

REFINITIV

DELTA REPORT

10-Q

PLRX - PLIANT THERAPEUTICS, INC.
10-Q - JUNE 30, 2024 COMPARED TO 10-Q - MARCH 31, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	2291
CHANGES	105
DELETIONS	2025
ADDITIONS	161

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** ~~June 30, 2024~~

☐ **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: 001-39303

PLIANT THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

260 Littlefield Avenue

331 Oyster Point Blvd., South San Francisco, CA

(Address of principal executive offices)

47-4272481

(I.R.S. Employer

Identification No.)

94080

(Zip Code)

Registrant's telephone number, including area code: (650) 481-6770

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, par value \$0.0001 per share	PLRX	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 1, 2024** ~~August 1, 2024~~, the registrant had **60,325,832** ~~60,801,425~~ shares of common stock, \$0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Report, contains forward-looking statements that involve risks, uncertainties, and assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Report include, but are not limited to, statements about:

- Our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- The success, cost and timing of our product development activities and clinical trials of our lead product candidate, bexotegraft (PLN-74809), including our expectations that the implementation of BEACON-IPF, a 52-week, randomized, double-blind, placebo-controlled Phase 2b trial in patients with idiopathic pulmonary fibrosis (IPF), as a pivotal adaptive Phase 2b/3 trial design will significantly shorten bexotegraft's late-stage development compared to standalone Phase 2b and Phase 3 trials, and our other product candidates;
- Our plans to initiate, recruit and enroll patients in, and conduct our clinical trials at the pace that we project;
- Our plans and strategy to obtain and maintain regulatory approvals of our product candidates;
- Our plans and strategy to obtain funding for our operations, including funding necessary to complete further development and, upon successful development, if approved, commercialize any of our product candidates;
- The effect and impact of new, existing and proposed laws and regulations;
- The potential benefit of orphan drug and Fast Track designations for bexotegraft;
- Our ability to compete with companies currently marketing or engaged in the development of treatments for fibrosis;
- Our plans and strategy regarding obtaining and maintaining intellectual property protection for our product candidates and the duration of such protection;
- Our plans and strategy regarding the manufacture of our product candidates for clinical trials and for commercial use, if approved;
- Our dependence on future collaborators for developing, obtaining regulatory approval for and commercializing product candidates in the collaboration;
- Our receipt and timing of any milestone payments or royalties under any future research collaboration or license agreements or arrangements;
- Our plans and strategy regarding the commercialization of any products that are approved for marketing and our ability to establish adequate pricing in the U.S. and international markets;
- The size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in combination with others;
- Our ability to attract and retain qualified employees and key personnel;

- Our expectations regarding government and third-party payor coverage and reimbursement; and
- Our expectations of obtaining a positive health technology assessment recommending our products.

These statements are based on the beliefs and assumptions of our management, which are in turn based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results and timing expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section entitled "Risk Factors" included under Part II, Item 1A in this Report. Furthermore, such forward-looking statements speak only as of the date of this Report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business involves significant risks, some of which are summarized below. The summary risk factors listed below should be read together with the text of the full risk factors discussed in "Part II, Item 1A - Risk Factors" in this Report. You should carefully consider the risks described below, as well as the other information in this Report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as in other documents that we file with the Securities and Exchange Commission, or the SEC. The occurrence of any of the events or developments described in this Report could have a material adverse effect on our business, financial condition, results of operations, growth prospects and stock price. In such an event, the market price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Need for Additional Capital

- We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations.

Risks Related to Research and Development and the Biopharmaceutical Industry

- We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.
- Our business is highly dependent on the success of our lead product candidate, bexotegrist and any other product candidates that we advance into the clinic. All of our product candidates will require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.
- Our approach to drug discovery and development in the area of fibrotic diseases is unproven and may not result in marketable products.
- Clinical development involves a lengthy, complex, and expensive process, with an uncertain outcome to support either a marketing authorization or positive pricing and reimbursement decisions.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of bexotegrist or any other product candidates.
- We may fail to obtain and maintain certain regulatory exclusivities and orphan designations in some jurisdictions and therefore fail to secure orphan exclusivity or other exclusivity extensions in those jurisdictions.
- Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than us.
- We may fail to secure an appropriate reimbursement price or a positive health technology assessment.
- The timelines of our clinical trials and the overall costs to conduct and complete the clinical trials may be adversely impacted due to disruptions caused by marketplace conditions, including the effects of health epidemics and pandemics, such as COVID-19, or other geopolitical conditions.

Risks Related to Our Intellectual Property

- Our success depends in part on our ability to obtain patent term extensions and to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- Our collaborators may assert ownership or commercial rights to inventions they develop from research we support, or that we develop from our use of the tissue samples or other biological materials which they provide to us, or otherwise arising from the collaboration.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials and for tissue samples and other materials required for our research and development activities.
- We rely on single-source third party suppliers located in foreign jurisdictions, including China, to manufacture our drug candidates. An interruption in this supply, caused by a business interruption or geopolitical events, could materially disrupt our research and development activities.
- If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

Risks Related to Managing Our Business and Operations

- The effects of health epidemics and pandemics, such as COVID-19 could adversely impact our business, including our preclinical studies and clinical trials.

- Our loss of key management personnel, or our failure to recruit additional highly skilled personnel, will impair our ability to develop current product candidates or identify and develop new product candidates, could result in loss of markets or market share and could make us less competitive.
- Effective December 31, 2023, we became a large accelerated filer and no longer qualify as a smaller reporting company, which will increase our costs and demands on management.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements.

