $1.2 million.

Elanco In-License 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 potential treatment of Lyme disease. The Company is required to make further cash payments under this agreement upon the achievement of various clinical milestones up to 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, including severance and change in control agreements, with six 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 varies, 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.

8. OUT-LICENSE AGREEMENTS

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 for the treatment of *Demodex* blepharitis and Meibomian Gland Disease. LianBio was 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 based upon the signing of an agreement for which the Company has no ongoing obligations, resulting in $2.5 million recognized as license fees and collaboration revenue in the accompanying Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2023.

On February 13, 2024, LianBio announced its plan to wind down its operations and on March 14, 2024 made a special cash dividend payment to the Company for $0.7 million (equivalent to $4.80 per share - see *Note 3*). On March 26, 2024, the Company executed an agreement with Xi An Grand Chang An Pharmaceutical Co., Ltd. ("GrandPharma"), a subsidiary of Grand Pharmaceutical Group Limited, and LianBio to transition the rights to develop and commercialize TP-03 in China for the treatment of *Demodex* blepharitis from LianBio to GrandPharma (the "Novation Agreement"). Upon execution of the Novation Agreement, the China Out-License agreement with LianBio was assigned to GrandPharma and a one-time payment of $2.5 million (the "Termination Payment) was triggered and due to the Company from LianBio within fifteen days. This Termination Payment was recorded to license fees and collaboration revenue in the Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2024 and to other receivables in the Condensed Balance Sheets as of March 31, 2024, as the $2.5 million cash payment was not yet received by the Company until April 5, 2024. The Novation Agreement amended the $15.0 million future development milestone payable on China regulatory approval of the China Out-License agreement with a combined condition of patent issuance related to TP-03 in China.

Simultaneous with the execution of the Novation Agreement, the Company entered into an agreement with LianBio to terminate the unvested third tranche of the equity warrants related to the purchase of 78,373 shares of LianBio common stock for a total cancellation payment of $0.4 million (the "Warrant Cancellation Payment"). This Warrant Cancellation Payment was recorded to license fees and collaboration revenue in the Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2024 and other receivables in the Condensed Balance Sheets as of March 31, 2024.

Through March 31, 2024, the Company received aggregate payments from LianBio totaling $83.2 million, comprised of (i) initial consideration of $15.0 million, (ii) $67.5 million for the achievement of specified milestones, and (iii) $0.7 million related to a special cash dividend.

As of March 31, 2024 the Company is eligible to receive further consideration from GrandPharma upon the achievement of additional TP-03 events, including: (i) additional regulatory and/or patent milestones of up to an aggregate of $20.0 million; (ii) China-based TP-03 sales threshold milestone payments of up to an aggregate of $100.0 million; and (iii) tiered low-to-high-teen royalties for China Territory TP-03 product sales.

9. CREDIT FACILITY AGREEMENT

On February 2, 2022, the Company executed the Credit Facility with Hercules and SVB that expires on February 2, 2027. As security for the obligations under the agreement, the Company granted a continuing security interest in substantially all of the Company's assets, excluding intellectual property on which there is a negative pledge. Concurrent with the execution of the Credit Facility, the Company made a $20.0 million draw.

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

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 drawdown 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 was drawn on or before September 15, 2023. The Company did not incur any lender fees as part of this First Amendment.

On August 23, 2023, the Company entered into a second amendment to the loan and security agreement (the "Second Amendment"). The Second Amendment updated the terms of the amount and proportion of the Company's cash required to be maintained at SVB or affiliates of SVB. The Company did not incur any lender fees as part of this Second 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. On March 15, 2024, the $15.0 million tranche related to the Company's NDA submission with the FDA for TP-03 in September 2022 and the $35.0 million tranche related to the FDA approval of XDEMVY in July 2023 both expired and were no longer available to be drawn as of period end. As of March 31, 2024, the Credit Facility provides for a remaining aggregate principal amount of up to $75.0 million with tranched availability as follows: $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 March 31, 2024.

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 March 31, 2024 and is accreted to interest expense through maturity.

As of March 31, 2024 and 2023, the effective interest rate for the full term of the Credit Facility was 11.96% and 12.12%, respectively. 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 March 31,	
	2024	2023
Interest expense for term loan	$ 869	$ 602
Accretion of end of term charge	80	53
Amortization of debt issuance costs	34	29
Total interest expense related to term loan	$ 983	$ 684

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)

	March 31, 2024	December 31, 2023
Term loan, gross	$ 30,000	$ 30,000
Debt issuance costs	(875)	(875)
Accretion of end of term charge	517	438
Accumulated amortization of debt issuance costs	291	256
Term loan, net	$ 29,933	$ 29,819

10. RELATED PARTY TRANSACTIONS

Consulting Agreements

The Company has a preexisting consulting agreement with a board member who was appointed in December 2021. During the year ended December 31, 2023, this consulting agreement provided 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.

On January 30, 2024, this consulting agreement with the board member was amended to provide for annual cash compensation of approximately $0.4 million and an additional option grant to purchase 10,000 shares of the Company's common stock, with exercise price of $27.49 per share. This amended 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.

During the three months ended March 31, 2024 and 2023, the Company recorded $0.1 million and $0.1 million, respectively, of selling, general and administrative expenses in the accompanying Condensed Statements of Operations and Comprehensive Loss related to this amended consulting agreement.

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 months ended March 31, 2024, the Company recorded $0.1 million 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.

11. SUBSEQUENT EVENTS

Credit Facility with Pharmakon Advisors, LP

On April 19, 2024, the Company executed a loan and security agreement (the "Pharmakon Credit Facility") with funds associated with Pharmakon Advisors, LP. The Company drew $75.0 million in the initial tranche of the term loan in April 2024, a portion of which was utilized to repay all outstanding indebtedness on the existing Credit Facility term loan, resulting in total net proceeds of $39.8 million. The agreement provides for three potential additional term loan tranches in principal amounts up to $25.0 million, $50.0 million, and $50.0 million, respectively, subject to customary conditions to funding and, in the case of the last two tranches, achieving minimum net sales milestones. The three potential additional term loan tranches may be requested on or prior to December 31, 2024, June 30, 2025 and December 31, 2025, respectively. The Pharmakon Credit Facility matures on April 19, 2029.

The loan bears interest at a floating rate based upon the secured overnight financing rate ("SOFR"), plus a margin of 6.75% per annum, and the SOFR is subject to a 3.75% floor. The agreement contains representations and warranties, and affirmative and negative covenants in each case. There is also no warrant coverage to the lenders and no financial covenants associated with the financing.

Equity Investment in Privately-held Eye Care Company

On April 5, 2024, the Company participated in an equity round of an early clinical-stage private eye care company. Pursuant to the terms of a Preferred Stock Purchase Agreement the Company purchased $3.0 million of preferred stock. Drs. Azamian and Link are board members and the Company's former director, Michael Ackermann, is an executive and board member of this private company. The Company owns a small minority of this private company.

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 and product candidates, opportunity and patient populations for our product and product candidates, including XDEMVY;
- 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 and our product candidates to meet existing or future regulatory standards;
- our plans relating to the further development and manufacturing of our product and 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 Jumpstart Our Business Startups Act of 2012 (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"), August 2023 (the "August 2023 Public Offering"), and March 2024 (the "March 2024 Public Offering", collectively the “Follow-On Public Offerings”), as well as proceeds from our sales agreement prospectus (the "2023 ATM Prospectus"), and drawdowns from our loan and security agreement (the "Pharmakon Credit Facility") with funds associated with Pharmakon Advisors, LP ("Pharmakon").

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 Securities and Exchange Commission ("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%, formerly known as TP-03, was approved by the U.S. Food and Drug Administration ("FDA") in July 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 may be as many as approximately 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.

XDEMVY targets and eradicates 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 with no GABA-Cl inhibition in humans.

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 have also completed, and/or have ongoing clinical trials for TP-03 for the potential treatment of MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme disease prophylaxis, among others.

We intend to further advance our pipeline with the lotilaner API to address several diseases in human medicine, including eye care, dermatology, and infectious disease prevention. We are investigating the development of our product candidates to address targeted diseases with high unmet medical needs, which currently include TP-03 for the potential treatment of MGD, TP-04, a novel gel formulation of lotilaner for the potential treatment of rosacea, and TP-05, a novel investigative oral formulation of lotilaner, for potential Lyme disease prophylaxis and community malaria reduction.

Recent Business and Clinical Highlights

XDEMVY: In July 2023, XDEMVY was approved by the FDA as the first and only approved therapeutic for *Demodex* blepharitis. 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.

- During the first quarter of 2024 we recognized $24.7 million in net product sales, an increase of 89% compared to the fourth quarter of 2023.
- Approximately 26,000 bottles of XDEMVY were delivered to patients during the first quarter of 2024, an increase of 65% compared to the fourth quarter of 2023.
- Approximately 8,000 ECPs have started patients on XDEMVY with more than 50% of ECPs prescribing XDEMVY to multiple patients as of May 3, 2024.
- Gross-to-net discounts remained consistent at approximately 55% given the impact of expected first quarter dynamics on net sales.
- We launched the "Mite Party" campaign, dynamic, multi-channel campaigns for XDEMVY, that was designed to elevate consumer awareness of *Demodex* blepharitis through relatable messaging and compelling visuals.
- We continued to expand payer coverage of XDEMVY.
- Secured several contracts, including two major commercial plans with approximately 18 million covered lives that placed XDEMVY on preferred status, and expect to begin recognizing the benefits of these contracts in the second quarter of 2024.
- We continue to be actively engaged in contracting discussions with all the key commercial and Medicare accounts and we remain on track for expected broad commercial coverage by the end of 2024 and broad Medicare coverage beginning in 2025.
- On track with plans to deploy approximately 50 additional sales force representatives and leaders by the end of the third quarter of 2024.
- Two additional independent meta-analyses of randomized controlled trials (Akhtar et al. and Talha et al.), demonstrating the efficacy of XDEMVY were published in peer-reviewed journals. To date, we are aware of four independent meta-analyses in total that have been published.

TP-03 Meibomian Gland Disease, Ersa Trial: In December 2023, we announced positive topline results of the Ersa Phase 2a clinical trial evaluating TP-03 (lotilaner ophthalmic solution, 0.25%) administered twice daily or three times a day for 12 weeks for the treatment of MGD in patients with *Demodex* mites. TP-03 demonstrated statistically significant and clinically meaningful improvements compared to baseline in two objective measures of the disease – the presence and quality

of liquid secretion as measured by the Meibomian Gland Secretion Score and the number of glands secreting normal (clear) liquid and was well tolerated. We plan to discuss and determine the potential regulatory path with the FDA by the end of 2024.

TP-04 Rosacea, Galatea Trial: On February 27, 2024, we announced positive topline results from the Galatea trial evaluating TP-04, a novel gel formulation of lotilaner, for the treatment of rosacea which demonstrated statistically significant improvements ($p<0.05$) in inflammatory lesions and Investigator's Global Assessment score (change in baseline and success rate) were observed compared to vehicle at week 12. TP-04 was generally well tolerated. We plan to discuss and determine the potential regulatory path with the FDA by the end of 2024.

TP-05 Lyme Disease, Carpo Trial: On February 22, 2024, we announced positive topline results from the Carpo trial, which demonstrated statistical significance in the mortality of ticks compared to vehicle ($p<0.001$), regardless of treatment arm, and was well tolerated. The Carpo trial is designed to evaluate TP-05, a novel investigative oral, non-vaccine pharmacological prophylactic for the potential prevention of Lyme disease in humans. The Carpo trial evaluated 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. We plan to discuss and determine the potential regulatory path with the FDA by the end 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: On February 13, 2024, LianBio Ophthalmology Limited ("LianBio") announced its plan to wind down its operations. On March 14, 2024, LianBio's Board of Directors made a special cash dividend payment to the Company of $0.7 million (equivalent to $4.80 per share, the fair value of the LianBio common stock).

On March 26, 2024, we executed an agreement with Xi An Grand Chang An Pharmaceutical Co., Ltd. ("GrandPharma"), a subsidiary of Grand Pharmaceutical Group Limited, and LianBio to transition the rights to develop and commercialize TP-03 in China for the treatment of *Demodex* blepharitis (the "Novation Agreement"). Upon execution of the Novation Agreement, the development and license agreement with LianBio (the "China Out-License"), was assigned to GrandPharma and a one-time payment of $2.5 million (the "Termination Payment") was triggered, which was received on April 5, 2024. Additionally, the Novation Agreement amended the $15.0 million future development milestone related to the approval of TP-03 for the treatment of *Demodex* blepharitis in the China Territory, as defined in the China Out-License, with a combined condition of issuance of a patent related to TP-03. All references to the China Out-License in this Quarterly Report on Form 10-Q shall refer to the China Out-License, as assigned from LianBio to GrandPharma, pursuant to the Novation Agreement.

Simultaneous with the execution of the Novation Agreement, we entered into an agreement with LianBio to terminate the third tranche of the equity warrants related to the purchase of 78,373 shares of LianBio common stock for a total cancellation payment of $0.4 million (the "Warrant Termination Payment"), which was received on April 5, 2024.

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, commercializing XDEMVY, 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, our subsequent follow-on public offerings in May 2022, August 2023, and March 2024, and our 2023 sales agreement prospectus, as well as proceeds from net product sales, our China Out-License, and drawdowns from the Credit Facility and the Pharmakon 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 $35.7 million and $23.4 million for the three months ended March 31, 2024 and 2023, 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 the potential Lyme disease 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 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 from GrandPharma related to the Novation Agreement.

Until such time as we can generate significant revenue from product sales and achieve profitability, if ever, we expect to finance our operations through 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 predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate 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 March 31, 2024, our aggregate cash, cash equivalents and marketable securities was $298.5 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 and the types of accounts we hold, but we 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 Item 1A of Part II of this Quarterly Report on Form 10-Q, 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.

Components of our Results of Operations

Comparison of the Three Months Ended

	Three Months Ended March 31,		
	2024	2023	Change
	(in thousands)		
Revenues:			
Product sales, net	$ 24,720	$ —	*
License fees and collaboration revenue	2,894	2,500	394
Total revenues	27,614	2,500	25,114
Operating expenses:			
Cost of sales	1,654	—	*
Research and development	12,066	12,356	(290)
Selling, general and administrative	51,578	15,096	36,482
Total operating expenses	65,298	27,452	37,846
Loss from operations before other income (expense)	(37,684)	(24,952)	(12,732)
Other income (expense):			
Interest income	3,117	2,293	824
Interest expense	(983)	(684)	(299)
Other income, net	605	6	599
Unrealized loss on equity investments	(585)	(65)	(520)
Change in fair value of equity warrants issued by licensee	(201)	(17)	(184)
Total other income, net	1,953	1,533	420
Net loss	$ (35,731)	$ (23,419)	$ (12,312)

* Not meaningful for further disclosure.

Product Sales, Net

During the three months ended March 31, 2024 we recognized revenue of $24.7 million from product sales, net of rebates, chargebacks, discounts, and other adjustments driven by approximately 26,000 prescriptions of XDEMVY to patients. During the three months ended March 31, 2023, there were no product sales, net recognized.

License Fees and Collaboration Revenue

For the three months ended March 31, 2024, we recognized $2.9 million of license fees and collaboration revenue including (i) $2.5 million for the Termination Payment related to the Novation Agreement and (ii) $0.4 million for the Warrant Termination Payment. During three months ended March 31, 2023 we recognized $2.5 million related to the achievement of a contractual milestone under the China Out License. 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 Novation Agreement to the extent other events occur, specifically related to (i) milestone achievement of certain regulatory events in the China Territory, and (ii) royalties and milestones from our licensee's product sales of TP-03 in the China Territory.

Cost of Sales

For the three months ended March 31, 2024, we recognized $1.7 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. During the three months ended March 31, 2023, there were no cost of sales recognized.