**Pliant Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)**

(In thousands, except number of shares and per share amounts)

	March 31, 2024	*December 31, 2023	June 30, 2024	*December 31, 2023
Assets				
Current assets				
Current assets				
Current assets				
Cash and cash equivalents				
Cash and cash equivalents				
Cash and cash equivalents				
Short-term investments				
Prepaid expenses and other current assets (Note 5)				
Total current assets				
Property and equipment, net				
Property and equipment, net (Note 4)				
Operating lease right-of-use assets (Note 14)				
Restricted cash				
Other non-current assets				
Total assets				
Liabilities and stockholders' equity				
Current liabilities				
Current liabilities				
Current liabilities				
Accounts payable				
Accounts payable				
Accounts payable				
Accrued research and development				
Accrued liabilities (Note 6)				
Operating lease liabilities, current (Note 14)				
Total current liabilities				
Operating lease liabilities, non-current (Note 14)				
Long-term debt (Note 7)				
Total liabilities				
Commitments and Contingencies (Note 13)	Commitments and Contingencies (Note 13)		Commitments and Contingencies (Note 13)	
Stockholders' equity				
Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023, and none issued or outstanding at March 31, 2024 and December 31, 2023 (Note 9)				
Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023, and none issued or outstanding at March 31, 2024 and December 31, 2023 (Note 9)				
Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023, and none issued or outstanding at March 31, 2024 and December 31, 2023 (Note 9)				

Common stock, \$0.0001 par value per share; 300,000,000 shares authorized at March 31, 2024 and December 31, 2023; and 60,318,542 and 59,921,002 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively; (Note 10)

Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized at June 30, 2024 and December 31, 2023, and none issued or outstanding at June 30, 2024 and December 31, 2023 (Note 9)

Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized at June 30, 2024 and December 31, 2023, and none issued or outstanding at June 30, 2024 and December 31, 2023 (Note 9)

Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized at June 30, 2024 and December 31, 2023, and none issued or outstanding at June 30, 2024 and December 31, 2023 (Note 9)

Common stock, \$0.0001 par value per share; 300,000,000 shares authorized at June 30, 2024 and December 31, 2023; and 60,425,144 and 59,921,002 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively; (Note 10)

Additional paid-in capital

Accumulated deficit

Accumulated other comprehensive (loss) gain

Total stockholders' equity

Total liabilities and stockholders' equity

* The condensed balance sheet as of December 31, 2023 has been derived from the audited financial statements as of that date.

The accompanying notes are an integral part of these condensed financial statements

Pliant Therapeutics, Inc. Condensed Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except number of shares and per share amounts)

	Three Months Ended March 31,			Three Months Ended June 30,		Six Months Ended June 30,		
	2024	2024	2023	2024	2023	2024	2023	2023
Revenue								
Operating expenses:								
Research and development								
Research and development								
Research and development								
General and administrative								
Total operating expenses								
Loss from operations								
Interest and other income (expense), net								
Interest expense								
Net loss								
Net loss per share - basic and diluted								
Shares used in computing net loss per share - basic and diluted								
Comprehensive loss:								
Net loss								
Net loss								
Net loss								
Net unrealized (loss) gain on short-term investments								
Total other comprehensive (loss) gain								
Net unrealized loss on short-term investments								
Total other comprehensive loss								
Comprehensive loss								

The accompanying notes are an integral part of these condensed financial statements.

Pliant Therapeutics, Inc. Condensed Statements of Stockholders' Equity (Unaudited)

(In thousands, except number of shares and per share amounts)

	Common Stock Shares	Additional Paid-In Capital	Additional Paid-In Capital	Accumulated Other Comprehensive Gain/(Loss)	Accumulated Other Comprehensive Gain/(Loss)	Accumulated Deficit	Accumulated Deficit	Total Stockholders' Equity	Total Stockholders' Equity	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Gain/(Loss)	Accumulated Deficit
Balance at December 31, 2023													
Balance at December 31, 2023													
Balance at December 31, 2023													
Issuance of common stock under benefit plans													
Stock-based compensation expense													
Net unrealized loss on short-term investments													
Net loss													
Balance at March 31, 2024													
Issuance of common stock under benefit plans													
Stock-based compensation expense													
Net unrealized loss on short-term investments													
Net loss													
Balance at June 30, 2024													

The accompanying notes are an integral part of these condensed financial statements.

Pliant Therapeutics, Inc.								
Condensed Statements of Stockholders' Equity								
(Unaudited)								
(In thousands, except number of shares and per share amounts)								
	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at December 31, 2022								
Balance at December 31, 2022								

Balance at December 31, 2022
Common stock issued in a public offering, net of offering expenses
Issuance of common stock under benefit plans
Stock-based compensation expense
Net unrealized gain on short-term investments
Net loss
Balance at March 31, 2023
Public offering expenses
Issuance of common stock under benefit plans
Stock-based compensation expense
Net unrealized loss on short-term investments
Net loss
Balance at June 30, 2023

The accompanying notes are an integral part of these condensed financial statements.

Pliant Therapeutics, Inc. Condensed Statements of Cash Flows (Unaudited)					
(In thousands)	(In thousands)	Three Months Ended March 31,	2023	Six Months Ended June 30,	2024 2023
		2024		(In thousands)	
Cash flows from operating activities	Cash flows from operating activities			Cash flows from operating activities	
Net loss					
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation expense					
Depreciation expense					
Depreciation expense					
Stock-based compensation expense					
Non-cash operating lease expense					
Net amortization (accretion) on short-term investments and debt					
Changes in operating assets and liabilities:					
Accounts receivable					
Accounts receivable					
Accounts receivable					
Prepaid expenses and other current assets					
Other non-current assets					
Accounts payable					
Accrued liabilities					
Operating lease liabilities					
Net cash used in operating activities					
Cash flows from investing activities					
Purchase of short-term investments					
Purchase of short-term investments					
Purchase of short-term investments					
Maturity of short-term investments					
Purchase of property and equipment					
Net cash used in (provided by) investing activities					
Net cash provided by (used in) investing activities					
Cash flows from financing activities					

Proceeds from issuances of common stock under benefit plans
Proceeds from issuances of common stock under benefit plans
Proceeds from issuances of common stock under benefit plans
Proceeds from term loan, net
Payment of offering costs
Proceeds from sale of common stock in a public offering
Net cash provided by financing activities
Net increase in cash and cash equivalents
Cash and cash equivalents and restricted cash at beginning of period
Cash, cash equivalents and restricted cash at end of period

Supplemental disclosures of cash flow information:
Cash paid for interest
Cash paid for interest
Cash paid for interest

Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets
Cash and cash equivalents
Cash and cash equivalents
Cash and cash equivalents
Restricted cash
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows

Supplemental disclosures of noncash investing and financing activities:
Net unrealized (loss) gain on short-term investments
Net unrealized (loss) gain on short-term investments
Net unrealized (loss) gain on short-term investments
Net unrealized loss on short-term investments
Net unrealized loss on short-term investments
Net unrealized loss on short-term investments
Purchase of property and equipment in accounts payable and accrued liabilities
Supplemental disclosures of cash flow information related to leases:
Right-of-use assets obtained in exchange for new operating lease liabilities
Right-of-use assets obtained in exchange for new operating lease liabilities
Right-of-use assets obtained in exchange for new operating lease liabilities

The accompanying notes are an integral part of these condensed financial statements.

Pliant Therapeutics, Inc.
Notes to Condensed Financial Statements
(Unaudited)

1. Organization and Description of Business

Pliant Therapeutics, Inc. (the “Company” or “Pliant” or “we” or “our” or “us”) is a late stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis with an initial focus on treating fibrosis by inhibiting integrin-mediated activation of TGF-β. Fibrosis refers to the abnormal thickening and scarring of connective tissue due to the production and deposition of excess collagen in the extra-cellular matrix. Fibrosis can occur in many different tissues including lung, liver, kidney, muscle, skin and the GI tract, and often causes severe and debilitating disease leading to organ failure. The Company is located in South San Francisco, California, and was incorporated in the state of Delaware in June 2015.

Public Offering

In January 2023, the Company completed a public offering of 9,583,334 shares of common stock, including the exercise in full of the underwriters' option to purchase 1,250,000 additional shares of common stock. The shares were offered at a price of \$30.00 per share, resulting in aggregate proceeds of approximately \$269.8 million, net of underwriting discounts, commissions and offering expenses payable by us.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”), for interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the unaudited interim condensed financial

statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited interim condensed financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of the Company's financial information. The results of operations for the three and six months ended March 31, 2024 June 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other interim period or for any other future year.

The financial information included herein should be read in conjunction with the audited financial statements and related notes in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 27, 2024 (the "2023 10-K").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses as well as the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, stock-based compensation expense, operating lease right-of-use ("ROU") assets and liabilities, accruals and prepayments for research and development costs, income taxes and uncertain tax positions. The Company assesses estimates on an ongoing basis, however, actual results could materially differ from those estimates.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three and six months ended March 31, 2024 June 30, 2024, as compared to the significant accounting policies described in Note 2 of the "Notes to the Financial Statements" in the Company's audited financial statements included in its 2023 10-K.

Recently Announced Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose information about their reportable segments' significant expenses on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Entities must adopt the changes to the segment reporting guidance on a retrospective basis, and early adoption is permitted. The Company is currently evaluating the impact of this standard on its disclosures and will adopt the ASU for its 2024 10-K.

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures", which expands disclosures in an entity's income tax rate reconciliation table and regarding cash taxes paid both in the U.S. and foreign jurisdictions. The Company is currently evaluating the impact of this standard on its disclosures and will adopt the ASU for its 2025 10-K.

3. Financial Instruments

The Company's short-term investments consist of U.S. Treasury securities, U.S. government agency securities and highly rated, investment-grade corporate debt securities with original maturities beyond three months at the date of purchase. The Company has classified and accounted for its short-term investments as available-for-sale securities as the Company may sell these securities at any time even prior to maturity and such investments represent cash available for current operations. As a result, short-term investments may include securities with maturities beyond twelve months that are classified within current assets in the Balance Sheets. The Company's short-term investments classified as available-for-sale are carried at fair market value with unrealized gains or losses recognized in the statements of operations and comprehensive loss.

The Company's cash equivalent Money Market Funds are classified as Level 1 in the fair value hierarchy because they are valued using quoted active market prices. The fair value of the Company's U.S. Treasury securities, U.S. government agency securities and corporate debt securities are classified as Level 2 because they are valued using observable inputs to quoted market prices other than Level 1 prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency and include U.S. government agency securities, U.S. Treasury securities and corporate debt securities.

There were no assets or liabilities recorded at fair value to the condensed balance sheets using Level 3 inputs as of March 31, 2024 June 30, 2024 and as of December 31, 2023.

The following tables show the Company's Money Market Funds, U.S. Treasury securities, U.S. government agency securities and corporate debt securities by significant investment category as of March 31, 2024 June 30, 2024 and December 31, 2023 (in thousands):

	As of March 31, 2024					As of December 31, 2023				
	As of June 30, 2024					As of December 31, 2023				
	Adjusted Cost	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value	
Money Market Funds										
U.S. Treasury securities										
U.S. Government agency securities										
Corporate debt securities										
Total financial assets										

	As of March 31, 2024					As of December 31, 2023				
	As of June 30, 2024					As of December 31, 2023				
	Adjusted Cost	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value	

Classified as:

- Cash equivalents
- Cash equivalents

Cash equivalents
Short-term investments
Total

The Company may sell certain of its short-term securities prior to their stated maturities for reasons including, but not limited to, managing liquidity, credit risk, duration and asset allocation.

There were no liabilities measured at fair value on a recurring basis as of **March 31, 2024** **June 30, 2024** and December 31, 2023. The Company evaluates transfers between levels at the end of each reporting period and there have been no transfers between fair value measurement levels during the **three** six months ended **March 31, 2024** **June 30, 2024**. In addition, there were no assets or liabilities measured at fair value on a non-recurring basis as of **March 31, 2024** **June 30, 2024** and December 31, 2023.

The Company records interest income, accretion income and amortization expense on Money Market Funds and U.S. Treasury, U.S. government agency and corporate debt securities to interest and other income (expense), net in its condensed statement of operations and comprehensive loss.

4. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	As of March 31, 2024	As of December 31, 2023	As of June 30, 2024	As of December 31, 2023
Laboratory equipment				
Leasehold improvements				
Furniture and fixtures				
Computer equipment and software				
Construction-in-progress				
Total property and equipment, gross				
Less: Accumulated depreciation				
Total property and equipment, net				

Depreciation expense was **\$0.5** \$0.6 million and **\$0.5 million** **\$1.1 million** for the three and six months ended **March 31, 2024** **June 30, 2024**, and **2023**, \$0.4 million and \$0.9 million for the three and six months ended **June 30, 2023**, respectively.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	As of March 31, 2024	As of December 31, 2023
	As of June 30, 2024	As of December 31, 2023
Prepaid research and development		
Interest receivable		
Prepaid licenses		
Prepaid insurance		
Prepaid licenses		
Interest receivable		
Other		
Total prepaid expenses and other current assets		

6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	As of March 31, 2024	As of December 31, 2023
	As of June 30, 2024	As of December 31, 2023
Accrued compensation and benefits		
Other accrued liabilities		
Total accrued liabilities		

Accrued compensation and benefits consist primarily of accrued bonuses and accrued vacation.