Research and Development Expenses

	Three Months Ended March 31,		
	2024	2023	Change
Direct external expenses:			
TP-03 program	$ 3,505	$ 3,004	$ 501
TP-04 program	550	600	(50)
TP-05 program	526	2,174	(1,648)
Other early-stage programs	79	180	(101)
Indirect expenses:			
Compensation and personnel-related	6,755	5,241	1,514
Other	651	157	494
Elanco milestone expenses	—	1,000	(1,000)
Total research and development expenses	$ 12,066	$ 12,356	$ (290)

Research and development expenses decreased by $0.3 million for the three months ended March 31, 2024, as compared to the prior year period. This decrease was primarily due to (i) $1.6 million of decreased TP-05 program expenses including $1.0 million for the food effect study and $0.5 million for the Carpo trial, and (ii) $1.0 million of prior period milestone expense related to our in-license agreement with Elanco. These decreases were partially offset by (i) $1.5 million of increased payroll and personnel-related costs (including increased stock-based compensation expense of $0.3 million) related to 20 employee additions period over period to drive our product development initiatives, (ii) $0.5 million of other indirect expenses, and (iii) $0.5 million of increased TP-03 program expenses primarily due to Phase 4 studies, which was partially offset by completion of the Ersa Phase 2a trial.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $36.5 million for the three months ended March 31, 2024, as compared to the prior year period. The increase was primarily due to (i) $11.3 million of increased payroll and personnel-related costs (including increased stock-based compensation expense of $1.2 million) for 122 corporate employee additions, period over period, to support our business growth and commercial leadership hires for our recent commercial launch of XDEMVY, (ii) $12.2 million of increased commercial and market research costs as we continued our commercial expansion for the recent commercial launch of XDEMVY, and (iii) $12.7 million of increased IT applications, legal, professional and other corporate expenses. We expect our field sales headcount and associated vendor expenses to continue to increase during 2024 due to further growth and expansion of our commercial activities for XDEMVY.

Other Income, Net

Other income, net increased by $0.4 million primarily due to (i) $0.8 million of increased interest income earned on our cash, cash equivalents and marketable securities, and (ii) $0.6 million of other income, net substantially related to dividend income from LianBio. These increases were partially offset by decreases in other income, net including (i) $0.5 million change in fair value of the LianBio common stock (ii) increased interest expense of $0.3 million on the Credit Facility, and (iii) $0.2 million change in fair value related to the final mark-to-market adjustment on the unvested third tranche equity warrant.

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 the issuance of common stock through our IPO, Follow-on Public Offerings, and the 2023 ATM Prospectus, as well as proceeds from net product sales, the China Out-License, and drawdowns from the Credit Facility and the Pharmakon Credit Facility. As of March 31, 2024, we had cash, cash equivalents and marketable securities of $298.5 million.

Follow-On Public Offerings

In August 2023, we completed the August 2023 Public Offering in which 5,714,285 shares of our common stock were sold at a public offering price of $17.50 per share. In September 2023, the underwriters partially exercised an option to purchase an additional 355,164 shares of our common stock at the public offering price of $17.50 per share. After giving effect

to the exercise of the underwriters' option, we sold a total of 6,069,449 shares and received aggregate net proceeds of $99.3 million, after deducting underwriting discounts, commissions, and other offering-related expenses.

In February 2024, we filed an automatic shelf registration statement on Form S-3 ASR (the "2024 Shelf Registration Statement"). On March 5, 2024 we completed an underwritten follow-on public offering under the 2024 Shelf Registration Statement on Form S-3 of 2,812,500 shares of our common stock, par value $0.0001 per share, and, in lieu of common stock to a certain investor, pre-funded warrants to purchase 312,500 shares of our common stock (the "March 2024 Public Offering"). The price to the public was $32.00 per share and $31.9999 per pre-funded warrant, which was the price to the public of each share of common stock sold in the March 2024 Public Offering, minus the $0.0001 exercise price per pre-funded warrant. We also granted the underwriters a 30-day option to purchase up to 468,750 additional shares of its common stock at the public offering price of $32.00 per share, which the underwriters exercised in full on March 1, 2024. We received approximately $107.7 million in aggregate net proceeds, after deducting underwriting discounts, commissions, and other estimated offering-related expenses.

Open Market Sales Agreement

During the year ended December 31, 2023, we sold 1,000,000 shares of our common stock for $20.00 per share under a sales agreement prospectus filed in November 2023, pursuant to the 2023 Shelf Registration Statement (defined below) covering the sale of up to $100.0 million of our common stock pursuant to an Open Market Sale Agreement™ (the "2023 ATM Prospectus") with Jefferies LLC ("Jefferies"). This resulted in net proceeds of $19.2 million, after deducting broker commissions and offering related expenses.

During the three months ended March 31, 2024, there were no sales of our common stock pursuant to the 2023 ATM Prospectus.

China Out-License

As of the date of this filing, we have received $86.1 million of total proceeds in connection with our China Out-License comprised of (i) $15.0 million of initial consideration, (ii) $67.5 million for the achievement of specified milestones, (iii) $0.7 million related to a special cash dividend, (iv) $2.5 million related to the Novation Agreement, and (v) $0.4 million related to the Warrant Termination Agreement.

As of March 31, 2024 the Company is eligible to receive further consideration from GrandPharma upon the achievement of additional TP-03 events, including: (i) $20.0 million of potential future regulatory and/or patent milestones; (ii) $100.0 million of potential future China-Based TP-03 sales threshold milestones; and (iii) tiered low-to-high-teen royalties for China Territory TP-03 product sales.

Credit Facilities

In February 2022, we executed the Credit Facility with Hercules and SVB. Concurrent with the execution of the Credit Facility we drew $20.0 million. This Credit Facility was amended in January 2023 and August 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 drawdown the 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 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 balance on the Credit Facility was $29.9 million as of March 31, 2024 and included a four-year period of interest-only payments. The agreement was extendable for a fifth year to February 2027 maturity, upon our expected achievement of required conditions. As of March 31, 2024, we had $75.0 million of remaining tranched availability.

On April 19, 2024 the Company executed the Pharmakon Credit Facility with Pharmakon. The Pharmakon Credit Facility provides a $75.0 million initial term loan which was drawn in April 2024, a portion of which was utilized to repay all outstanding indebtedness associated with the prior Credit Facility, for total net proceeds of $39.8 million. The Pharmakon Credit Facility provides for three potential additional term loan tranches in principal amounts up to $25.0 million, $50.0 million, and $50.0 million, respectively, subject to customary conditions to funding and, in the case of the last two tranches, achieving minimum net sales milestones. The three additional tranches may be requested on or prior to December 31, 2024, June 30, 2025 and December 31, 2025, respectively. The Pharmakon Credit Facility matures on April 19, 2029.

The Pharmakon Credit Facility will bear interest at a floating rate based upon the secured overnight financing rate ("SOFR"), plus a margin of 6.75% per annum. The SOFR is subject to a 3.75% floor. The Pharmakon Credit Facility contains representations and warranties, affirmative and negative covenants in each case. There is also no warrant coverage to the lenders and no financial covenants associated with the financing.

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 $280.4 million as of March 31, 2024.

We believe that our cash, cash equivalents and marketable securities of $298.5 million as of March 31, 2024 is sufficient to fund our current and planned operations for at least the next twelve months from this Quarterly Report on Form 10-Q. We also anticipate having additional availability from our Pharmakon Credit Facility of at least $25.0 million on or prior to December 31, 2024 and another $100 million contingent on reaching certain sales milestones. 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 Statements

In February 2024, we filed the 2024 Shelf Registration Statement, which permits us to offer and sell from time to time, in one or more series of issuances and on terms that we will determine at the time of the offering, our common stock, preferred stock, debt securities, warrants, units or any combination of such securities.

In November 2023, we filed a shelf registration statement on Form S-3 that was declared effective by the SEC on November 21, 2023, (the "2023 Shelf Registration Statement"), which replaced the November 2021 Shelf Registration Statement, as defined below, and permits us to offer up to $300.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, including in units from time to time.

As part of the 2023 Shelf Registration Statement, we concurrently filed the 2023 ATM Prospectus with Jefferies. Under the terms of the 2023 ATM Prospectus, Jefferies will act as the Company's sales agent and is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold. In December 2023, we sold 1,000,000 shares of our common stock under the 2023 ATM Prospectus for $20.00 per share and received net proceeds of $19.2 million, after deducting broker commission and offering-related expenses.

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 "2021 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. The 2023 Shelf Registration Statement replaced the 2021 Shelf Registration Statement.

Also, as part of the 2021 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 "2021 ATM Prospectus") with Jefferies LLC. We did not sell any shares of our common stock under the 2021 ATM Prospectus. On July 31, 2023, in connection with the August 2023 Public Offering, we terminated the sales agreement prospectus relating to the 2021 ATM Prospectus.

Other Liquidity Risks

We expect to incur significant operating losses for the foreseeable future, and for 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 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 Pharmakon 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:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (37,789)	$ (21,970)
Investing activities	(102,224)	11,294
Financing activities	108,771	5,013
Net decrease in cash and cash equivalents	$ (31,242)	$ (5,663)

Net Cash Used in Operating Activities

Net cash used in operating activities was $37.8 million for the three months ended March 31, 2024, which primarily consisted of our net loss of $35.7 million and a net decrease in net operating assets and liabilities of $8.6 million, partially offset by a net increase in non-cash and other changes of $6.5 million. The net decrease in net operating assets and liabilities was primarily due to an increase in accounts receivable of $13.3 million and a decrease in accrued payroll and benefits of $7.3 million, partially offset by an increase in accounts payable and other accrued liabilities of $12.3 million. The net non-cash and other charges were primarily related to stock-based compensation expense of $5.5 million and unrealized loss on equity investments of $0.6 million.

Net cash used in operating activities was $22.0 million for the three months ended March 31, 2023, which primarily consisted of our net loss of $23.4 million and net decrease in net operating assets and liabilities of $1.4 million, partially offset by a net increase in non-cash and other changes of $2.9 million. The net decrease in net operating assets and liabilities was primarily due to an increase in accounts receivable of $2.5 million, a decrease in accrued payroll and benefits of $1.3 million, and a decrease in accounts payable and other accrued liabilities of $1.0 million, partially offset by a decrease in other receivables of $3.2 million. The net increase in non-cash and other charges were primarily related to stock-based compensation expense of $3.9 million, partially offset by net amortization/accretion on marketable securities of $1.5 million.

Net Cash Used in Provided by Investing Activities

Net cash used in investing activities was $102.2 million for the three months ended March 31, 2024, and primarily relates to $104.6 million of purchased investments and $0.2 million of purchased furniture, fixtures, office equipment and leasehold improvements for our laboratory and administrative offices, partially offset by $2.5 million of proceeds from maturities of investments.

Net cash provided by investing activities was $11.3 million for the three months ended March 31, 2023, and primarily related to $40.3 million of proceeds from maturities of investments, partially offset by $28.7 million of purchased investments and $0.3 million of purchased furniture, fixtures and leasehold improvements for our laboratory and administrative offices.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $108.8 million for the three months ended March 31, 2024, and primarily relates to $98.6 million of net proceeds from the issuance of common stock and $9.4 million of net proceeds from the issuance of pre-funded warrants related to the March 2024 Public Offering, and $0.8 million of proceeds from employee stock option exercises.

Net cash provided by financing activities was $5.0 million for the three months ended March 31, 2023, which substantially relates to proceeds from the Credit Facility.

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"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of these Condensed Financial Statements, as well as the reported revenue earned and 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, 2023.

While our significant accounting policies are described in the notes to our financial statements also included in this Annual Report on Form 10-Q, we believe these critical accounting policies are the most important to understanding and evaluating our reported financial results.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in the notes to which they relate within these accompanying Condensed Financial Statements.

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 March 31, 2024.

JOBS Act Accounting Election

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

We will remain an emerging growth company until the *earliest of* (1) 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

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, is processed, recorded, summarized and reported within the time periods specified in the SEC’s rules and forms. These disclosure controls and procedures include, among other processes, controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow for timely decisions regarding required disclosure.

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2024. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2024, the Company's disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose 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 rules and forms, and 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 by Exchange Act Rule 13a-15(f) and 15d-15(f) during the period covered by this report that have materially affected, or are 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 control 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 on 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

Investing in our common stock is speculative and involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and the related notes. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Special Note Regarding Forward-Looking Statements."

Risks Related to our Business and Operations

We are an early commercial-stage biopharmaceutical company with a limited operating history and a single product approved for commercial sale. We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.

We have one product, XDEMVY, which recently obtained FDA approval for the treatment of *Demodex* blepharitis in the U.S. in July 2023. We have incurred net losses each year since our company's formation in 2016. We have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock, convertible promissory notes and the sale of our common stock in our IPO, subsequent Follow-On Public Offerings, and under our 2023 ATM Prospectus, as well as proceeds from product sales, net, our China Out-License and draws from our Credit Facility and Pharmakon Credit Facility. For the three months ended March 31, 2024 and 2023 our net losses were $35.7 million and $23.4 million, respectively. As of March 31, 2024 and December 31, 2023, we had an accumulated deficit of $280.4 million and $244.7 million, respectively. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indicator of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. We initiated sales and marketing activities to commercialize XDEMVY in August 2023. We expect to incur operating losses over the next several years and for the foreseeable future until our revenue from product sales from XDEMVY and any other approved products exceeds expenses, which may never occur. We may never achieve profitability and, even if we do, we may not be able to sustain or increase our profitability. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our accumulated deficit and working capital.

We expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses will increase substantially if and as we:

- continue to commercialize XDEMVY and any other products for which we may obtain marketing approval;
- enhance our product development and planned future commercialization efforts of our product candidates, including through hiring additional clinical, regulatory, quality control and scientific personnel;
- seek marketing approvals and reimbursement for our product candidates;
- prepare for and initiate additional preclinical, clinical and other studies for our product candidates;
- change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;

- create additional infrastructure to support our operations as a public company, including adding operational, financial and management information systems and personnel;
- seek to identify, assess, acquire or develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments in connection with the development or approval of our product candidates;
- maintain, protect, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond our expectations if, among other things:

- there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates;
- we are required by regulatory authorities to perform clinical trials or studies in addition to, or different than, those that we currently expect; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

We expect to continue to expend substantial resources in connection with our commercialization efforts. If we are successful in commercializing more product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We expect to expand our development, regulatory, operational, sales, marketing, and distribution capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As we advance our research and development programs and commercialization efforts, we expect to experience continued growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs, manufacturing, quality control, sales, marketing, and distribution. To manage our anticipated future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and execution of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations also could lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of our product candidates. We cannot assure you that the services of such

third-party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to successfully commercialize XDEMVY, obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

We are highly dependent on the expertise of our executive officers, as well as the other members of our scientific and clinical teams and certain advisors to develop and soundly execute our business strategy. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain key person insurance for any of our executives or employees.

Recruiting and retaining qualified scientific, clinical, and sales and marketing personnel, are critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and our business, prospects, financial condition and results of operations may be adversely affected.

Many of our employees have become or will become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

Our information technology systems, or those of our third-party contract research organizations ("CROs") or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of XDEMVY and our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality, availability and integrity of such confidential information. We also have outsourced elements of

our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs, contract manufacturing organization ("CMO"), and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, interruptions or cyber incidents resulting from the conflict between Russia and Ukraine, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. Further, due to the political uncertainty involving Russia and Ukraine, there is an increased likelihood that escalation of tensions could result in cyber attacks that could either directly or indirectly impact our operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the commercial operations of XDEMVY and further development of our product candidates could be delayed.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology and cybersecurity will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. Our inability to use or access our information systems at critical points in time could adversely affect the timely and efficient operation of our business. Any delayed sales, significant costs or lost customers resulting from these technology failures could adversely affect our business, operations, and financial results. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption to our commercial operations of XDEMVY and further development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, including private lawsuits or class actions under the California Consumer Privacy Act ("CCPA"), which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

We maintain specific coverage to mitigate losses associated with certain cybersecurity incidents that impact our or our third parties' systems, networks, and technologies.

Product liability lawsuits against us could cause us to incur substantial liabilities, could divert our resources and could limit or delay our commercialization of XDEMVY or any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the commercialization of XDEMVY and the testing of our product candidates in human clinical trials and will continue to face risk if we commercially sell any future products we may develop. The sale of XDEMVY and any approved products in the future as well as the use of product candidates by us in clinical trials may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that XDEMVY or our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- the inability or delay of our efforts to commercialize XDEMVY or any products that we may develop;
- decreased demand for XDEMVY or any product candidates or products that we may develop;
- withdrawal of regulatory approval, recall, restriction on the approval or a black box warning or contraindication for XDEMVY or any future product candidates, if approved;

- delay, variation or termination of clinical trials;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects or challenges with clinical trial enrollment;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or new labeling requirements, marketing or promotional restrictions; and
- loss of revenue.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our product candidates advance through clinical trials. Insurance coverage is increasingly expensive, thus we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product or clinical trial liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Our employees, independent contractors, including our CROs and CMOs, commercial partners, consultants, suppliers, service providers, and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees, independent contractors, including our CROs and CMOs, commercial partners, consultants, suppliers, service providers, and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar foreign regulatory authorities, including those laws that require the reporting of true, complete, and accurate information to such foreign regulatory authorities; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete, and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, imprisonment, other sanctions, contractual damages, reputational harm, future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Health epidemics may affect our ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, health epidemics could cause substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.

Our business, operations and clinical development timelines could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of CROs upon whom we rely. Moreover, our clinical development timelines and plans could be affected by health epidemics as we and the third-party manufacturers and clinical research organizations that we engage may face disruptions. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the health epidemics or patients not having a desire to enroll in clinical trials due to concerns. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if patients do not want to participate in follow up visits due to concerns regarding health epidemics or if quarantines

impede patient movement or interrupt healthcare services. There may be shortages in the raw materials used in the manufacturing of our product candidates or laboratory supplies for our preclinical studies and clinical trials, in each case, because of ongoing efforts to address the outbreak.

We cannot assure that the inability to collect such clinical data would not have an adverse impact on our clinical trial results. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to health epidemics could be adversely impacted.

We may experience disruptions that could severely impact our business, preclinical studies, and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, including receiving any required investigational new drug ("IND");
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- manufacturing disruptions;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- delays in the transport of clinical trial materials;
- changes in local regulations as part of a response to a health epidemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- difficulties recruiting or retaining patients for our planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the outbreak;
- interruption of or changes in key clinical trial activities, such as clinical trial site monitoring, implementation of virtual monitoring, use of local testing labs, or home delivery of study drugs, due to limitations on travel imposed or recommended by federal or state governments, employers and others, use of new digital technologies for subject visits or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire a particular disease related to a health epidemic while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays in the operations of the FDA which may impact review and approval timelines;
- delays in regulatory approvals for our product candidates due to the FDA focusing on clinical trials related to therapies and vaccines targeting health epidemics;
- refusal of the FDA to accept data, including from clinical trials in affected geographies or failure to comply with updated FDA guidance and expectations related to the conduct of clinical trials during a health epidemic; and

- interruption or delays to our sourced discovery and clinical activities.

The response to a health epidemic may redirect resources with respect to regulatory matters in a way that would adversely impact our ability to pursue marketing approvals. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions. Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, CROs and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of a health epidemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The extent to which the health epidemic impacts our business, clinical trials, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration of the pandemic, its severity, the actions to contain the virus or address its impact, and how quickly and to what extent government orders and mandates are lifted and normal economic and operating activities can resume. Further, while the potential economic impact of any health epidemic may be difficult to assess or predict, it could result in significant disruptions of global financial markets, which could reduce our ability to access capital, which could in the future negatively affect our liquidity. To the extent a health epidemic adversely affects our business, clinical trials, results of operations and financial condition, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section. The ultimate impact of a health epidemic is highly uncertain and subject to change.

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

Any unplanned event, such as earthquakes, fires, flood, explosion, extreme weather, health epidemics, pandemics, power outages, telecommunication failures, war or other military conflict, terrorist activities or other natural or manmade accidents or incidents could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Unfavorable global and geopolitical economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global and geopolitical economy and in the global financial markets. Financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures in healthcare and other settings. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships (including inflation) may also affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, net, business and results of operations. The current inflationary environment related to increased aggregate demand, supply chain constraints and the effects from the armed conflict in Ukraine (including the effects of the sanctions that were implemented in response to the conflict and the resulting impacts on the commodity market and supply chains) and Israel have also increased our operating expenses and may continue to affect our operating expenses. Our operational costs, including the cost of energy, materials, labor, distribution and our other operational and facilities costs are subject to market conditions and are being adversely affected by inflationary pressures. Global and geopolitical economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations. A significant worsening of global and geopolitical economic conditions could precipitate or materially amplify the other risks described herein.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our accompanying Balance Sheets. The value of our investments may be adversely affected by interest rate fluctuations, inflation, downgrades in credit ratings, illiquidity in the capital markets, health epidemics and other factors that may result in other-than-

temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Risks Related to Development and Commercialization

We have only recently obtained regulatory approval for XDEMVY in the U.S. and commenced the commercial launch of XDEMVY. We have limited experience as a commercial company and generating revenue from product sales. If the commercial launch of XDEMVY is unsuccessful or any future approved products are unsuccessful, we may never be profitable.

We recently received approval by the FDA for XDEMVY for the treatment of *Demodex* blepharitis in the U.S. and began generating revenue from product sales during the third quarter of 2023. Our ability to become and remain profitable is heavily dependent on our ability to continue to generate revenue from XDEMVY. The success of our commercialization will depend on a number of factors, including, among others, the continued development of our commercial organization, including our internal sales and marketing team and distribution capabilities, our ability to navigate the significant expenses and risks involved with the development and management of such capabilities, satisfying any post-marketing regulatory requirements, our ability to secure and maintain adequate healthcare coverage and the acceptance of XDEMVY by patients, ECPs and third-party payers. Further, our commercial success is dependent on our ability to educate ECPs, patients and others in the medical community about *Demodex* blepharitis. If XDEMVY, or any other future approved product, does not achieve an adequate level of acceptance, coverage, pricing or reimbursement, we may not generate significant revenue from product sales and we may not be profitable. Even if we successfully commercialize XDEMVY in the U.S., we may be unable to achieve or maintain profitability, unless XDEMVY is approved in other jurisdictions or for additional indications. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues from product sales of XDEMVY, or any future approved products, or if or when we might achieve profitability.

If we are unsuccessful in accomplishing our objectives, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize XDEMVY or any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We are heavily dependent on the successful commercialization of XDEMVY and the development, regulatory approval, and commercialization of our current and future product candidates.

We currently have one product approved for commercial sale, XDEMVY (lotilaner ophthalmic solution) 0.25%, which was approved by the FDA in July 2023 for the treatment of *Demodex* blepharitis in the U.S. The success of our business, including our ability to generate revenue from product sales in the future, will primarily depend on the successful commercialization of XDEMVY and the successful development, regulatory approvals and commercialization of our product candidates in one or more jurisdictions. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve a number of challenging objectives, including:

- timely receipt of regulatory approvals from applicable regulatory authorities for our product candidates for which we successfully complete clinical development;
- successful and timely completion of preclinical and clinical development of our product candidates;
- successfully educating ECPs about *Demodex* blepharitis and related diagnosis;
- successful commercial launch following any regulatory approval, including leveraging our commercial infrastructure in-house or with one or more collaborators;
- commercial acceptance of XDEMVY and any of our other product candidates by patients, the medical community and third-party payers;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development, both in the U.S. and internationally, of our product candidates;
- making any required post-marketing approval commitments to applicable regulatory authorities;

- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- obtaining an IND prior to commencing clinical trials in the U.S. for drug for a particular indication, such as TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme disease prophylaxis and community malaria reduction;
- a continued acceptable safety and efficacy profile both prior to and following any marketing approval of our product candidates;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- obtaining favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our existing or acquired product candidates;
- obtaining coverage and adequate reimbursement for customers and patients from government and third-party payers for XDEMVY and other potential product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate significant revenue that is large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, retain key employees and continue our operations.

We may not be successful in educating ECPs and the market about the need for treatments specifically for Demodex blepharitis and other diseases or conditions targeted by XDEMVY or our product candidates. XDEMVY or other product candidates that we may develop may fail to achieve market acceptance by ECPs, other healthcare providers and patients, or adequate formulary coverage, pricing or reimbursement by third-party payers and others in the medical community, and the market opportunity for these products may be smaller than we estimate.

XDEMVY, or any current or future product candidate that receives marketing approval, may fail to gain sufficient market acceptance by ECPs or other healthcare providers, patients, third-party payers and others in the medical community. Before the approval of XDEMVY, there was no approved prescription therapeutic for *Demodex* blepharitis and the only other current treatments include over-the-counter and off-label remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products. Efforts to educate the medical community, patients and third-party payers on the benefits of XDEMVY and our other product candidates may require significant resources and may not be successful.

Although XDEMVY is approved for the treatment of *Demodex* blepharitis, ECPs and potential patients may not have sufficient information about, or recognize the need for a treatment specifically targeting *Demodex* blepharitis. It is possible that ECPs may continue to rely on other treatments for treating symptoms consistent with *Demodex* blepharitis. A key tenet of our continued commercialization strategy is to educate ECPs on *Demodex* blepharitis and how to diagnose it with a simple slit lamp examination as well as raise patient awareness of *Demodex* blepharitis. However, our efforts may prove to be unsuccessful, and we may not be able to develop this new market for XDEMVY. We may still not achieve success in promotional efforts for XDEMVY, and ECPs may continue to use existing treatments rather than XDEMVY or any other product candidate and potential patients may not inquire as to XDEMVY. It is also possible that ECPs and patients may not be

willing to adopt XDEMVY for the treatment of *Demodex* blepharitis because of the possibility that the disease will recur despite mite eradication and the potential for periodic use of XDEMVY.

In addition, if generic versions of any products that compete with XDEMVY or any of our product candidates are approved for marketing by the FDA or comparable foreign regulatory authorities, they could be offered at a substantially lower price than we expect to offer for XDEMVY or our other product candidates, if approved. As a result, ECPs, patients and third-party payers may choose to rely on such products rather than XDEMVY or our product candidates, if approved.

If XDEMVY or any other product candidate that we develop does not achieve an adequate level of acceptance, formulary coverage, pricing or reimbursement we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of XDEMVY or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages of XDEMVY, or our product candidates, if approved, compared to alternative treatments, including the existing standard-of-care, and the perceptions by members of the healthcare community of the same;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of ECPs to prescribe these therapies;
- the strength and effectiveness of our marketing and distribution support, which may be adversely impacted by health epidemics;
- publicity concerning our products or competing products and treatments;
- the timing of market introduction of competitive products;
- the perception by patients or physicians that the diseases we are targeting, including *Demodex* blepharitis, are not burdensome;
- the potential for our competitors to limit our access to the market through anti-competitive contracts or other arrangements;
- the availability of third-party formulary coverage and adequate reimbursement;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

The sales, marketing, and distribution of XDEMVY or any future approved products may be unsuccessful or less successful than anticipated. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market XDEMVY or any future approved products on acceptable terms, we may be unable to successfully commercialize XDEMVY or any future approved products.

We recently began commercializing our first product, XDEMVY, in the U.S. The success of our commercialization efforts for XDEMVY and any future approved products is subject to the effective execution of our business plan, including, among others, the continued development of our internal sales, marketing and distribution capabilities. For example, we have established an internal infrastructure as well as an ECP-focused sales and distribution infrastructure to market XDEMVY and our product candidates in the U.S., and have completed hiring in areas to support commercialization, including sales management, sales representatives, marketing, access and reimbursement, sales support and distribution. There are significant risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain and

appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of these capabilities could or negatively affect the success of our commercialization efforts and business. For example, the commercialization of XDEMVY may not develop as planned or anticipated, which may require us to, among other items, adjust or amend our business plan and incur significant expenses.

Further, given our lack of experience commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if the commercialization of XDEMVY or any future approved products does not develop as planned, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

Further, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Further, in order to continue to commercialize XDEMVY or commercialize any product candidates, if approved, we must continue to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell and market our product candidates. We may not be successful in accomplishing these required tasks.

The sizes of the market opportunities for our product or product candidates, particularly XDEMVY for the treatment of Demodex blepharitis and TP-03 for the treatment of MGD, have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.

Our assessment of the potential market opportunity for XDEMVY and other product candidates that we develop is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and our own internal epidemiology and market research studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the studies we have conducted are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. The potential market opportunities for the treatment of *Demodex* blepharitis and for the treatment of MGD is difficult to precisely estimate, because patients often have multiple ocular surface diseases and the symptoms have significant overlap, leading to frequent misdiagnosis of the various conditions. Therefore, our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and our own epidemiology studies and market research, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions and the bases of the studies and research we have conducted are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for XDEMVY or any of our other product candidates may be smaller than we expect, and as a result our revenue from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.

Due to the patients presenting at ECP clinics with multiple ocular surface diseases, there is overlap in market size estimates for blepharitis and MGD. Therefore, if XDEMVY receives regulatory approval for the treatment of both *Demodex* blepharitis and MGD, our opportunity could be less than our forecasts because the actual market for XDEMVY might be significantly smaller than our estimates.

Even though we obtained regulatory approval with respect to XDEMVY for Demodex blepharitis, we may not be able to obtain regulatory approval for additional indications, such as MGD, or we may be required to conduct additional trials, which would limit our ability to realize the full market potential of XDEMVY or increase the costs of developing TP-03 for MGD.

We are exploring the therapeutic potential for TP-03 in MGD as an additional indication. If we are successful, the indication for use of TP-03 could potentially be broadened beyond the treatment of Demodex blepharitis to include MGD as an additional indication. However, there can be no assurance that we will obtain approval for any other indication, including MGD or for any broadened indication beyond the treatment of Demodex blepharitis. If we fail to maintain required approvals for these additional or broadened indications, or if regulatory approvals are delayed, we will not realize the full market potential of TP-03. Additionally, the FDA or other comparable foreign regulatory authority may require us to conduct additional clinical trials before seeking regulatory approval.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. XDEMVY and our product candidates, if approved, will also compete with existing branded, generic and off-label products.

The development and commercialization of new drug products is highly competitive. We face competition with respect to XDEMVY and our product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide and existing treatments. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors also may obtain FDA approval or other regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payers, particularly Medicare and the competent authorities of the individual European Union Member States (collectively the "EU Member States"), seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Additionally, while XDEMVY is approved for the treatment of blepharitis or *Demodex* blepharitis specifically, a number of other treatments are currently available for blepharitis in the U.S. Current treatments for blepharitis in the U.S. include over the counter remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products. If ECPs were to continue to prescribe these other existing treatments instead of XDEMVY, our business would be adversely affected.

Although we obtained FDA approval of XDEMVY, and even if we obtain FDA approval of any of our product candidates, we may never obtain approval or authorization for such product candidates, including XDEMVY, in any other jurisdiction or commercialize such product candidates in the U.S. or in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products, including XDEMVY, outside of the U.S., we will need to comply with additional onerous but varying regulatory requirements of other countries regarding safety and efficacy on a country-by-country basis.

Approval by the FDA in the U.S. does not ensure approval by comparable regulatory authorities in other countries or jurisdictions nor does it ensure that we will be able to successfully commercialize XDEMVY or any other approved products in the U.S. or in other jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Further, successful commercialization in the U.S. does not guarantee successful commercialization in other jurisdictions. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we, or our collaboration partners, fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our ability to realize the full market potential of our products will be harmed.

Our future product candidates may cause significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval or cause us to abandon or limit further clinical development or commercialization of those product candidates. In addition, significant adverse events, toxicities or other undesirable side effects may be identified during post-marketing surveillance for XDEMVY, or future approved products, which could result in regulatory action or negatively affect our ability to market the product.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Commission or other comparable foreign regulatory authorities.

During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval.

Our understanding of the relationship between our product candidates and these adverse events may change as we gather more information, and additional unexpected adverse events or an increase in adverse event rates may occur. If additional clinical experience indicates that any of our product candidates have side effects or causes serious or life-threatening side effects, participant recruitment for trials and the ability of enrolled subjects to complete trials could be negatively impacted, and the development of the product candidate may fail or be delayed, which would severely harm our business, prospects, operating results and financial condition.

Additionally, if we or others later identify undesirable side effects or adverse events caused by XDEMVY or one of our product candidates that receives marketing approval, a number of potentially significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw approvals of such product or require additional warnings on the label such as a black box warning, a contraindication or other limitations on the product's approved use, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- the product may be seized by regulatory authorities;
- there may be a recall of the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;

- we may be required to create and implement a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, including ECPs, and/or other elements to assure safe use;
- the product may become less competitive;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer and there may be resulting harm to physician or patient acceptance of our product.