7. Long-term Debt

In May 2022, as amended in October 2022, we entered into a term loan facility (the "Oxford Loan Agreement") with Oxford Finance LLC (the "Lender") for up to \$100.0 million. In connection with the Oxford Loan Agreement, we granted a security interest in substantially all of our current and future assets. There are no warrants or financial covenants associated with the Oxford Loan Agreement. At closing, we entered into a term loan for \$10.0 million and we decided not to draw upon the additional \$65.0 million that became available to us over the course of 2023 as certain conditions related to the development of bexotegrag and one of our preclinical product candidates were satisfied. As of December 31, 2023, the time period to draw upon the additional \$65.0 million had lapsed.

On March 11, 2024, we entered into an Amended and Restated Loan and Security Agreement (the "Amended Loan Agreement") with the Lender to borrow a series of term loans up to an aggregate principal amount of \$150.0 million (the "Term Loans"), of which \$50.0 million is subject to the Lender's sole discretion.

Pursuant to the Amended Loan Agreement, we drew an initial Term Loan of \$30.0 million, inclusive of \$10.0 million in principal amount previously outstanding under the Oxford Loan Agreement. We may borrow up to an additional \$70.0 million of Term Loans at our option upon the satisfaction of certain conditions related to the development of bexotegragr. In connection with the Amended Loan Agreement, the Company granted the Lender a security interest in substantially all of the Company's assets now owned or hereafter acquired, excluding intellectual property to the extent the aggregate amount of Term Loans advanced and outstanding does not exceed \$50.0 million (but including the right to payments and proceeds of intellectual property) and certain customary exceptions.

The principal amount outstanding under the Term Loans will accrue interest at a floating per annum rate equal to (i) the greater of (a) 1-month term Chicago Mercantile Exchange ("CME") Term Secured Overnight Financing Rate ("SOFR") on the last business day of the month that immediately precedes the month in which the interest will accrue and (b) three and one-half percent (3.50%) plus (ii) five and one-quarter percent (5.25%), subject to an agreed upon floor of 8.75%. Beginning on July 1, 2028, which may be extended to July 1, 2029 (subject to certain conditions set forth in the Amended Loan Agreement), the Company is required to repay the Term Loans in consecutive equal monthly payments of principal, together with applicable interest, in arrears. All unpaid principal and accrued and unpaid interest with respect to each Term Loan will be due and payable in full on March 1, 2029, which may be extended to March 1, 2030 (subject to certain conditions set forth in the Amended Loan Agreement).

The Company will be required to make a final payment of 5.50% (or 7.25% if the amortization date of the Term Loans has been extended to July 1, 2029 (as discussed above)) of the original principal amount of the Term Loans that were drawn, payable at maturity or upon any earlier acceleration or prepayment of the Term Loans. The Company may prepay the Term Loans in whole or in part, subject to a prepayment fee equal to (i) if prepaid on or before the first anniversary date of the funding date of such Term Loan, 3.00% of the principal amount of the applicable Term Loan prepaid, (ii) if prepaid after the first anniversary and on or before the second anniversary of the funding date of such Term Loan, 2.00% of the principal amount of the applicable Term Loan prepaid, and (iii) if prepaid after the second anniversary and on or before the third anniversary of the funding date of such Term Loan prepaid, 1.00% of the principal amount of the applicable Term Loan prepaid.

The Agreement contains representations and warranties, affirmative, and negative covenants, and events of default that are customary for loans of this type. The occurrence of an event of default could result in the acceleration of the obligations under the Amended Loan Agreement, termination of the Term Loan commitments and the right by the Lender to foreclose on the collateral securing the obligations. During the existence of an event of default, the Term Loans would accrue interest at a rate per annum equal to 5.00% above the otherwise applicable interest rate.

The estimated fair value of the term loan as of **March 31, 2024** **June 30, 2024** was measured using Level 3 inputs and approximates the carrying value recorded to the balance sheet. The effective interest rate for the term loan is **11.93%** **11.60%** and **interest 11.79%** for the three and six months ended **June 30, 2024** and **12.69%** for the three and six months ended **June 30, 2023**. **Interest** expense during the three and six months ended **March 31, 2024 and 2023** **June 30, 2024** was **\$0.44** **\$0.9** million and **\$0.30** **\$1.3** million, respectively and during the three and six months ended **June 30, 2023** was **\$0.3** million and **\$0.6** million, respectively.

Future maturities of debt as of **March 31, 2024** **June 30, 2024** are as follows (in thousands):

	As of March 31, 2024	As of June 30, 2024
2028		
2029		
Thereafter		
Total payments		
Less: unamortized debt issuance costs		
Accretion of final payment		
Total		

8. Novartis Collaboration and License Agreement (the "Novartis Agreement")

In 2019, we entered into the Novartis Agreement with Novartis Institutes for BioMedical Research, Inc. ("Novartis") for the development and commercialization of our preclinical product candidate, PLN-1474, and up to three additional integrin research targets. We assessed the Novartis Agreement in accordance with ASC 606 and determined that Novartis was a customer and identified the following performance obligations: (1) to provide worldwide license rights to PLN-1474, (2) to provide research and development services for PLN-1474, (3) to provide non-exclusive license rights to integrin research targets, and (4) to provide research and development services on integrin research targets.

On February 17, 2023, Novartis exercised their right to terminate the Novartis Agreement. The termination took effect on April 18, 2023, and effective upon the termination, all rights and licenses granted to Novartis under the Novartis Agreement, including PLN-1474, the related investigational new drug ("IND"), and the validated research target, reverted back to us. The payment obligations of Novartis with respect to future milestones, royalties and research and development funding were also terminated.

Revenues associated with the Novartis Agreement for the three and six months ended **March 31, 2024 and 2023**, **June 30, 2024** were nil, and **\$1.3 million** **\$0.2 million** and **\$1.6 million** for the three and six months ended **June 30, 2023**, respectively, which consisted of revenue generated from research and development services.