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

As we participate in the Medicaid Drug Rebate Program and other governmental pricing programs, failure to comply with obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Under the Medicaid Drug Rebate program, a participating manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by the state Medicaid program as a condition of having federal funds being made available for drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to the Centers for Medicare and Medicaid Services ("CMS"). These data include the average manufacturer price and, in the case of innovator products, the best price for each drug, which, in general, represents the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. If we fail to pay the required rebate amount or report pricing data on a timely basis, we may be subject to civil monetary penalties and/or termination from the Medicaid Drug Rebate program. Additionally, civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we misclassify or misreport product information. CMS could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

The Affordable Care Act of 2010 ("ACA") (addressed further above in the section on “Business – Government Regulatory – Coverage and Reimbursement”) made significant changes to the Medicaid Drug Rebate Program, and CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate Program under the ACA. CMS also issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value based purchasing arrangements; and provide definitions for “line extension,” “new formulation,” and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula. While the regulatory provisions that purported to affect the applicability of the best price and average manufacturer price exclusions of manufacturer-sponsored patient benefit programs, in the context of pharmacy benefit managers ("PBM") “accumulator” programs were invalidated by a court, such programs may continue to negatively affect us in other ways. Our failure to comply with these price reporting and rebate payment options, as well as PBM “accumulator” programs, could negatively impact our financial results.

Federal law requires that a manufacturer also participate in the 340B Drug Pricing program ("340B program") in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B “ceiling price” ("340B ceiling price") for the manufacturer’s covered outpatient drugs to a specified “covered entities,” including community health centers and other entities that receive certain federal grants, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. If we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties and/or such failure also could be grounds for Health Resources and Services Administration to terminate our agreement to participate in the 340B program, in which case our covered outpatient drugs would no longer be eligible for federal payment under the Medicaid or Medicare Part B program.

Further, the Inflation Reduction Act of 2022 ("IRA") establishes a Medicare Part D inflation rebate scheme (the first rebate period is in fourth quarter 2022 through third quarter 2023) and a drug price negotiation program, with the first

negotiated prices to take effect in 2026. It also makes several changes to the Medicare Part D benefit, including the creation of a new manufacturer discount program in place of the current coverage gap discount program (beginning in 2025). Manufacturers may be subject to civil monetary penalties for certain violations of the negotiation and inflation rebate provisions and an excise tax during a noncompliance period under the negotiation program. Drug manufacturers may also be subject to civil monetary penalties with respect to their compliance with the new Medicare Part D manufacturer drug discount program.

Pricing and rebate calculations are complex, vary across products and programs, and are often subject to interpretation by the manufacturer, governmental agencies, and courts. A manufacturer that becomes aware that its Medicaid reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, is obligated to resubmit corrected data up to three years after those data originally were due. Restatements and recalculations increase the costs for complying with the laws and policies governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. They also may affect the 340B ceiling price and therefore liability under the 340B program.

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, due to government invoicing delays or otherwise, the Company may need to adjust accruals, potentially adversely, 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.

Finally, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare programs and purchased by the Department of Veterans Affairs ("VA"), Department of Defense ("DoD"), Public Health Service, and Coast Guard (collectively, the "Big Four agencies") and certain federal grantees, a manufacturer is required to participate in the VA Federal Supply Schedule ("FSS") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the "non-federal average manufacturer price" ("Non FAMP"), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, we will be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Under Section 703 of the National Defense Authorization Act for Fiscal Year 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through DoD's Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non FAMP and FCP for the calendar year that the product was dispensed. A manufacturer that overcharges the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations

We may expend our limited resources on the commercialization of XDEMVY for the treatment of Demodex blepharitis and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. We are currently focused on the

commercialization, of XDEMVY for the treatment of *Demodex* blepharitis. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on the most viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for TP-03 and other product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for XDEMVY, TP-03 for other indications and other product candidates, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The terms of approvals and ongoing regulation of XDEMVY and any other current product candidates or product candidates we develop could require substantial expenditure of resources and may limit how we manufacture and market our products, which could materially impair our ability to generate revenue from product sales.

XDEMVY, and any other product candidate for which we obtain regulatory approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA, the European Medical Agency ("EMA") and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practice ("cGMP") requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Accordingly, we and our contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control for XDEMVY and any other approved products. If we are not able to comply with post-approval regulatory requirements, we could have the regulatory approvals for our products, including XDEMVY, withdrawn by regulatory authorities and our ability to market XDEMVY or any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

If XDEMVY or any of our product candidates that are approved for marketing are found to have been improperly promoted for off-label uses by us, or if ECPs misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other foreign regulatory authorities strictly regulate the marketing of and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other foreign regulatory authorities as reflected in the product's approved labeling. Any regulatory approval that the FDA or a foreign regulatory authority grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective. For example, the FDA-approved label for XDEMVY is limited to the treatment of *Demodex* blepharitis, and we are not permitted to promote XDEMVY for any other uses, unless and until such uses are approved.

In addition, although we believe XDEMVY and our product candidates may exhibit a lower risk of side effects or more favorable tolerability profile or better symptomatic improvement than other products for the indications we are studying, without head-to-head data, we will be unable to make comparative claims for XDEMVY or our product candidates, if approved. If we receive regulatory approval for any of our products and are found to have promoted XDEMVY or any of our products or product candidates, if approved, for off-label uses, we may become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, our management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our brand and reputation could be damaged. The FDA has also previously requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they determine our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations. We

cannot, however, prevent an ECP from using XDEMVY or our product candidates in ways that fall outside the scope of the approved indications, as he or she may deem appropriate in his or her medical judgment. ECPs may also misuse XDEMVY or our product candidates, if approved, or use improper techniques, which may lead to adverse results, side effects or injury and, potentially, subsequent product liability claims. Furthermore, the use of XDEMVY or our product candidates, if approved, for indications other than those approved by the FDA and/or other regulatory authorities may not effectively treat such conditions, which could harm our brand and reputation among ECPs and patients.

Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates do not meet safety or efficacy endpoints or are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. The research and development of drugs is an extremely risky industry. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Failure or delay can occur at any time during the clinical trial process. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting preclinical studies and clinical trials. Clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. We currently generate revenue from product sales for one product, and we may never be able to develop or commercialize additional marketable products.

The results of preclinical and early clinical trials of our product candidates and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. For example, we may not be able to replicate the safety and efficacy results of our Phase 2b/3 clinical trials for *Demodex* blepharitis in clinical trials for other indications in the future. Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and other challenges with enrolling and maintaining trial subjects, relatively smaller sample size in earlier trials, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. Furthermore, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. The failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.

If we are unable to complete preclinical or clinical trials of current or future product candidates, due to safety concerns, or if the results of these trials are not satisfactory to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization. Even if we are able to obtain marketing approvals for any of our product candidates, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Each of our product candidates will require additional clinical development, management of clinical, preclinical (for some of our product candidates) and/or manufacturing activities, regulatory approval in multiple jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant

marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Any recommendations by the FDA regarding our applications or clinical trials could cause delay of any regulatory approval by the FDA and cause our expenses to increase. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, or any other product candidates that we may develop, including:

- we may experience delays in or failure to reach agreement on acceptable terms with prospective CROs, vendors and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- we may fail to obtain sufficient enrollment in our clinical trials, our enrollment needs may grow larger than we anticipate, or participants may fail to complete our clinical trials at a higher rate than we anticipate;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may decide, or regulators or institutional review boards ("IRBs) or ethics committees may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial at a prospective clinical trial site or at all or may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may need to delay or suspend one or more trials until we complete additional financing transactions or otherwise receive adequate funding;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate trials;
- regulatory authorities may determine that the planned design of our clinical trials is flawed or inadequate;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- we may not be able to timely or at all obtain INDs for a product candidate;
- we may modify a preclinical study or clinical trial protocol;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit;

- we may experience delays due to the outbreak of health epidemics, including with respect to the conduct of ongoing clinical trials, receipt of product candidates or other materials, submission of NDAs, filing of INDs, and starting any clinical trials for other indications or programs; and

- we may experience manufacturing delays due to health epidemics in our supply chain caused by a shortage of raw materials, a lack of employees on site at our suppliers due to illness, or a lack of productivity at our suppliers due to local or national government quarantine restrictions on coming to the workplace.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:

- incur unplanned costs;

- be delayed in obtaining marketing approval for our product candidates;

- not obtain marketing approval at all;

- obtain marketing approval in some countries and not in others;

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

- be subject to additional post-marketing testing requirements; or

- have the product removed from the market after obtaining marketing approval.

We cannot be certain whether any of our planned clinical trials will begin on schedule or any preclinical studies we plan to initiate will begin on our intended schedule, or whether any such studies or clinical trials will need to be restructured or will be completed on schedule, or at all. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, or are unable to achieve clinical endpoints due to unforeseen events, such as health epidemics, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to generate additional revenue from product sales. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

Our product candidates still require significant testing. We only recently began clinical trials to test TP-04 and TP-05 in humans and, as a company, we have limited experience in this area.

We are early in our development efforts for our product candidates and indications, including TP-03 for the treatment of MGD, TP-04 for the treatment of rosacea and TP-05 for potential Lyme disease prophylaxis and community malaria reduction. The risk of failure for product candidates in early development is high. Extensive clinical trials are necessary to demonstrate the safety and efficacy of such product candidates in humans. Clinical trials may fail to demonstrate that such product candidates are safe for humans and effective for indicated uses. Further, we intend to leverage data from the TP-03 preclinical studies and clinical safety assessments for the treatment of *Demodex* blepharitis to satisfy the preclinical study requirements for TP-03 for the treatment of MGD, and TP-04 and TP-05 and other indications. For MGD, we announced the enrollment of our first patient in the Phase 2a Ersa trial studying TP-03 for the potential treatment of MGD and in December 2023 reported positive topline results. For rosacea, we conducted the Phase 1 Galatea trial with TP-04 and initiated the Phase 2a Galatea trial, for the treatment of rosacea in March 2023. In February 2024, we announced positive topline results and plan to discuss and determine the potential regulatory path with the FDA. With respect to Lyme disease, in December 2022 we announced positive topline results from the completed Callisto trial and enrollment of the first patient in the Carpo trial. The Carpo trial, evaluating TP-05, a novel investigative oral, non-vaccine pharmacological prophylactic for the potential prevention of Lyme disease in humans is a randomized, double-blind, placebo-controlled trial that evaluated 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. In February 2024, we announced positive topline results from the Carpo trial and plan to discuss and determine the potential regulatory path with the FDA. The FDA may reject our use of data from

TP-03 preclinical studies for the treatment of *Demodex* blepharitis for other indications or require additional studies to augment the data to advance for clinical development. The FDA may also reject our use of data from preclinical studies conducted by third parties for Lyme disease and require us to conduct additional preclinical studies before advancing to additional clinical trials. In addition, data from preclinical studies conducted by third parties may not be as reliable as data from studies conducted by us and since we did not conduct the studies, there may be weaknesses in the studies design or results that we may not be aware of.

In part because of our limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, we cannot be certain that our clinical trials will be completed on time, that our planned clinical trials will be initiated on time, if at all, that our planned development programs would be acceptable to the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

We have and may continue to encounter difficulties or delays enrolling patients in our clinical trials, which could cause delays in or adverse effects of our clinical development activities.

We have and may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We have and may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons. For example, we recently experienced delays related to our Carpo trial with topline results pushed out to February 2024 as a result of patient enrollment delays. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- costs to, or lack of adequate compensation for, prospective patients;
- difficulties of enrolling patients or patients continuing to participate in follow-up visits due to ongoing or new health epidemics; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition would reduce the number and types of
patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Moreover, potential patients and their doctors may be inclined to use existing therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue from product sales and adversely affect our commercial prospects.

Before we can initiate clinical trials in the U.S. for our product candidates, we must submit the results of preclinical testing and any previous clinical studies to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND. The initiation of clinical trials in the EU Member States will be subject to similar requirements concerning approval by competent national authorities and the receipt of a positive opinion from the relevant ethics committees. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- failure to demonstrate efficacy of the product;
- any interruptions or delays in the supply of our product candidates for our clinical trials;
- a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- any failure or delay in reaching an agreement with CROs, vendors and clinical trial sites;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices ("GCP") or regulatory requirements or other third parties not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred, disqualified or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;
- one or more IRBs, other ethics committees refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- changes in regulatory requirements and policies, which may require us to amend clinical trial protocols to comply with these changes and resubmit our clinical trial protocols to IRBs or ethics committees for reexamination.

Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize the commercial prospects of our product candidates and our ability to generate revenue from product sales.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. For example, if we make manufacturing or formulation changes to our product candidates, we may need to conduct

additional studies to bridge our modified product candidates to earlier versions. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our product candidates will harm our commercial prospects and our ability to generate revenue from product sales.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties, such as our China Out-License. We are evaluating the opportunities for the development and commercialization of our product candidates in other foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities if we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

For example, the pharmaceutical industry in the China Territory is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in the China Territory regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development of TP-03 by GrandPharma under the China Out-License and reduce the current benefits we believe are available to us. The China Territory authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by GrandPharma or our other partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our partner's business activities in the China Territory. Additionally, to the extent that we enter into collaborations with third parties for development and/or commercialization of our products or product candidates in foreign markets, we will be unable to directly control development and commercial activities or whether such third parties continue to develop or commercialize such products or product candidates. For example, on February 13, 2024, LianBio announced its completion of a comprehensive strategic review and determined to initiate the wind down of its operations, including the sale of remaining pipeline assets, the delisting of its American Depositary Shares, deregistration under Section 12(b) of the Exchange Act, and workforce reductions. In March 2024, we executed the Novation Agreement with GrandPharma and LianBio to transition the rights to develop and commercialize TP-03 in China for the treatment of *Demodex*

blepharitis. As of the date of this filing, it is uncertain if and when we will receive any future milestone consideration under the China Out-License.

Another example of the changing regulatory requirements is that in the European Union ("EU"), the European Commission has presented a proposal to reform the current EU pharmaceutical legislation. The proposal intends to reduce the regulatory data protection period and orphan market exclusivity period for new medicinal products. It is currently uncertain if the proposal will be adopted in its current form and it is uncertain if and when the revised legislation would enter into force.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. In some countries, particularly the countries in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We have conducted a number of our completed clinical trials for our product candidates at sites outside the U.S., and the FDA may not accept data from trials conducted in such locations.

Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with certain ethical and policy principles, including GCP standards. Among other requirements, the trial data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with certain U.S. laws and regulations. There can be no assurance the FDA will accept data from clinical trials conducted outside of the U.S. There can also be no assurance that the comparable foreign regulatory authority in any jurisdiction in which we seek regulatory approval for our product candidates will accept data from clinical trials conducted outside such jurisdiction. If the FDA or any such foreign regulatory authority does not accept the data from any trial that we have conducted outside the U.S., it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the U.S. and if we conduct trials outside of the U.S., we may face risks, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange rate fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural or legal differences in the standards for medical practice and clinical research;
- diminished protection of intellectual property in some countries;
- different cultural attitudes to self-reported adverse events (such as burning, stinging, blurry vision) leading to a different safety profile; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

Managing our obligations under our in-license and out-license agreements and other strategic agreements may divert management time and attention, causing delays or disruptions to our business.

We have entered into two license agreements with Elanco: (i) a license agreement 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 ("Eye and Derm Elanco Agreement") and (ii) 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" and with the Eye and Derm Elanco Agreement, the "Elanco Agreements"), and have also entered into the China Out-License as discussed elsewhere herein. We also may in the future enter into in-license or out-license agreements with multiple licensors and strategic agreements, which, subject us to various obligations, including diligence obligations, reporting and notification obligations, payment obligations for achievement of certain milestone as well as other material obligations. We may need to devote substantial time and attention to ensuring that we successfully integrate these transactions into our existing operations and are compliant with our obligations under these agreements, which may divert management's time and attention away from our research and development programs or other day-to-day activities.

Our in-license, out-license, and strategic agreements are also complex and certain provisions in those agreements may be susceptible to multiple interpretations. In the event of any disagreement about the interpretation of these provisions, our management may need to devote a disproportionate amount of its attention to resolving these disagreements. Such disruptions may cause delays in our research and development programs and other business objectives.

Our operating activities may be restricted by certain covenants in our license and other strategic agreements, which could limit our development and commercial opportunities.

In connection with our in-license, out-license, or other collaborations or strategic alliances, we may agree to and be bound by negative covenants which may limit our development and commercial opportunities. For example, pursuant to the Elanco Agreements, we made certain covenants to only engage with third party suppliers previously approved by Elanco, and only under certain circumstances. These provisions may inhibit our development efforts, prevent us from forming strategic collaborations to develop and potentially commercialize any other product candidates and may materially harm our business, financial condition, results of operations and prospects.

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

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.

Risks Related to our Financial Position and Need for Additional Capital

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced activities in 2016. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing our company, raising capital, identifying and developing product candidates, establishing licensing arrangements and/or acquiring necessary technology, undertaking research, preclinical studies and clinical trials of our product candidates, establishing arrangements for the manufacture of XDEMVY and other product candidates and longer-term planning for commercialization efforts of XDEMVY and our other potential product candidates. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have limited experience in obtaining marketing approvals, manufacturing commercial scale product or arranging for a third party to do so on our behalf, or conducting sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing products. In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We may not be successful as we transition from a company with a research and development focus to a company capable of supporting commercial activities.

Due to the recently initiated commercialization of XDEMVY and our continued development of our pipeline of product candidates through clinical trials and other indications, our capital requirements are difficult to predict and may change. We may need to obtain substantial additional funding to achieve our goals and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.

Since our inception, we have funded our operations through private placements of preferred stock, convertible promissory notes, the sale of our common stock in our IPO and the Follow-On Public Offerings, and the 2023 ATM Prospectus, as well as proceeds from product sales, net, our China Out-License, and draws on our Credit Facility and Pharmakon Credit Facility. We expect our expenses to increase substantially and we will require a larger amount of capital to fund our commercialization efforts, the development of our product candidates and the maintenance and expansion of our operations and capabilities. These expenditures will include costs associated with marketing and selling any products approved for sale, including XDEMVY, conducting non-clinical studies and clinical trials, obtaining regulatory approvals, securing manufacturing and supply of product candidates, costs associated with in-licensing assets consistent with our core strategy and other unanticipated costs. Further, as a public company, we incur significant legal, accounting and other costs associated with operating as a public company.

We believe that our cash, cash equivalents and marketable securities of $298.5 million as of March 31, 2024 and expected sales of XDEMVY is sufficient to fund our current and planned operations for at least the next twelve months from the date of filing this Quarterly Report on Form 10-Q.

We will need to raise substantial additional capital to complete the development and commercialization of XDEMVY and our other product candidates through one or more of: equity offerings, draws from our Pharmakon Credit Facility, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources.

Due to the complexities of our transition to a commercial-stage company, it is challenging to estimate the actual amounts necessary to successfully commercialize any products approved for sale. We may need to raise additional funds earlier than currently anticipated if we choose to pursue additional indications for our product candidates, acquire new product candidates or otherwise expand our business more rapidly than we presently planned. We have based these estimates on assumptions that may prove to be incorrect or require adjustment because of our ongoing business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the cost and timing, receipt and amount of sales and marketing capabilities of any current and future products, including the success of our commercialization efforts involving XDEMVY;
- market acceptance of our current and future products, including XDEMVY, and the impact of any competing products;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for any current or future products;
- the scope and costs of manufacturing development and commercial manufacturing activities and our ability to scale them up;
- the scope, rate of progress, costs and results of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates, including the potential for regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post-marketing studies or risk evaluation and mitigation strategies that could be required by regulatory authorities;

- suspensions or delays in enrollment of our ongoing and future clinical trials, issues with data collection, or changes to the number of subjects we decide to enroll in clinical trials, including as a result of health pandemics, competing trials, or otherwise;
- the costs of commercialization activities for any current or future products that are approved for sale, including marketing, sales, and distribution costs, and any discounts or rebates to obtain access;
- potential changes in the regulatory environment and enforcement rules;
- 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 ability to satisfy our outstanding debt obligations;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the sales and marketing activities associated with the commercialization of our products, including XDEMVY, and the development of our product candidates;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs related to any future collaboration or licensing partners upon the achievement of negotiated milestones;
- the costs associated with any product liability or other lawsuits related to our products;
- the expense needed to attract and retain skilled personnel; and
- the costs associated with being a public company.

Commercialization efforts of any current or future products, including our commercialization efforts involving XDEMVY, identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for our product candidates. In addition, our product candidates, if approved, may not achieve adequate product sales or commercial success. Although we initiated commercialization of XDEMVY for the treatment of Demodex blepharitis in August 2023, we will need to continue to sustain our existing capital resources to fund our future operating expenses and capital expenditure requirements. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, limit, reduce or eliminate our research and development programs or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our research and development efforts. Alternatively, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time we can generate substantial revenue from product sales, including from XDEMVY, our only approved product, we expect to finance our cash needs through possible combinations of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. For example, in May 2022, August 2023, and March 2024, we completed the Follow-On Public Offerings, in which we received total net proceeds of $74.2 million, $99.3 million, and $107.7 million, respectively (after deducting underwriting discounts, commissions and other estimated offering-related expenses) through the issuance of 5,889,832 shares of our common stock in the May 2022 Public Offering, 6,069,449 shares of our common stock in the August 2023 Public Offering, and 2,812,500 shares of common stock, and in lieu of common stock to a certain investor, pre-funded warrants to purchase 312,500 shares of our common stock in the

March 2024 Public Offering. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions. For example, the Pharmakon Credit Facility restricts our ability to pursue certain transactions that we may believe to be in our best interests without the prior written consent of Pharmakon, including but not limited to: disposing of assets, engaging in mergers, acquisitions, and similar transactions, incurring additional indebtedness, granting liens, making investments, paying dividends or making distributions or certain other restricted payments in respect of equity, prepaying other indebtedness, entering into restrictive agreements, undertaking fundamental changes or amending certain material contracts, in each case subject to certain customary exceptions and negotiated carve outs.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our shares to decline. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or continued and future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC, as receiver, and SVB was subsequently transferred into a new entity, SVBB. On March 12, 2023, the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception. Such parties also announced, among other items, that Silicon Valley Bridge Bank has assumed the obligations and commitments of former SVB and commitments to advance under existing credit agreements with former SVB will be honored by SVBB in accordance with and pursuant to the terms of such credit agreements. In March 2023, First Citizens Bank assumed all of SVBB's obligations and commitments, and SVBB began operating as SVB, a division of First Citizens Bank. Unless otherwise noted herein, all references to SVB or Silicon Valley Bank shall refer to Silicon Valley Bank, a division of First Citizens Bank. In light of the foregoing, the Company does not believe it has exposure to loss as a result of SVB's receivership.

We currently maintain cash held on deposit at financial institutions in the U.S., including at SVB. 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, to the extent such loss exceeds the FDIC insurance limitation, and such a failure could have a material adverse effect upon our liquidity, operations and our results of operations.

Additionally, we and other parties with whom we conduct business may be unable to access funds in such deposit account or other accounts, including money market funds, held with a financial institution or lending arrangements with such a financial institution. Our ability and any of our counter-party's ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from financial institutions in the future and uncertainty remains over liquidity concerns in the broader financial services industry.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Our existing indebtedness may limit our flexibility in financing and operating our business and adversely affect our business, financial condition and results of operations.

On April 19, 2024 we entered into the Pharmakon Credit Facility with Pharmakon. The Pharmakon Credit Facility provides a $75.0 million initial term loan which was drawn in April 2024, a portion of which was utilized to repay all outstanding indebtedness, for total net proceeds of $39.8 million. The Pharmakon Credit Facility provides for three potential additional term loan tranches in principal amounts up to $25.0 million, $50.0 million, and $50.0 million, respectively, subject to customary conditions to funding and, in the case of the last two tranches, achieving minimum net sales milestones, which may be requested on or prior to December 31, 2024, June 30, 2025 and December 31, 2025, respectively. The Pharmakon Credit Facility contains representations and warranties, affirmative and negative covenants in each case, which is customary for financings of this type. However, there are no financial covenants. The Pharmakon Credit Facility contains representations and warranties, affirmative and negative covenants in each case customary for financings of this type. Certain of the customary negative covenants limit our ability to, among other things, dispose of assets, engage in mergers, acquisitions, and similar transactions, incur additional indebtedness, grant liens, make investments, pay dividends or make distributions or certain other restricted payments in respect of equity, prepay other indebtedness, enter into restrictive agreements, undertake fundamental changes or amend certain material contracts, in each case subject to certain customary exceptions and negotiated carve outs. However, there are no financial covenants.

Such restrictions could limit our ability to take certain actions and could reduce our flexibility to run and manage our business which could have an adverse effect on our results of operations. Our obligations under the Pharmakon Credit Facility are secured by a lien in substantially all of our assets, subject to certain exclusions. If we were unable to repay amounts due under the Pharmakon Credit Facility, Pharmakon could proceed against such assets. Any declaration by Pharmakon of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause or to incur debt or assume contingent liabilities, and subject us to other risks.

In the future, we may enter into transactions to acquire other businesses, products or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. For example, our Pharmakon Credit Facility may restrict our ability to pursue certain mergers, acquisitions or consolidations without obtaining the prior consent of Pharmakon or repaying our outstanding loan amounts.

We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions or partnerships may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history which we expect to continue, we do not expect to become profitable in the near future, and we may never achieve profitability. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs"), and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not yet completed an ownership change analysis. If a requisite ownership change occurs, the amount of remaining tax attribute carryforwards available to offset taxable income and reduce income tax expense in future years may be restricted or eliminated. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state, and local income taxation are complex and are constantly under review by legislators, the U.S. Department of Treasury, and the Internal Revenue Service. Changes to tax laws (which may have retroactive application) have occurred and are likely to continue to occur in the future, which could adversely affect our shareholders.

Risks Related to Reliance on Third Parties

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials of TP-03, TP-04 and TP-05 and other product candidates, and we expect to continue to rely upon third parties to conduct additional clinical trials of potential future product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third party, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our development activities.

Our reliance on these third parties for such development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EC also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EC or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP or other applicable regulations. In addition, our clinical trials must be conducted with product produced under current applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. In addition, the operations of our CROs and other third-party service providers may be constrained or disrupted by health epidemics. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. Although we plan to carefully manage our relationships with our CROs, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of any product candidates.

We contract with third parties for the commercial manufacture of XDEMVY and for the manufacture of our product candidates for preclinical studies, clinical trials and eventual commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of XDEMVY or our product candidates or compounds or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our commercialization or development efforts.

We do not have any, and have no plans to acquire any, manufacturing facilities. We produce in our laboratory relatively small quantities of compounds for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the commercial manufacture of XDEMVY and the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture of our product candidates, if approved. We currently have limited manufacturing arrangements and expect that XDEMVY and each of our product candidates will only be covered by single source suppliers for the foreseeable future. For example, we purchase our API for XDEMVY, lotilaner, from Elanco, who sources through a single source supplier. This reliance increases the risk that we will not have sufficient quantities of XDEMVY or our product candidates or any future approved products, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our commercialization or development efforts.

Furthermore, all entities involved in the preparation of XDEMVY for commercial sale or other therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for XDEMVY and our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of XDEMVY, investigational products and future products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of XDEMVY or our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Foreign regulatory authorities, including the European Commission and the competent authorities of the EU Member States, may require compliance with similar requirements. The facilities and quality systems of our third-party contractor manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP regulations. We have little or no control over the production processes of third-party manufacturers, CMOs or other suppliers. The third-party manufacturing facilities used in the production of API and our drug products are located outside of the U.S. and require FDA approval, which our third-party manufacturers may have limited experience with obtaining. Our CMOs and other suppliers are subject to inspection by the FDA and may receive observations that they may not be able to resolve in a timely or effective manner, which could impact whether our products can be approved on a timely basis, if at all.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of XDEMVY, components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture XDEMVY or other materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture XDEMVY or our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture XDEMVY or our product candidates. If we elect to or are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. If any of our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture XDEMVY or our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer.

Our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to meet commercial demands for XDEMVY or any other future product that is approved;
- requirements to cease development or to recall batches of XDEMVY or our product candidates;
- an inability to initiate or continue clinical trials of our product candidates under development;

- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of an existing or future collaborator, including by Elanco Agreements; and
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities.

XDEMVY, our product candidates and any future products that we may develop may compete with other products and product candidates for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could prevent or delay commercialization efforts of XDEMVY or any future products, if approved, clinical development of product candidates or marketing approval of current or future product candidates.

We or our third-party manufacturers may encounter shortages in the raw materials or API necessary to produce XDEMVY or our product candidates in the quantities needed in sufficient quantities for our commercialization or to meet an increase in demand, or for our clinical trials, as a result of capacity constraints or delays or disruptions in the market for the raw materials or APIs, including shortages caused by the purchase of such raw materials or APIs by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or APIs necessary to manufacture sufficient quantities of XDEMVY or our product candidates, may have a material adverse effect on our business.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of XDEMVY or our product candidates in sufficient quality and quantity, which would delay or prevent us from commercializing, conducting clinical trials and developing our product candidates.

In order to successfully commercialize XDEMVY and to conduct clinical trials of our product candidates, we will need to manufacture XDEMVY and our product candidates in large quantities. We, or our manufacturing partners, may be unable to maintain or successfully increase the manufacturing capacity for XDEMVY or any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or our manufacturing partners, are unable to successfully scale up the manufacture of XDEMVY or our product candidates in sufficient quality and quantity, the commercialization of XDEMVY or the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and commercialization of XDEMVY or marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

Risks Related to Intellectual Property

Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect XDEMVY or our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the U.S. Patent and Trademark Office ("USPTO") during patent prosecution and additional procedures to attack the validity of a

patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a nonexclusive, nontransferable, irrevocable, paid-up license for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants. If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology that is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Additionally, the new unitary patent system that came into effect in Europe in June 2023 has increased the complexity and uncertainty of European patent laws and would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

The development and commercialization of our products, including our lead product XDEMVY, for the treatment of Demodex blepharitis, 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, is dependent on intellectual property we license from Elanco. If we breach our agreements with Elanco or the agreements are terminated, we could lose license rights that are important to our business.

Pursuant to the Elanco Agreements we acquired exclusive, worldwide, sublicensable licenses to certain intellectual property of Elanco for the development, marketing and commercialization of lotilaner for (i) the treatment, prevention, palliation or cure of any eye or skin disease or condition in humans and (b) all other applications in humans, respectively. The Elanco Agreements impose various development, regulatory, commercial diligence, financial and other obligations on us. If we fail to comply with our obligations under the Elanco Agreements, or otherwise materially breach either Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the applicable Elanco Agreement. If we fail to meet any milestones by the achievement deadlines set forth in either Elanco Agreement for any reason other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may terminate the applicable Elanco Agreement.

If either Elanco Agreement is terminated or if our field of use in the Eye and Derm Elanco Agreement is reduced to eye and skin conditions only by Elanco, we would lose our applicable license in the country where such license was terminated and all rights therein to the licensed intellectual property would revert to Elanco. The loss of the license from Elanco would prevent us from developing and commercializing TP-03, TP-04 and TP-05 in any country where the license is terminated and could subject us to claims of breach of contract and patent infringement by Elanco if any continued research, development, manufacture or commercialization of TP-03, TP-04 or TP-05 is covered by the affected patents. If Elanco terminates the Eye and Derm Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicensable, royalty-free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for the treatment, palliation, prevention or cure of any eye or skin disease or condition in humans. If Elanco terminates the All Human Uses Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicensable, royalty-free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize

lotilaner and any licensed products for all applications in humans other than the treatment, palliation, prevention or cure of any eye or skin disease or condition. Accordingly, the loss of our license or the termination of our license for skin diseases and conditions or of our license for other use in humans with Elanco would materially harm our business.

If we are unable to obtain and maintain sufficient intellectual property protection for XDEMVY or our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to XDEMVY, our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to XDEMVY, our product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued that protect XDEMVY or our product candidates or their intended uses or that effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including U.S. Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the scope of patent protection outside of the U.S. is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the U.S., or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing or will pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. As noted above, the Novation Agreement amended the $15.0 million future development milestone payable on China regulatory approval of the China Out-License agreement with a combined condition of patent issuance related to TP-03 in China. If we are not able to obtain the aforementioned patent issuance in China, the likelihood we achieve the associated milestone, as well as commercialization in the China Territory would be substantially decreased.

Further, we may not be aware of all third-party intellectual property rights potentially relating to XDEMVY or our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our ability to commercialize our products, is highly uncertain. Because we have not yet conducted a formal patent landscape analysis related to XDEMVY or our product candidates, we may not be aware of issued patents that a third party might assert are infringed by XDEMVY or one of our current or future product candidates, which could materially impair our ability to commercialize XDEMVY or our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, including XDEMVY, TP-03, TP-04 or TP-05, we may not successfully find patents that our products or product candidates, including XDEMVY, TP-03, TP-04 or TP-05, may infringe. If we are unable to confirm that our products do not infringe third-party patents, others could preclude us from commercializing XDEMVY or our product candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing or, in some cases, not published at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patents or pending patent applications may be challenged in the courts or patent offices in the U.S. and abroad. For example, we may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in post-grant review or interference procedures, oppositions, derivations, revocations, reexaminations, or inter partes review proceedings, in the U.S. or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or

product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize XDEMVY or our current or future product candidates.