9. Preferred Stock

Under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue two classes of shares: preferred stock and common stock. The preferred stock may be issued in series, and the Company's board of directors is authorized to determine the rights, preferences, and terms of each series. These rights, preferences and terms could include dividend rights, conversion rights, voting rights, terms of redemptions, liquidation preferences and sinking fund terms. As of **March 31, 2024** **June 30, 2024** and December 31, 2023, the Company was authorized to issue 10,000,000 shares of preferred stock and there was no outstanding preferred stock as of **March 31, 2024** **June 30, 2024** and December 31, 2023.

10. Common Stock

As of **March 31, 2024** **June 30, 2024** and December 31, 2023, the Company was authorized to issue 300,000,000 shares of common stock at a par value of \$0.0001 per share. The common stock has the following rights and privileges:

Voting

The holders of shares of common stock are entitled to one vote for each share of common stock held at any meeting of stockholders and at the time of any written action in lieu of a meeting.

Dividends

The holders of shares of common stock are entitled to receive dividends, when declared by the Company's board of directors. Cash dividends may not be declared or paid to holders of shares of common stock until all unpaid dividends on preferred stock have been paid in accordance with their terms. No dividends have been declared or paid by the Company since its inception. The terms of the Oxford Loan Agreement restrict our ability to declare and pay dividends.

Liquidation

Subject to the preferential rights of holders of preferred stock then outstanding, the holders of shares of common stock are entitled to share ratably in the Company's remaining assets available for distribution to its stockholders in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company.

Shares reserved for future issuance

	As of March 31, 2024	As of December 31, 2023
	As of June 30, 2024	As of December 31, 2023
Outstanding stock option awards		
Vesting of RSUs		
Vesting of PSUs*		
Shares of common stock available for future grants under the 2020 Stock Option and Incentive Plan		
Shares of common stock available for future issuance under the 2020 Employee Stock Purchase Plan		
Shares of common stock available for future issuance under the 2022 Inducement Plan		
Total shares reserved for future issuance		

*PSUs granted and outstanding based on target level of achievement of 100% 55% as measured on June 30, 2024.

11. Equity Incentive Plans and Stock-Based Compensation

In 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan, as amended in 2018, 2019 and 2020 (the "2015 Plan"), which provided for the grant of incentive stock options, nonqualified stock options or other awards including stock appreciation rights and restricted stock awards to the Company's employees, officers, directors, advisors, and consultants. In May 2020, the board of directors adopted the 2020 Stock Option and Incentive Plan (the "2020 Plan") and suspended the 2015 Plan. Awards outstanding under either the 2015 Plan or 2020 Plan that are cancelled, expire or otherwise terminated subsequent to May 2020 will become available for issuance as common stock under the 2020 Plan. Additionally, the 2020 Plan is subject to automatic increases on January 1 of each year beginning January 1, 2021. The number of shares added each January 1 will be equal to the lesser of: (i) 5% of the outstanding shares on the immediately preceding December 31 or (ii) such amount as determined by the compensation committee of the board of directors.

The 2020 Plan provides for the grant of incentive stock options, nonqualified stock options or other awards including stock appreciation rights, restricted stock awards and restricted stock units to the Company's employees, officers, directors, advisors and consultants. As of March 31, 2024, the 2020 Plan had 4,562,694 shares of common stock available for future issuance.

In 2022, the board of directors adopted the 2022 Inducement Plan ("Inducement Plan"), under which the Company may grant nonqualified stock options or other awards including stock appreciation rights and restricted stock awards. As of March 31, 2024, 700,000 shares of common stock were available for issuance.

Options under the 2020 Plan and Inducement Plan may be granted for periods of up to 10 years and at prices no less than the market price of the Company's common stock on the date of grant, provided, however, that the exercise price of an incentive stock option granted to a 10% shareholder shall not be less than 110% of the fair value of the shares on the date of grant and the option is not exercisable after the expiration of five years from the date of grant.

Incentive Stock Options and Nonqualified Stock Options

Stock options issued under either the 2015 Plan, the 2020 Plan or the Inducement Plan generally vest over four years and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the respective plans.

The Company used Black-Scholes option pricing model to estimate stock-based compensation expense for stock option awards with the following assumptions:

	Three months ended March 31,	
	2024	2023
Expected volatility	85.28% - 86.42%	80.97% - 81.41%
Risk-free interest rate	4.04% - 4.28%	3.42% - 4.18%
Expected dividend	—	—
Expected term (in years)	5.99 - 6.06	5.77 - 6.08
Underlying common stock fair value	\$15.19 - \$17.44	\$21.94 - \$34.65

The Company granted 1,338,465 stock options under the 2020 Plan during the three months ended March 31, 2024.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Expected volatility	85.58% - 86.46%	81.16% - 81.66%	85.28% - 86.46%	80.97% - 81.66%
Risk-free interest rate	4.17% - 4.60%	3.44% - 3.88%	4.04% - 4.60%	3.42% - 4.18%

Expected dividend	—	—	—	—
Expected term (in years)	5.31 - 6.08	5.31 - 6.07	5.31 - 6.08	5.31 - 6.08
Underlying common stock fair value	\$11.51 - \$15.36	\$22.33 - \$26.50	\$11.51 - \$17.44	\$21.94 - \$34.65

A summary of option activity under the 2015 Plan and the 2020 Plan is as follows:

	Number of Options	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value	Number of Options	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023								
Granted								
Exercised								
Exercised								
Exercised								
Forfeited								
Forfeited								
Forfeited								
Outstanding as of March 31, 2024								
Outstanding as of March 31, 2024								
Outstanding as of March 31, 2024								
Exercisable as of March 31, 2024								
Vested and expected to vest as of March 31, 2024								
Outstanding as of June 30, 2024								
Outstanding as of June 30, 2024								
Outstanding as of June 30, 2024								
Exercisable as of June 30, 2024								
Vested and expected to vest as of June 30, 2024								

As of March 31, 2024 June 30, 2024, there were \$53.9 million \$53.8 million of unrecognized compensation costs that are expected to be recognized over the weighted-average period of 2.8 2.7 years related to stock options. Aggregate intrinsic value represents the difference between the fair value of the underlying common stock and the exercise price as of March 31, 2024 June 30, 2024. The weighted-average grant date fair value of options granted during the three months ended March 31, 2024 was \$17.29 per share.

Restricted Stock Units

The service-based condition for restricted stock units (“RSUs”) is generally satisfied over two years or three years. The following table sets forth the outstanding RSUs and related activity for the three and six months ended March 31, 2024 June 30, 2024.

	Restricted Stock Units	Restricted Stock Units	Weighted Average Grant Date Fair Value	Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested and outstanding as of December 31, 2023					
Granted					
Released					
Forfeited					
Unvested and outstanding as of March 31, 2024					
Unvested and outstanding as of June 30, 2024					

As of March 31, 2024 June 30, 2024, the Company had \$22.9 million \$19.1 million of unrecognized stock-based compensation expense related to outstanding RSUs expected to be recognized over a weighted-average period of 2.0 1.8 years.

Performance-Based Restricted Stock Units

Performance-based restricted stock units (“PSUs”) vest upon the achievement of market and performance conditions. Market conditions include the Company’s total shareholder return (“TSR”) relative to the NASDAQ Biotechnology Index over the term of the award ending on June 30, 2024. Additionally, the number of shares of common stock issued upon vesting will range from 0% to 200% of the PSUs based on achievement of certain targets.

The fair value of the TSR PSUs were derived from a Monte Carlo simulation model that used the following key assumptions:

Valuation date share price	\$	17.57
Award term (years)		1.92
Volatility		70.62 %
Correlation coefficient		0.3508
Average peer group volatility		79.69 %
Average peer group correlation coefficient		0.4397
Risk-free interest rate		2.84 %

The following table sets forth measurement period for the outstanding PSUs associated with TSR goal concluded on the last trading day of the second quarter 2024 and related activity in July 2024, upon certification of the TSR results by the compensation committee of the board of directors, the award recipients vested in a total of 155,292 shares of common stock, representing 55% achievement. The 155,292 PSUs were outstanding as of June 30, 2024 with a weighted average grant date fair value of \$29.15 per share. There were no additional grants, forfeitures or vesting of the PSUs associated with market conditions during the three six months ended March 31, 2024:

	Performance Stock Units	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2023	328,752	\$29.15
Forfeited	(46,407)	\$29.15
Unvested balance at March 31, 2024	282,345	\$29.15

June 30, 2024.

As of March 31, 2024 June 30, 2024, the Company had \$1.2 million \$0.2 million of unrecognized stock-based compensation expense related to unvested outstanding PSUs expected to be recognized over a remaining weighted-average period of 0.29 0.1 years.

2020 Employee Stock Purchase Plan

In June 2020, the Company adopted the Company's 2020 Employee Stock Purchase Plan (the "2020 ESPP"). The 2020 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1 of each calendar year, beginning January 1, 2021, by the least of (1) 1.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (2) 700,000 shares or (3) such lesser amount as determined by the administrator of the 2020 ESPP, which is the compensation committee of the board of directors of the Company.

Under the 2020 ESPP, eligible employees may purchase shares of our common stock through payroll deductions that cannot exceed 15% of each employee's salary. The 2020 ESPP provides for a six-month offering period. At the end of the purchase period, eligible employees are permitted to purchase shares of common stock at the lower of 85% of the fair market value at the beginning of the offering period or 85% of the fair market value at the end of the purchase period, subject to tax limitations on the total value of the purchase. The 2020 ESPP is considered a compensatory plan, and the Company recorded \$0.1 million and \$0.2 million \$0.3 million in stock-based compensation expense for the three and six months ended March 31, 2024 June 30, 2024 and 2023, \$0.1 million and \$0.3 million for the three and six months ended June 30, 2023, respectively. During the three and six months ended March 31, 2024 June 30, 2024, 68,882 shares of common stock were issued under the 2020 ESPP with 1,336,085 shares remaining available for issuance under the 2020 ESPP. The Company used Black-Scholes option pricing model to estimate stock-based compensation expense for the 2020 ESPP with the following assumptions:

		Three months ended March 31,			Three and Six Months Ended June 30,		
		2024	2023		2024	2023	
Risk-free interest rate	Risk-free interest rate	5.27%	5.20%	Risk-free interest rate	5.27 %	5.20 %	
Expected term of options (in years)	Expected term of options (in years)	0.50	0.50	Expected term of options (in years)	0.50	0.50	
Expected stock price volatility	Expected stock price volatility	63.92%	69.15%	Expected stock price volatility	63.92 %	69.15 %	
Expected dividends	Expected dividends	—	—	Expected dividends	—	—	

Stock-Based Compensation Expense

The following table presents the components and classification of stock-based compensation expense for the Company's stock-based awards for the three and six months ended March 31, 2024 June 30, 2024 and 2023 (in thousands):

	Three Months Ended March 31,				Three Months Ended June 30,				Six Months Ended June 30,			
	2024	2024	2023	2023	2024	2023	2024	2023	2024	2023	2024	2023
Stock options and ESPP												
Restricted stock units												
Performance-based restricted stock units												
Total stock-based compensation expense												

Research and development expenses

General and administrative expenses

12. Income Taxes

For the three and six months ended March 31, 2024 June 30, 2024 and 2023, the Company did not record an income tax provision. The Company will continue to maintain a 100% valuation allowance on total deferred tax assets. The Company believes it is more likely than not that the related deferred tax asset will not be realized. As a result, the Company's effective tax rate will remain at 0% because there are no estimated or discrete items that would impact the tax provision.

13. Commitments and Contingencies

Purchase Commitments

The Company has contractual arrangements with research and development organizations and suppliers; however, these contracts are generally cancellable on 30 days' notice and the obligations under these contracts are largely based on services performed.

14. Leases

New Operating Lease

On September 28, 2023, the Company entered into a lease agreement with HCP BTC, LLC, a Delaware limited liability company ("the Landlord") for a premise consisting of approximately 100,904 square feet of office and laboratory space located at Oyster Point Blvd, South San Francisco, California (the "Oyster Point Lease"), which the Company intends to use as single unified Company headquarters. The lease term of approximately seven years will start upon the Landlord's substantial completion of tenant improvements, and may be extended for a period of eight years at then prevailing market rates for a comparable property. Future lease payments are approximately \$43.7 million \$43.4 million which represent the non-cancellable periods of the lease. We excluded extension options that are not reasonably certain to be exercised from our lease terms. Our lease payments consist primarily of fixed rental payments for the right to use the underlying leased assets over the lease term. Additionally, the Company provided a letter of credit to the Landlord in the amount of \$1.4 million in connection with the Oyster Point Lease, which has been recognized as restricted cash as at March 31, 2024 of June 30, 2024.