Our owned and licensed patent estate includes patent applications, many of which are at an early stage of prosecution. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or ability to sell our products without infringing third-party patents or patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

Furthermore, while we seek to protect the trademarks we use in the U.S. and in other countries, we may be unsuccessful in obtaining registrations and/or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands and trademarks unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the U.S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, that does not infringe the existing rights of third parties and that is acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications relating to XDEMVY or our product

candidates, our competitive position, business, financial condition, results of operations and prospects would be adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of XDEMVY or our product candidates in any jurisdiction. Because we have not yet conducted a formal patent landscape analysis related to XDEMVY or our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of XDEMVY or our current or future product candidates, which could materially impair our ability to commercialize XDEMVY or our product candidates. Even if we diligently search third-party patents for potential infringement by our products, including XDEMVY, or product candidates, we may not successfully find patents that our products or product candidates may infringe. If we are unable to confirm that our products, including XDEMVY, do not infringe third-party patents, others could preclude us from commercializing XDEMVY or our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market XDEMVY or our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products, including XDEMVY.

We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to XDEMVY or our product candidates, but may not be able to do so, which may cause us to alter or delay our commercialization or development plans.

The commercialization of XDEMVY and the development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. In 2019 and 2020, we entered into the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, respectively. We plan to utilize these license rights in developing and marketing XDEMVY, and our TP-03,TP-04 and TP-05 product candidates. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of XDEMVY in other jurisdictions or our product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for the commercialization of XDEMVY in other jurisdictions or the development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of XDEMVY or that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the following:

- the potential market for the product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for XDEMVY or our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations that we have entered into and may enter in the future may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of any product or product candidates that achieve marketing approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with XDEMVY or our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;

- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of our products or product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms or we may fail to comply with our obligations under such agreements and our business could be harmed.

In addition to the Elanco Agreements, from time to time we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all.

If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under any license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or

impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. In each of the Elanco Agreements, Elanco retains, and future licensors could retain, the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce such licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. If our licensors do not adequately protect such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

In addition to the above risks, intellectual property rights that we license in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that our patents or patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

Although we have pending U.S. and foreign patent applications in our portfolio, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;

- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those claimed in our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our products or product candidates or uses thereof in the U.S. or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our products or product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries.

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and, even if resolved in our favor, are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and biopharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents are directed to various types of products or methods of use. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties. The scope of patents is subject to interpretation by the courts, and the interpretation is not always uniform. The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be

able to do this. Proving invalidity may be difficult. For example, in the U.S., proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

In the U.S., the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. While we may apply for patent term extensions on patents covering XDEMVY and other product candidates that may receive FDA approval, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. To counter infringement or unauthorized use, we may be required to file infringement or other intellectual property-related claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from making, using, or selling the invention at issue. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-

examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from making, using or selling the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There also could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith Act signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a nonexclusive, nontransferable, irrevocable, paid-up license for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants. If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology that is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Furthermore, certain foreign and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may rely on trade secret and proprietary know how which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidate, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Despite these efforts, our assignment agreements may not be self-executing and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially, and adversely affect our business, financial condition, results of operations, and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. The assignment risks of this paragraph could also pertain to any intellectual property licensed-in to us. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or

information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

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

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, or at research institutions. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We or our licensors may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- the U.S. Supreme Court, other U.S. federal courts, U.S. Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our licensors' patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;

- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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

Patent rights are of limited duration. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. A patent term extension based on regulatory delay may be available in the U.S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to Government Regulation

Our industry is highly regulated by the FDA and comparable foreign regulatory authorities. We must comply with extensive, strictly enforced regulatory requirements to develop, obtain, and maintain marketing approval for XDEMVY or any of our product candidates, if approved.

XDEMVY and any product candidates we develop and the activities associated with their development and commercialization, including their design, testing, manufacturing, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution are very heavily regulated. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and have relied and expect to continue to rely on third-party CROs to assist us in this process. Securing FDA or comparable foreign regulatory approval such as a marketing authorization from the European Commission or the competent authorities of the individual EU Member States requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate's safety and efficacy for its intended use. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. It takes years to complete the testing of a new drug and development delays and/or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed, halted, not authorized, or approval of any of our products may be delayed or may not be obtained due to any of the following:

- any preclinical study or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;
- negative or inconclusive results from a preclinical study or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if

other studies or trials relating to the development program are ongoing or have been completed and were successful;

- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;

- the facilities that we utilize, or the processes or facilities of third-party vendors, including without limitation the contract manufacturers who are or will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and

- we may encounter delays or rejections based on changes in FDA regulations, standards or policies or the regulations, standards or policies of comparable foreign regulatory authorities during the period in which we develop a product candidate or the period required for review of any final marketing approval before we are able to market any product candidate.

In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent marketing approval at any stage of the approval process.

Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Failure to demonstrate adequately the quality, safety and efficacy of any of our product candidates would delay or prevent marketing approval of the applicable product candidate. We cannot assure you that if clinical trials are completed, either we or our potential collaborators will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could restrict or regulate post-approval activities, impact pricing and reimbursement and affect our ability to profitably sell XDEMVY or any other product candidates for which we obtain marketing approval and prevent or delay marketing approval of product candidates. Among policy makers and payers both federally and on the state level in the U.S. and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The ACA substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (i) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B program; (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased from 50% in 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (which, under the IRA, will be replaced by a new manufacturer discount program starting in 2025); (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) created a licensure framework for follow on biologic products; and (viii) established a Center for Medicare & Medicaid Innovation, at the

CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial challenges to certain aspects of the ACA, as well as efforts by Congress to modify, and agencies to alter the implementation of, certain aspects of the ACA. For example, Congress eliminated the tax penalty for not complying with the ACA's individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole" (which, under the IRA, will be replaced by a new manufacturer discount program starting in 2025). In the future, Congress may consider other legislation to modify elements of the ACA or other health care reform measures, agencies may further alter their implementation of elements of the ACA or other such measures, and other judicial challenges to elements of the ACA or other such measures may be brought. The extent to which any such changes may impact our business or financial condition is uncertain.

It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures including those that may be adopted in the future, may result in more rigorous coverage criteria, and less favorable payment methodologies, or other downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement or restriction on coverage under Medicare or other government programs may result in a similar reduction or restriction by private payers.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws. Subsequent legislation extended the 2% reduction, generally to 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. The American Taxpayer Relief Act of 2012 among other things, also reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and related services and, accordingly, the results of our financial operations. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 which first affected physician payment in 2019. It is unclear how the introduction of the Medicare quality payment program will impact our business.

The IRA introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program which could negatively affect the profitability of our product candidates. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme and a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologics without generic or biosimilar competition will be capped by reference to, among other things, a specified Non FAMP starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. This or any other legislative change could impact the market conditions for our products.

In the EU, the European Commission has published a proposal that intends to reduce the regulatory data protection period and orphan market exclusivity period for new medicinal products. Although it is currently uncertain if the proposal will be adopted in its current form and it is uncertain if and when the revised legislation would enter into force, this reform can impact our product candidates in the EU.

There has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills and initiatives, as well as state efforts, designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the U.S. have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Additionally, states have

established Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits.

We expect that these and other healthcare reform measures in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may hinder us in generating revenue, attaining profitability or commercializing our drugs, once marketing approval is obtained.

In the EU, the European Commission has published a proposal that intends to reduce the regulatory data protection period for new medicinal products, which would allow generic competitors to obtain marketing authorization for generic products relying on our data earlier than under the current laws and we may be faced with earlier generic competition and lower prices for our product on the EU market. The legislative process for this reform is expected to take several years. Although it is currently uncertain if the proposal will be adopted in its current form and it is uncertain if and when the revised legislation would enter into force, this reform could impact our product candidates in the EU.

In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. The requirements may differ across the EU Member States. In markets outside of the U.S. and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Also, at the national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the U.S., the European Union or any other jurisdiction. If we or any third parties we may engage with are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our employees, independent contractors, clinical trial investigators, contract research organizations, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the U.S. and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. We adopted a code of conduct applicable to all of our employees immediately following the completion of our IPO, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

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

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

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations. For example, we source our API for XDEMVY, lotilaner, from Elanco, who sources through a single source supplier. If such manufacturers become subject to such injunctions or sanctions due to non-compliance, it could delay, prevent or impair our commercialization efforts, which could have an adverse effect on our business.

The pharmaceutical legislation reform as proposed by the European Commission in April 2023 would, if adopted, also impose stricter rules regarding the 'Environmental Risk Assessment' that pharmaceutical manufacturers are obliged to perform. Under the proposal for new legislation, non-compliance with the Environmental Risk Assessment requirements could result in the withdrawal or refusal of a marketing authorization.

We may be subject to federal, state and foreign healthcare and abuse laws and false claims laws, as well as information privacy and security laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, criminal sanctions, contractual damages, reputational harm, and diminished profits and future earnings.

ECPs and third-party payers will play a primary role in the recommendation and prescription of XDEMVY and any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our arrangements with ECPs, patients, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect our business or financial arrangements and relationships through which we market, sell and distribute our products. As a biopharmaceutical company, federal and state healthcare laws and regulations pertaining to fraud and abuse are applicable to our business and may affect our ability to operate. These laws are further described in the section titled "Business - Government Regulation - Other Regulatory Matters."

We have entered into consulting and scientific advisory board arrangements with physicians and other ECPs, including some who could influence the use of XDEMVY or our product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of XDEMVY or our product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Various state and federal regulatory and enforcement agencies continue actively to

investigate violations of health care laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Efforts to ensure that our collaborations or business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgements, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as "Trade Laws", prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

For XDEMVY, or if we receive marketing approval for another product candidate, we are and will continue being subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payer is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payer. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product

will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the U.S.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations.

Coverage and reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for XDEMVY or any other product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, XDEMVY or any other product for which we obtain marketing approval. Assuming we obtain coverage for XDEMVY or another given product by a third-party payer, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payers to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

We expect to experience pricing pressures in connection with the sale of XDEMVY or any of our other product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the U.S., many countries require approval of the sale price of a product before it can be marketed and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and/or adverse publicity and could negatively affect our financial condition, operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission ("FTC")), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Though we are not directly subject to HIPAA information privacy and security provisions – other than with respect to providing certain employee benefits, depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Furthermore, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, in California, the CCPA, as amended by the California Privacy Rights Act ("CPRA"), creates transparency requirements, grants to California consumers (as that term is broadly defined) several rights with regard to their personal information, and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide disclosures to California consumers, and provides such consumers with ways to opt-out of certain sales of personal information. The CPRA introduced significant amendments to the CCPA and established and funded the CPPA. The amendments introduced by the CPRA went into effect on January 1, 2023, and implementing regulations continue to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and potential damages. Other states including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut, have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislations on our business as additional information and guidance becomes available. Similarly, there are a number of legislative proposals in the U.S, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. The CCPA and other state laws could impact our business activities depending on how they are interpreted and exemplify the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and have been proposed and enacted in other states.

The FTC also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

Activities outside of the U.S. require adherence to local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. EU Member States and the United Kingdom ("UK"), as well as other jurisdictions where we may in the future operate, have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation ("GDPR") imposes certain obligations and restrictions on the ability to collect, analyze, use, store, disclose, transfer, or otherwise process personal data, including health-related information from clinical trial subjects. The GDPR imposes a broad range of obligations and restrictions relating to the processing and protection of personal data, including obligations to having a legal basis for processing personal data (which may result in some instances in obtaining the consent of the individuals to whom the personal data relates), providing detailed information about the processing activities disclosed to the individuals, dealing with restrictions on sharing of personal data with third parties, and the transferring of personal data out of the EU, having contractual arrangements in place where required (such as with clinical trial sites and vendors), reporting in certain instances

personal data breaches to data protection authorities and/or affected individuals, appointing data protection officers, conducting data protection impact assessments, responding to privacy rights requests, and keeping records of processing activities. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to alleviate problems caused by such breaches. This may be onerous and if our efforts to comply with the GDPR or other applicable EU laws and regulations are not successful, it could adversely affect our business. Recent scrutiny and reevaluation of legal mechanisms to allow for the transfer of personal data from the European Economic Area ("EEA"), Switzerland, or UK to the U.S. may impact our ability to transfer personal data or otherwise may cause us to incur significant costs to do so legally. Although there are legal mechanisms to allow for the transfer of personal data from the EEA, Switzerland, and the UK to the U.S., uncertainty about compliance with EU data protection laws remains and data protection authorities from the different EU Member States may interpret the GDPR differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. Enforcement by EU and UK regulators is generally active, and failure to comply with the GDPR or applicable Member State/UK local law may result in substantial fines, amongst other things (such as notices requiring compliance within a certain timeframe). The GDPR provides for fines and other administrative penalties in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Further, the UK Government may amend/update UK data protection laws, which may result in changes to our business operations and potentially incur commercial cost.

Additionally, European/UK data protection laws, including the GDPR, generally restrict the transfer of personal data from the EEA (including the EU), UK, and Switzerland, to the U.S. and most other countries (except those deemed to be adequate by the European Commission/UK Secretary of State as applicable) unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. This may cause us to incur significant compliance costs for implementing lawful transfer mechanisms, conducting data transfer impact assessments, and implementing additional measures where necessary to ensure that personal data transferred are adequately protected in a manner essentially equivalent to the EU. The GDPR provides different transfer mechanisms we can use to lawfully transfer personal data from the EU to countries outside the EU. An example is relying on adequacy decisions of the European Commission, such as the EU-U.S. Data Privacy Framework which was adopted by the European Commission in 2023 ("EU-U.S. Data Privacy Framework"). The adequacy decision concludes that the U.S. ensures an adequate level of protection (compared to that of the EU) for personal data transferred from the EU to U.S. companies participating in the EU-U.S. Data Privacy Framework. The adequacy decisions of the European Commission are subject to periodic reviews and may be amended or withdrawn. Another example of a lawful transfer mechanism under the GDPR is using the EU Standard Contractual Clauses (“EU SCCs”) as approved by the European Commission in 2021. In order to use the EU Standard Contractual Clauses mechanism, the exporter and the importer must ensure that the importer may guarantee a level of personal data protection in the importing country’s level of protection must be adequate that is essentially equivalent to that of the EEA. It follows from case law of the Court of Justice of the European Union and the European Data Protection Board that compliance with EU data transfer obligations involves conducting transfer impact assessments, which includes documenting detailed analyses of data access and protection laws in the countries in which data importers are located, which can be costly and time-consuming. Data importers must also expend resources in analyzing their ability to comply with transfer obligations, including implementing new safeguards and controls to further protect personal data In the UK, international transfer mechanisms have been approved, including: the International Data Transfer Agreement and the International Data Transfer Addendum to the EU SCCs. The UK Information Commissioner’s Office has issued and maintains guidance on how to approach undertaking risk assessments for transfers of UK data to non-adequate countries outside the UK.

A lack of valid transfer mechanisms for data subject to EU/UK data protection laws could increase exposure to enforcement actions as described above, and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate/work with certain third parties and/or requiring an increase in our data processing capabilities in the EU/UK). Further, the European/UK data protection laws (including laws on international data transfers as set out above) may also be updated/revised, accompanied by new guidance and/or judicial/regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and/or adverse publicity and could negatively affect our financial condition, operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain personal data, as well as the providers who share this personal data with us, may contractually limit our ability to use and disclose the personal data. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. We cannot

assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy and data protection laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security- related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

Risks Related to Ownership of our Common Stock

The stock price of our common stock may be volatile or may decline regardless of our operating performance and you could lose all or part of your investment.

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- our failure to achieve product development or commercialization goals or regulatory approval milestones in the timeframe we announce;
- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory actions with respect to our product or product candidates;
- regulatory or legal developments in the U.S. and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- changes in hospital or ECP practices;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- financing or other corporate transactions, or inability to obtain additional funding;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float; and

- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biopharmaceutical companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If securities or industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

We are an "emerging growth company" and "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company as defined in the JOBS and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act");
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation; and
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes."

The JOBS Act permits an emerging growth company such as us, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2025, the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (b) the last day of the fiscal year (a) in which we have total annual gross revenue 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 (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-

voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

Sales of a substantial number of shares of our common stock in the public market could cause the price of our common stock to fall.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 31, 2024, we had 37,749,468 shares of common stock outstanding. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933 (the Securities Act") and various vesting agreements.