Though the Oyster Point Lease will be accounted for as a single contract, the office space was occupied in March 2024 while the laboratory space is expected to be was occupied in the second quarter of June 2024. Accordingly, the Company measured and allocated consideration to each lease component as of March 31, 2024. component. The Company has recognized a right-of-use asset ("ROU") or aggregate lease liability of \$23.7 million \$29.8 million as at March 31, 2024 of June 30, 2024, discounted at 9.23% weighted average discount of 9.30%, the Company's estimated incremental borrowing rate during the three and six months ended March 31, 2024 June 30, 2024.

The undiscounted future non-cancellable lease payments of the Company's operating lease liability as of March 31, 2024 June 30, 2024 were as follows (in thousands):

Operating Lease					
2024 (remainder of the year)					
2025					
2026					
2027					
2028					
2029 and thereafter					
Total undiscounted lease payments					
Less: Present value discount					
Total operating lease liabilities current					
Total operating lease liabilities non-current					

The weighted-average remaining lease terms and discount rates related to the Company's operating leases were as follows:

			As of March 31, 2024		As of March 31, 2023	
			Six Months Ended June 30,			
			2024		2023	
Weighted-average remaining lease term (in years)	Weighted-average remaining lease term (in years)	6.9		Weighted-average remaining lease term (in 2.1 years)	6.9	1.1
Weighted-average discount rate	Weighted-average discount rate	9.4%		8.2%	Weighted-average discount rate	9.3% 13.5%

Variable lease costs comprise primarily of the Company's proportionate share of operating expenses, property taxes, and insurance. Short-term lease expense and variable lease payments recorded in operating expenses were immaterial for the three and six months ended March 31, 2024 June 30, 2024 and 2023. Lease expenses for each of the three and six months ended March 31, 2024 June 30, 2024 and 2023 are as follows (in thousands):

		As of March 31, 2024		As of March 31, 2023	
		Three Months Ended June 30,		Six Months Ended June 30,	
		2024		2023	
Operating lease costs					
Other variable costs					
Total expense					

15. Defined Contribution Plan

The Company sponsors a defined contribution plan under Section 401(k) of the Internal Revenue Code covering substantially all full-time U.S. employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. The Company made contributions to the plan of \$0.3 million \$0.5 million and \$0.8 million for each of the three and six months ended March 31, 2024 June 30, 2024 and \$0.3 million and \$0.6 million for the three and six months ended 2023, respectively.

16. Net Loss Per Share Attributable to Common Stockholders

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been antidilutive:

	Three Months Ended March 31,		Six Months Ended June 30,	
	2024	2024	2023	2023
Options to purchase common stock				
Restricted stock units				
Performance-based restricted stock units*				
Total				
*No unvested performance-based restricted stock units are included above as none of the contingently issuable shares would be issued assuming the end of our reporting period was the end of the relevant PSU award contingency period				
*Represents TSR based PSUs outstanding based on level of achievement of 55% as measured on June 30, 2024.				

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

The following discussion and analysis should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Report, as well as our audited financial statements and related notes included in our 2023 10-K. This discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intention, beliefs and projections. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in the section titled “Risk Factors” under Part II, Item 1A of this Report and under Part I, Item 1A of our 2023 10-K. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “should,” “will” or the negative of these terms or other similar expressions.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate we have conducted exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Overview

We are a late-stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis and related diseases. Our initial focus is on treating fibrosis by inhibiting integrin-mediated activation of TGF-β. We have applied our deep understanding of fibrosis biology, along with our medicinal chemistry and translational medicine expertise to develop a set of proprietary tools designed to discover and de-risk product candidates quickly and efficiently. Our wholly owned lead product candidate, bexotegrast (PLN-74809), is an oral, small molecule, dual selective inhibitor of αvβ6 and αvβ1 integrins that we are developing for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. We are currently conducting a Phase 2b trial in patients with IPF and a Phase 2a trial in patients with PSC. We announced positive data from our Phase 2a INTEGRIS-IPF trial in May 2023. 2023 and positive long-term data from our Phase 2a INTEGRIS-PSC trial in July 2024. We are currently conducting BEACON-IPF, a 52-week, randomized, double-blind, placebo-controlled adaptive Phase 2b 2b/3 trial in patients with IPF. We announced positive interim data from our Phase 2a INTEGRIS-PSC trial in September 2023 and February 2024. We expect to release final data from the INTEGRIS-PSC trial in mid-2024.

In January 2023, we received FDA clearance of investigational new drug application, or IND, for our third clinical program to date, PLN-101095, a small molecule, dual selective inhibitor of integrins αvβ8 and αvβ1 for the treatment of solid tumors that are resistant to immune checkpoint inhibitors. We are currently dosing the third of five dose cohorts in a Phase 1 open label dose-escalation trial of PLN-101095 as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors. Preliminary data could be available as is expected in late 2024 or early as late 2024. 2025.

Our fourth program, PLN-101325, is in development for treatment of muscular dystrophies, including Duchenne muscular dystrophy. PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of integrin α7β1. In the first quarter of 2024, we received regulatory clearance was received for the conduct of a first-in-human Phase 1 clinical study of PLN-101325 which is anticipated to be initiated in 2024. PLN-101325.

Recent Highlights

Bexotegrast Highlights

- Acceleration of bexotegrast development plan with implementation of BEACON-IPF as Results from a pivotal, adaptive Phase 2b/3 trial in patients with idiopathic pulmonary fibrosis (IPF). The adaptive design implementation, based on acceptance by the European Union (EU) and other global health authorities, is expected to significantly shorten bexotegrast's late-stage development compared to standalone Phase 2b and Phase 3 trials. As part of the adaptive Phase 2b/3 implementation, the Phase 2b portion of BEACON-IPF was upsized from 267 patients to 360 patients. Enrollment is progressing and we expect to complete enrollment of the upsized Phase 2b study in the first quarter of 2025.
- Completion of a 12 week 12-week Phase 2a PET imaging trial measuring the effects of bexotegrast on in IPF showed reduced total lung collagen and improved forced vital capacity (FVC) in IPF patients, suggesting potential for reversal of fibrosis. This Results from this randomized, double-blind, placebo-

controlled trial was conducted at Massachusetts General Hospital. The trial's primary endpoint is the change in total lung collagen in 10 participants with IPF following once-daily treatment with (NCT05621252) showed that bexotegrest at 160 mg for 12 weeks. Collagen will be evaluated with PET imaging, utilizing a collagen-binding probe. The secondary endpoint is safety and tolerability. Exploratory endpoints include change in FVC, cough severity and fibrosis biomarkers. Conduct of this trial has been completed, with topline data expected in the coming weeks.