We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding warrant or options, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, including pursuant to our ATM program, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. For example, in March 2024 we completed a follow-on public offering of 2.8 million shares of our common stock at a public offering price of $32.00 per share and, in lieu of common stock to a certain investor, pre-funded warrants to purchase 312,500 shares of our common stock at a price of $31.9999 per pre-funded warrant, for aggregate net proceeds of approximately $107.7 million (after deducting underwriting discounts, commissions and other estimated offering-related expenses) and in the fourth quarter of 2023 we raised approximately $19.2 million, after deducting broker commissions and fees, through sales under our ATM program. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Our officers, directors and holders of more than 5% of our outstanding common stock acting together, will, due to their holdings of our common stock, have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, or the other rules and regulations of the SEC, or any securities exchange relating to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management and we will incur significant legal, accounting and other expenses. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more

difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Global Market LLC. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. We must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Therefore, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engaging outside consultants, continue to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This requires us to incur substantial professional fees and internal costs to maintain compliance.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Our Pharmakon Credit Facility also contains a negative covenant that prohibits us from paying dividends subject to limited exceptions. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the cost of manufacturing XDEMVY or our other product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- the level of demand for XDEMVY or our product candidates should they receive approval, which may vary significantly;

- the risk/benefit profile, cost and reimbursement policies with respect to XDEMVY or our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the gross-to-net yields for XDEMVY or our other product candidates, if approved;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit patients for preclinical studies and clinical trials, and any delays caused by difficulties in such recruitment efforts;
- our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the changing and volatile U.S., European and global economic environments, including the impact of current or future health pandemics; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and

- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation will further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

Securities Trading Plans of Directors and Executive Officers

In May 2023, Bobak Azamian, Chief Executive Officer, adopted a Rule 10b5-1 trading plan to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the sale of up to 291,000 shares of common stock held by Dr. Azamian between August 23, 2023 and July 24, 2024. Dr. Azamian terminated the trading plan effective January 8, 2024.

In May 2023, Jose Trevejo, former Chief Medical Officer, adopted a Rule 10b5-1 trading plan to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the sale of up to 6,107 shares of common stock held by Dr. Trevejo between August 17, 2023 and May 16, 2024. Dr. Trevejo terminated the trading plan effective January 12, 2024.

Item 6. Exhibits

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Date	Filed Herewith
10.1#	Separation Agreement, dated February 21, 2024, by and between Registrant and Jose Trevejo.					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: May 8, 2024

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

Date: May 8, 2024

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

Separation Agreement

The following agreement ("***Agreement***") between José M. Trevejo ("***you***") and Tarsus Pharmaceuticals, Inc. (the "***Company***" and, together with you, the "***Parties***") confirms your separation from employment and offers you certain benefits to which you would not otherwise be entitled, conditioned upon your provision of a general release of claims and the obligations set forth in this Agreement.

WHEREAS, you have served as the Chief Medical Officer of the Company since February 7, 2022;

WHEREAS, the Company notified you on January 11, 2024 that you would be separating from the Company; and

WHEREAS, you desire to fully and finally resolve any and all disputes and to set forth your complete agreement and release of claims.

NOW, THEREFORE, with the intent to be legally bound hereby, and in consideration of the mutual promises contained herein, the receipt and adequacy of which is hereby acknowledged, the Parties agree as follows:

1. Separation from Employment: Your last day of employment with the Company will be February 17, 2024 (the "***Separation Date***").

2. Final Pay and Benefits: You acknowledge and agree that the Company has provided you with your final pay, less lawful deductions (the "***Final Pay***") through the Separation Date, in a timely manner and in accordance with your state's or commonwealth's law. Whether or not you execute this Agreement, you will be entitled to, and are not releasing your rights to, any benefits required to be provided to you pursuant to any employee benefit plans in which you are a participant. You may also have rights to continue your group health coverage under the federal law commonly called "COBRA," or a state or commonwealth law equivalent.

3. Severance Benefits:

a. *Severance Pay:* The Company will pay you severance in the form of a lump sum cash severance payment equal to twelve (12) months of your current annualized salary ("***Severance Pay***"). The payments will be made pursuant to the Company's standard payroll procedures within fourteen (14) calendar days of the Effective Date (defined below). The Severance Pay will be treated as taxable compensation, but is not intended by either party to be treated, and will not be treated, as compensation for purposes of eligibility or benefits under any benefit plan of the Company. The Company will apply standard tax and other applicable withholdings to payments made to you.

b. *Severance Bonus*: The Company will also pay your 2023 annual target bonus, based 90% on the fiscal year 2023 Company performance score, and based 10% on individual performance in the Company's complete and absolute discretion (the "***Severance Bonus***") approved by the Compensation Committee (the "***Committee***") of the Company's Board of Directors (the "***Board***"). This Severance Bonus will be paid in a lump sum by March 22, 2024. The determinations of the Board or the Committee with respect to the 2023 Bonus Amount will be final and binding. The Severance Bonus will be treated as taxable compensation, but is not intended by either party to be treated, and will not be treated, as compensation for purposes of eligibility or benefits under any benefit plan of the Company. The Company will apply standard tax and other applicable withholdings to payments made to you.

c. *COBRA Premiums:* The Company will also pay the COBRA premiums for you and, if applicable, your dependents, for your continued group health coverage to the appropriate health insurer, for up to twelve (12) months after your Separation Date, provided you elect COBRA coverage. However, the Company will discontinue any such payment of COBRA premiums upon the earlier of (i) the date when you become eligible for substantially equivalent health insurance in connection with new employment, or (ii) the expiration of your continuation coverage under COBRA. You agree to immediately notify the Company in the event of (i) above.

d. *Additional Equity Benefits:* The Company will provide the additional equity benefits described in the Equity paragraph below.

e. *Paid Administrative Leave:* The Company will place you on paid garden leave from January 18, 2024, to February 17, 2024. During this period, the Company will continue to pay your full salary and the employer portion of your health insurance or COBRA premiums, and you will continue to vest in your equity awards. Further, during this period, you will be expected to provide services to assist in the transition of your responsibilities as reasonably requested by the Company (the "***Garden Leave Services***").

f. *Acknowledgement & Consideration:* You acknowledge the above benefits ("***Severance Benefits***") include some benefit you would not have been entitled to if had you not signed this Agreement.

4. Equity:

a. *Stock Options***.** You were granted the options set forth in the table below (each, an "***Option***" and collectively, the "***Options***") to purchase shares of the Company's common stock ("***Common Stock***") under the Company's 2020 Equity Incentive Plan (the "***2020 Plan***"). You acknowledge and agree that vesting of your Options will cease as of your Separation Date, and your rights to exercise your Options will be in accordance with the 2020 Plan and your Stock Option Agreements. The table below sets forth the number of vested and unvested shares subject to each Option as of your Separation Date. As consideration for entering into this Agreement, the Company will accelerate the vesting of your Options such that following the Effective Date, you will be vested in an additional number of shares subject to each of the Options as if you remained in continuous service with the Company through March 31, 2024 (as further set forth in the table below).

Date of Grant	Number of Option Shares Granted	Exercise Price Per Share	Vested Option Shares Outstanding as of the Separation Date	Unvested Option Shares Outstanding as of the Separation Date	Number of Option Shares Eligible for Acceleration	Remaining Unvested Option Shares Post-Acceleration
2/1/2022	116,424	$20.64	58,212	58,212	2,425	55,787
3/8/2023	45,459	$15.00	0	45,459	11,364	34,095

All unvested shares subject to the Options that are not eligible for acceleration as set forth in the table above will be forfeited to the Company on the Separation Date, in accordance with the terms and conditions set forth in the Stock Option Agreement governing each of the Options.

As additional consideration, your Options, to the extent vested as of the Separation Date or which are eligible for vesting acceleration as of the Effective Date and as set forth in the table above, will remain exercisable until the 12-month anniversary of your Separation Date, subject to their earlier termination in accordance with the 2020 Plan. To the extent the extension of the post-termination exercise period applies to an Option that is an incentive stock option with an exercise price that is lower than the current fair market value of the Company's Common Stock, you understand that the effect of the extension will be to disqualify the Option as an incentive stock option. To the extent the extension of the post-termination exercise period applies to an Option that is an incentive stock option with an exercise price that is equal to or greater than the current fair market value of the Company's Common Stock, the extension will not immediately disqualify the Option as an incentive stock option; however, such Option will automatically become a nonstatutory stock option three (3) months after the Separation Date. If you exercise an Option that is not an incentive stock option at the time of exercise, you will be required to make arrangements satisfactory to the Company to satisfy all applicable withholding obligations.

The Stock Option Agreements governing the Options will remain in full force and effect, and you agree to remain bound by those agreements.

b. *Restricted Stock Units*. You were granted the awards of restricted stock units ("***RSUs***") set forth in the table below pursuant to the 2020 Plan. You acknowledge and agree that vesting of your RSUs will cease as of your Separation Date. The table below sets forth the number of vested and unvested shares subject to each award of RSUs as of your Separation Date.

Date of Grant	Number of RSUs Granted	Number of RSUs Vested as of the Separation Date	Number of RSUs Unvested as of the Separation Date
2/1/2022	30,197	7,549	22,648
3/8/2023	30,792	0	30,792

All unvested RSUs will be forfeited to the Company on the Separation Date, in accordance with the terms and conditions set forth in the Restricted Stock Unit Agreement governing each of the awards of RSUs.

c. Except as set forth in (a) and (b) above, you acknowledge and agree that you do not have any other rights to receive, acquire, possess or vest into any additional shares of Common Stock or any other shares, warrants, securities, derivative securities or other class of capital stock of the Company or any of its parent, subsidiary or affiliated entities, in connection with your service with the Company.

5. Employee Representations: You acknowledge that the Company relies on these representations by you entering into this Agreement:

a. You do not have any claim against the Company or the Releasees (defined below), or otherwise have not made internal, administrative, or judicial complaints, claims, or actions against or regarding the Company or the Releasees, for claims you are releasing in this Agreement;

b. You have reported to the Company any work-related injuries or occupational illnesses sustained by you during your employment with the Company;

c. To your knowledge, you have been properly provided any leaves of absence requested and available to you based on your or your family members' health or medical condition or

military service, and have not been subjected to any improper treatment, conduct, or actions due to a request for or taking such leave;

d. You have received all compensation due to date because of services you performed for the Company;

e. You have been properly provided paid time off and, consistent with the Company's non-accrual vacation policy, you will not have any accrued, but unused vacation time or paid time off as of the Separation Date for which you are entitled to payment; and

f. You are not aware of any conduct by any person that violates Company policy or the Company's legal, compliance, or regulatory obligations, or any other suspected ethical or compliance issues by the Company or the other Releasees, which you have not brought to the attention of the Company.

6. Return of Company Property: You acknowledge and agree that as a condition precedent for the Severance Benefits, you must return to the Company all of its property and data of any type in your possession, custody, or control including, but not limited to keys, access codes or devices, physical or electronically stored documents or files, computer equipment, cell phone, and passwords. You further agree to return all the Company's property and data in substantially the same working condition in which they were issued to you, normal wear and tear excepted. Notwithstanding the foregoing, (i) an inadvertent failure by you to return such property, if immaterial, will not constitute a breach of this Agreement; and (ii) you may retain compensation-related and personnel documents pertaining to your employment, and materials distributed to shareholders generally.

7. Proprietary Information: You acknowledge that you are bound and continue to be bound by the Company's Proprietary Information and Inventions Agreement (the "***Confidentiality Agreement***"), a copy of which is attached as Exhibit A.

8. General Release and Waiver of Claims by You: To the fullest extent permitted by law, you on behalf of yourself, your heirs, family members, executors, estates, agents and assigns, or any controlled affiliate and any trust or other entity of which you or your heirs, estates or family directly or indirectly hold a majority beneficial interest, fully, finally, and forever release and discharge the Company and its owners, agents, officers, shareholders, employees, directors, attorneys, subsidiaries, affiliates, successors, investors, and assigns (collectively "***Releasees***"), of and from all claims and potential claims, which may legally be waived by private agreement, whether known or unknown, which you have asserted or could assert against the Company, arising out of or relating in any way to acts, circumstances, facts, transactions, or omissions based on facts, occurring up to and including the date you sign this Agreement (the "***Released Claims***"). The Released Claims specifically include, but are not limited to: claims under common law or equity; claims for additional compensation or benefits arising out of your employment or your separation from employment; wage and hour claims; unlawful discharge; breach of contract; breach of the covenant of good faith and fair dealing; fraud; violation of public policy; defamation; physical injury; emotional distress; negligence; claims under Title VII of the 1964 Civil Rights Act; the Age Discrimination in Employment Act ("***ADEA***"); Older Workers Benefit Protection Act ("***OWBPA***"); the Employee Retirement Income Security Act of 1974 ("***ERISA***"); the Americans with Disabilities Act; the Workers Adjustment and Retraining Notification Act; the Equal Pay Act; the Family Medical Leave Act; the Civil Rights Act of 1866; the Pregnancy Discrimination Act; the Massachusetts Wage Act, the Massachusetts Fair Employment Practices Act; the California Fair Employment and Housing Act, or the California Labor Code, and any other federal, state, or local laws, constitution, rule, ordinance, order, and/or regulations, including their amendments and respective implementing regulations. Notwithstanding the foregoing, nothing in this Agreement is a waiver of any claims (i) to enforce this Agreement; (ii) for any obligation of the Company pursuant to this Agreement; or (iii) regarding any rights of indemnification, rights to receipt of legal fees

and expenses, rights of insurance coverage, or rights to obtain contribution in the event of the entry of a judgment against you as a result of any act or failure to act for which both you and the Company are jointly responsible, to which you may be entitled.

By signing below, you expressly waive any benefits of Section 1542 of the Civil Code of the State of California, which provides:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

9. Protected Rights:

a. You understand that nothing in this Agreement limits your ability to file a charge or complaint with, to provide documents or information voluntarily or in response to a subpoena or other information request to, or to participate in an investigation or proceeding conducted by, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, or any other federal, state, or local government agency or commission (each, a "***Government Agency***"). You further understand this Agreement does not limit your ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. This Agreement does not limit your right to receive an award for information provided to any Government Agency.

You understand that nothing in this Agreement: (i) applies to claims for unemployment or workers' compensation benefits; (ii) applies to claims arising after the date you sign this Agreement; (iii) applies to claims for reimbursement of expenses under the Company's expense reimbursement policies; (iv) applies to claims for any vested rights under the Company's ERISA-covered employee benefit plans as applicable on the date you sign this Agreement; (v) applies to claims that controlling law clearly states may not be released by private agreement; (vi) limits or affects your right, if any, to challenge the validity of this Agreement under the ADEA or the OWBPA; (vii) applies to a non-disclosure or non-disparagement clause agreed to before a dispute arises involving a nonconsensual sexual act or sexual contact, including when the victim lacks capacity to consent, or relating to conduct that is alleged to constitute sexual harassment; (viii) precludes you from exercising your rights, if any, under Section 7 of the National Labor Relations Act ("***NLRA***") or under similar state law to engage in protected, concerted activity with other employees, including discussing your compensation or terms and conditions of employment; or (ix) prevents you from discussing or disclosing information about unlawful or criminal acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful or waives your right to testify in an administrative, legislative, or judicial proceeding concerning alleged criminal conduct or alleged sexual harassment on the part of the Company, or on the part of the agents or employees of the Company, when you have been required or requested to attend such a proceeding pursuant to a court order, subpoena, or written request from an administrative agency or the legislature. However, by signing this Agreement, you are waiving your right to recover any individual relief, including any backpay, frontpay, reinstatement or other legal or equitable relief, in any charge, complaint, or lawsuit or other proceeding brought by you or on your behalf by any third party, except for any right you may have to receive a payment or award from a Government Agency (and not the Company) for information provided to said Government Agency and except as provided under applicable law.

b. Notwithstanding your confidentiality obligations to the Company under the Confidentiality Agreement, this Agreement, and otherwise, you understand that as provided by the Federal Defend Trade Secrets Act, you will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret made: (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

c. You understand that upon the Effective Date, this Agreement will be final and binding. You promise not to pursue any claim released by this Agreement. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints against the Releasees, you shall do no more than simply say you cannot provide counsel or assistance. If you break this promise, or otherwise breach your obligations under the Agreement, you agree to pay the Company's costs and expenses, including reasonable attorneys' fees, related to the defense of any claims covered by this Agreement or any Releasee's efforts to enforce this Agreement. Notwithstanding the foregoing, although you are releasing claims you may have under the ADEA and the OWBPA, you may challenge the knowing and voluntary nature of this release before a court, the Equal Employment Opportunity Commission, or any other Government Agency charged with the enforcement of any employment laws.

10. Confidentiality: Except as required by law and subject to the Protected Rights paragraph above, you must keep the existence, contents, terms, and conditions of this Agreement confidential and may not disclose them except to your immediate family, accountant(s), attorneys, financial or tax advisers, or under subpoena or court order. If asked for information about this Agreement, you will simply respond that you and the Company have separated on agreed terms. Any breach of this Confidentiality paragraph shall be deemed a material breach of this Agreement.

11. Cooperation: You agree to reasonably cooperate with the Company relating to matters within your knowledge or responsibility. Without limiting this commitment, you agree (i) to meet with Company representatives, its counsel, or other designees at mutually convenient times and places with respect to any items within the scope of this provision; (ii) to provide truthful testimony regarding same to any court, agency, or other adjudicatory body; and (iii) to provide the Company with notice of contact by any non-governmental adverse party or such adverse party's representative, except as may be required by law. The Company will reimburse you for reasonable expenses in connection with the cooperation described in this paragraph. Any request for cooperation by the Company pursuant to this paragraph will not interfere with your pursuit, acceptance, or performance of duties in respect of other employment (including self-employment). In connection with any cooperation pursuant to this paragraph, the Parties shall each use their good-faith best efforts to reconcile and accommodate any conflicts in scheduling related to such cooperation, and the Company shall minimize, to the extent reasonably possible, the time required of you in connection with such requested cooperation.

12. No Disparagement: Subject to the Protected Rights paragraph above, you agree that you will never make any disparaging, defamatory, or negative statements public or privately, online or offline, orally or in writing about the Company or its directors, officers, products, services or business practices, your employment with the Company, or the termination of that employment. Similarly, the Company shall instruct the Company's current executive team members: Bobak Azamian, Jeff Farrow, Aziz Mottiwala, Sesha Neervannan, Dianne Whitfield, Bryan Wahl, and Cara Miller to not make any disparaging, defamatory, or negative statements, public or privately, online or offline, orally or in writing, about you, your employment with the Company, or the termination of that employment. Notwithstanding the foregoing, nothing in this Agreement prohibits you from (i) providing truthful testimony or information necessary to enforce any agreement between you and the Company or pursuant to a subpoena, court order

or other legal process; (ii) correcting or refuting any incorrect, defamatory, disparaging, or derogatory statements, made against you; or (iii) making truthful non-defamatory, non-disparaging, or non-derogatory statements in the context of seeking new employment or as part of your employment with any succeeding employer during normal competition.

13. No Admission of Liability: This Agreement shall not be construed or contended by you to be an admission or evidence of any wrongdoing, unlawful conduct, or liability by the Company or the Releasees. This Agreement shall be afforded the maximum protection allowable under Federal Rule of Evidence 408 and/or any other state or federal law of similar effect. However, the Parties agree that this Agreement may be used as evidence in a subsequent proceeding in which any of the Parties allege a breach of this Agreement or as a complete defense to any lawsuit brought by any party.

14. Headings; Sub-Headings: Headings and sub-headings of the paragraphs and sub-paragraphs of this Agreement are intended solely for convenience of reference and no provision of this Agreement is to be construed based upon the heading or sub-heading of any paragraph or sub-paragraph.

15. Complete and Voluntary Agreement: This Agreement, including its exhibits, constitutes the entire agreement between you and the Company regarding the subject hereof and supersedes all prior negotiations and agreements, whether written or oral, relating to such subject. Notwithstanding the foregoing, this Agreement shall not supersede obligations you may have under any agreements with the Company regarding the non-disclosure of trade secrets and confidential or proprietary information, prohibiting solicitation of customers, suppliers, or employees, prohibiting competition with the Company, assigning intellectual property, or providing for a dispute resolution mechanism. You acknowledge that neither the Company, the Releasees, nor their agents or attorneys have made any promise, representation or warranty, either express or implied, written or oral, which is not contained in this Agreement to induce you to execute the Agreement. You acknowledge that you have executed this Agreement in reliance only upon the promises, representations and warranties herein, and that you are executing this Agreement voluntarily and free of any duress or coercion. This Agreement is binding on and is for the benefit of the Parties and their respective successors, assigns, heirs, personal representatives, executors, administrators, and other legal representatives.

16. Severability: The provisions of this Agreement are severable, and if any part of the Agreement is found to be invalid or unenforceable, the other parts shall remain valid and enforceable.

17. Modification; Counterparts; Electronic/PDF Signatures: You agree this Agreement may not be altered, amended, modified, or otherwise changed, except by another written agreement that specifically refers to this Agreement, executed by authorized representatives of each party to this Agreement. This Agreement may be executed in several counterparts, each of which shall constitute an original and all of which together shall constitute the same instrument. Counterparts may be delivered via facsimile, electronic mail, or other electronic transmission method, and may be executed using any electronic signature method complying with the United States ESIGN Act of 2000 (*e.g.*, www.docusign.com). Any such counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

18. Interpretation and Construction of Agreement: This Agreement shall be construed and interpreted under the laws of the state or commonwealth where you were last employed by the Company (Massachusetts) without regard to conflict-of-laws principles. Moreover, this Agreement shall not be construed against either Party as the author or drafter of the Agreement.

19. Review of Separation Agreement; Effective Date: You understand that you must sign this agreement no earlier than your Separation Date (February 17, 2024) and deliver it to me at email bobby@tarsusrx.com no later than February 23, 2024 (the "***Consideration Period***"). You also agree that you have had at least twenty-one (21) calendar days to consider this Agreement, and that changes to this Agreement, whether material or immaterial, do not toll or restart the Consideration Period. If you choose to sign this Agreement before the Consideration Period ends, you represent: (i) you freely chose to do so after carefully considering its terms; (ii) you are knowingly and voluntarily waiving the remainder of the Consideration Period; and (iii) your decision to waive the remainder of the Consideration Period was not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the Consideration Period, or by providing different terms to you for signing this Agreement prior to the expiration of the Consideration Period. You affirm that you were advised to consult with an attorney before signing this Agreement. You also understand you may revoke this Agreement within seven (7) calendar days of signing (the "***Revocation Period***") and that the Company will only provide you with the Severance Benefits after that Revocation Period has expired. Any revocation must be made in writing and delivered to me at email bobby@tarsusrx.com. This Agreement is effective on the eighth (8th) calendar day after you sign it, provided that you have not revoked it (the "***Effective Date***").

(Remainder of Page Intentionally Left Blank; Signatures Follow Below)

The Parties have read this agreement and understand its legal and binding effect. The Parties are acting voluntarily, deliberately, and of their own free will in signing this agreement.

DocuSigned by:
By: Bobak Azamian
93C46A9590B5429...
Bobak Azamian
Chief Executive Officer
Tarsus Pharmaceuticals, Inc.

Date: 2/21/2024

DocuSigned by:
Jose Trevejo
9A0E42CCFF02498...
José M. Trevejo

Date: 2/20/2024
*** Do not sign before February 17, 2024 ***

Exhibit
Exhibit A: Confidentiality Agreement

EXHIBIT A
Confidentiality Agreement

PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

The following confirms and memorializes an agreement that Tarsus Pharmaceuticals, Inc., a Delaware corporation (the "Company") and I (José Trevejo) have had since the commencement of my employment (which term, for purposes of this agreement, shall be deemed to include any relationship of service to the Company that I may have had prior to actually becoming an employee) with the Company in any capacity and that is and has been a material part of the consideration for my employment by Company:

1. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict with this Agreement or my employment with Company. I will not violate any agreement with or rights of any third party or, except as expressly authorized by Company in writing hereafter, use or disclose my own or any third party's confidential information or intellectual property when acting within the scope of my employment or otherwise on behalf of Company. Further, I have not retained anything containing any confidential information of a prior employer or other third party, whether or not created by me.

2. Company shall own all right, title and interest (including patent rights, copyrights, trade secret rights, mask work rights, sui generis database rights and all other intellectual property rights of any sort throughout the world) relating to any and all inventions (whether or not patentable), works of authorship, mask works, designs, know-how, ideas and information made or conceived or reduced to practice, in whole or in part, by me during the term of my employment with Company to and only to the fullest extent allowed by California Labor Code Section 2870 (which is attached as Appendix A) (collectively "Inventions") and I will promptly disclose all Inventions to Company. Without disclosing any third party confidential information, I will also disclose anything I believe is excluded by Section 2870 so that the Company can make an independent assessment. I hereby make all assignments necessary to accomplish the foregoing. I shall further assist Company, at Company's expense, to further evidence, record and perfect such assignments, and to perfect, obtain, maintain, enforce, and defend any rights specified to be so owned or assigned. I hereby irrevocably designate and appoint Company as my agent and attorney-in-fact, coupled with an interest and with full power of substitution, to act for and in my behalf to execute and file any document and to do all other lawfully permitted acts to further the purposes of the foregoing with the same legal force and effect as if executed by me. If anything created by me prior to my employment relates to Company's actual or proposed business, I have listed it on Appendix B in a manner that does not violate any third party rights or disclose any confidential information. Without limiting Section 1 or Company's other rights and remedies, if, when acting within the scope of my employment or otherwise on behalf of Company, I use or disclose my own or any third party's confidential information or intellectual property (or if any Invention cannot be fully made, used, reproduced, distributed and otherwise exploited without using or violating the foregoing), Company will have and I hereby grant Company a perpetual, irrevocable, worldwide royalty-free, non-exclusive, sublicensable right and license to exploit and exercise all such confidential information and intellectual property rights.

3. I grant permission to Company (inclusive of any person or entity acting in the Company's behalf) to take and use visual and/or audio images ("Images") of me. Images include any type of recording, including but not limited to photographs, digital images, drawings,

renderings, voices, sounds, video recordings, audio clips or accompanying written descriptions, in any tangible form. Company shall own the Images and all rights relating thereto, and I hereby assign all right, title, and interest to the foregoing to the Company. I shall further assist Company, at Company's expense, to further evidence, record and perfect such assignments, and to perfect, obtain, maintain, enforce, and defend any rights specified to be so owned or assigned. I hereby irrevocably designate and appoint Company as my agent and attorney-in-fact, coupled with an interest and with full power of substitution, to act for and in my behalf to execute and file any document and to do all other lawfully permitted acts to further the purposes of the foregoing with the same legal force and effect as if executed by me. The Images may be used for any legal purpose, and in any manner or media without notifying me, non-limiting examples of which include Company websites, publications, promotions, broadcasts, advertisements, social media, posters and theater slides. I waive any right to inspect or approve the finished images or any printed or electronic matter that may be used with them, or to be compensated for them. I release Company and its employees and agents, including any entity authorized to publish, broadcast and/or distribute a finished product containing the Images, from any claims, damages, or liability which I may ever have in connection with the taking, use, or distribution of the Images.

4. To the extent allowed by law, paragraphs 2 and 3 includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively "Moral Rights"). To the extent I retain any such Moral Rights under applicable law, I hereby ratify and consent to any action that may be taken with respect to such Moral Rights by or authorized by Company and agree not to assert any Moral Rights with respect thereto. I will confirm any such ratifications, consents and agreements from time to time as requested by Company.

5. I agree that all Inventions and all other business, technical and financial information (including, without limitation, the identity of and information relating to customers or employees) I develop, learn or obtain during the term of my employment that relate to Company or the business or demonstrably anticipated business of Company or that are received by or for Company in confidence, constitute "Proprietary Information." I will hold in confidence and not disclose or, except within the scope of my employment, use any Proprietary Information. However, I shall not be obligated under this paragraph with respect to information I can document is or becomes readily publicly available without restriction through no fault of mine. Upon termination of my employment, I will promptly return to Company all items containing or embodying Proprietary Information (including all copies), except that I may keep my personal copies of (i) my compensation records, (ii) materials distributed to shareholders generally and (iii) this Agreement. I also recognize and agree that I have no expectation of privacy with respect to Company's telecommunications, networking or information processing systems (including, without limitation, stored computer files, email messages and voice messages) and that my activity and any files or messages on or using any of those systems may be monitored at any time without notice.

6. Until one year after the term of my employment, I will not encourage or solicit any employee or consultant of Company to leave Company for any reason (except for the bona fide firing of Company personnel within the scope of my employment).

7. I agree that during the term of my employment with Company (whether or not during business hours), I will not engage in any activity that is in any way competitive with the business or demonstrably anticipated business of Company, and I will not assist any other person or organization in competing or in preparing to compete with any business or demonstrably anticipated business of Company.

8. I agree that this Agreement is not an employment contract for any particular term and that I have the right to resign and Company has the right to terminate my employment at will, at any time, for any or no reason, with or without cause. In addition, this Agreement does not purport to set forth all of the terms and conditions of my employment, and, as an employee of Company, I have obligations to Company which are not set forth in this Agreement. However, the terms of this Agreement govern over any inconsistent terms and can only be changed by a subsequent written agreement signed by the President of Company.

9. I agree that my obligations under paragraphs 2, 3, 4, 5 and 6 of this Agreement shall continue in effect after termination of my employment, regardless of the reason or reasons for termination, and whether such termination is voluntary or involuntary on my part, and that Company is entitled to communicate my obligations under this Agreement to any future employer or potential employer of mine. My obligations under paragraphs 2, 3, 4 and 5 also shall be binding upon my heirs, executors, assigns, and administrators and shall inure to the benefit of Company, its subsidiaries, successors and assigns.

10. Any dispute in the meaning, effect or validity of this Agreement shall be resolved in accordance with the laws of the State of California without regard to the conflict of laws provisions thereof. I further agree that if one or more provisions of this Agreement are held to be illegal or unenforceable under applicable California law, such illegal or unenforceable portion(s) shall be limited or excluded from this Agreement to the minimum extent required so that this Agreement shall otherwise remain in full force and effect and enforceable in accordance with its terms. This Agreement is fully assignable and transferable by Company, but any purported assignment or transfer by me is void. I also understand that any breach of this Agreement will cause irreparable harm to Company for which damages would not be an adequate remedy, and, therefore, Company will be entitled to injunctive relief with respect thereto in addition to any other remedies and without any requirement to post bond.

NOTICE: This agreement does not affect any immunity under 18 USC Sections 1833(b) (1) or (2), which read as follows (note that for purposes of this statute only, individuals performing work as contractors or consultants are considered to be employees):

> (1) An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.
>
> (2) An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the

individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order.

I HAVE READ THIS AGREEMENT CAREFULLY AND I UNDERSTAND AND ACCEPT THE OBLIGATIONS WHICH IT IMPOSES UPON ME WITHOUT RESERVATION. NO PROMISES OR REPRESENTATIONS HAVE BEEN MADE TO ME TO INDUCE ME TO SIGN THIS AGREEMENT. I SIGN THIS AGREEMENT VOLUNTARILY AND FREELY, IN DUPLICATE, WITH THE UNDERSTANDING THAT THE COMPANY WILL RETAIN ONE COUNTERPART AND THE OTHER COUNTERPART WILL BE RETAINED BY ME.

Date: 1/18/2022

Employee:

DocuSigned by:
Jose Trevejo
9A0E42CCFE02498...
Signature

Jose Trevejo
Name (Printed)

Accepted and Agreed to:

TARSUS PHARMACEUTICALS, INC.

By: DocuSigned by:
Bobby Azamian
5FCD9AEEC54040B...

Name: Bobby Azamian

Title: CEO

APPENDIX A

California Labor Code Section 2870. Application of provision providing that employee shall assign or offer to assign rights in invention to employer.

(a) Any provision in an employment agreement which provides that an employee shall assign, or offer to assign, any of his or her rights in an invention to his or her employer shall not apply to an invention that the employee developed entirely on his or her own time without using the employer's equipment, supplies, facilities, or trade secret information except for those inventions that either:

(1) Relate at the time of conception or reduction to practice of the invention to the employer's business, or actual or demonstrably anticipated research or development of the employer; or

(2) Result from any work performed by the employee for his employer.

(b) To the extent a provision in an employment agreement purports to require an employee to assign an invention otherwise excluded from being required to be assigned under subdivision (a), the provision is against the public policy of this state and is unenforceable.

APPENDIX B

PRIOR MATTER

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: May 8, 2024

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: May 8, 2024

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

Exhibit 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

In connection with the Quarterly Report of Tarsus Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 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: May 8, 2024

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

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

In connection with the Quarterly Report of Tarsus Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 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: May 8, 2024

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