- **Completion of INTEGRIS-PSC Phase 2a trial in patients with primary sclerosing cholangitis (PSC) with data readout expected mid-year.** As previously announced, at a once-daily dose of 320 mg bexotegrest was well tolerated over 12 weeks of treatment and demonstrated reduced total lung collagen as measured by positron emission tomography (PET) imaging, improvements in FVC and reduced cough severity across all time points compared to placebo. These results provide further support of bexotegrest's antifibrotic mechanism of action and suggest the potential for reversal of fibrosis.
- **Enrollment remains on track in BEACON-IPF, a pivotal adaptive Phase 2b/3 trial of bexotegrest in patients with no drug-related severe idiopathic pulmonary fibrosis (IPF).** The BEACON-IPF Phase 2b trial is a 52-week, multinational, randomized, dose-ranging, double-blind, placebo-controlled trial evaluating bexotegrest at once-daily doses of 160 mg or 320 mg. At the 320 mg dose, in 360 patients with IPF. Enrollment is expected to be complete in the first quarter of 2025 with data anticipated in mid-2026.
- **INTEGRIS-IPF Phase 2a trial results published in the American Journal of Respiratory and Critical Care Medicine (AJRCCM).** Also known as the "Blue Journal", AJRCCM is a leading peer-reviewed journal published by the American Thoracic Society. The publication *Bexotegrest in Patients with Idiopathic Pulmonary Fibrosis: The INTEGRIS-IPF Study* reviews the previously reported positive results from the multinational, randomized, double-blind, placebo-controlled INTEGRIS-IPF Phase 2a trial that enrolled 119 patients with IPF.
- **Positive long-term data from the INTEGRIS-PSC 320 mg cohort showed bexotegrest reduced both Enhanced Liver Fibrosis (ELF) scores was well tolerated up to 40 weeks of treatment and PRO-C3 levels demonstrated continued improvements across multiple fibrotic and showed improvements in hepatocyte function and bile flow by contrast MRI imaging relative to placebo at Week 12. cholestatic endpoints.** The final 24-week Phase 2a data readout from the 320 mg dose group is expected showed bexotegrest was well tolerated up to 40 weeks of treatment and showed improvement in mid-2024. liver stiffness, statistically significant reduction in alkaline phosphatase (ALP) and evidence of continued improvement in hepatocyte function and bile flow. Pliant recently met with U.S. Food and Drug Administration (FDA), with the Agency expressing support for a 52-week, dose-ranging Phase 2b trial employing non-invasive endpoints. Pliant continues to evaluate the best path forward for this program.

Pipeline Programs

- **Muscular dystrophy program cleared for conduct of Phase 1 study.** PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of integrin $\alpha\beta1$. The Company recently received regulatory clearance from Australia's Research Ethics Committee (HREC) for the conduct of a first-in-human Phase 1 clinical study of PLN-101325 which is being developed as a potential treatment for muscular dystrophies, including Duchenne muscular dystrophy (DMD).
- **Phase 1 trial of PLN-101095 in solid tumors is progressing with dosing of the third of five cohorts.** PLN-101095 is an oral, small molecule, dual selective inhibitor of $\alpha\beta8$ and $\alpha\beta1$ integrins designed to block TGF- β activation in the tumor microenvironment. The Company is currently enrolling the third of five cohorts in the Phase 1 open label, dose-escalation trial of PLN-101095 as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors. Preliminary data could be available as is expected in late 2024 or early as late 2024, 2025.

Corporate Highlights

- **Loan facility with Oxford Finance LLC (Oxford), upsized by \$50 million PLN-101325 applications beyond muscular dystrophies.** PLN-101325 is a monoclonal antibody that acts as an allosteric agonist of integrin $\alpha\beta1$, currently in development for treatment of muscular dystrophies. Based on preclinical data, PLN-101325 may have the potential to treat additional indications in organ systems outside of muscle. The Company is currently generating additional evidence in support of potential expansion of the scope of PLN-101325 prior to initiating a total Phase 1 trial.

Corporate Highlights

- **Appointment of \$150 million of available non-dilutive capital.** To date, the Company has drawn a total of \$30 million from the facility. The remaining funds available under this facility, along with Steve Kroghes to the Company's March 31, 2024 cash Board of Directors. Mr. Kroghes brings over 30 years of financial and cash equivalents corporate strategy experience in leading and short-term investments guiding life science companies across all stages of \$483.9 million are expected to fund Pliant's anticipated operating expenses and capital expenditure requirements through 2026. development. Most recently, Mr. Kroghes served as Chief Financial Officer of Denali Therapeutics.

Since inception, we have had significant operating losses. Our net loss was \$47.0 million \$55.9 million and \$37.5 million \$41.2 million for the three months ended March 31, 2024 June 30, 2024 and 2023, respectively. Our net loss for the six months ended June 30, 2024 and 2023 was \$102.8 million and \$78.7 million, respectively. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of \$546.7 million \$602.6 million and cash, cash equivalents, and short-term investments of \$483.9 million \$438.1 million. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will increase in connection with our ongoing activities, as we:

- perform research and development activities to identify and develop product candidates;
- advance product candidates into and through clinical development;
- require the manufacture of supplies to support research and development, preclinical studies and clinical trials;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- expand our operational, financial and management systems and increase personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- invest in or in-license other technologies or product candidates.

Components of Operations

Revenue

We have not generated any revenue from product sales and do not expect to do so in the near future. Our revenue to date has been derived from a Collaboration and License Agreement with Novartis, or the "Novartis Agreement," that was executed in 2019.

Under the terms of the Novartis Agreement, we received an upfront license fee payment of \$50.0 million for the worldwide, exclusive license to PLN-1474, an α v β 1 inhibitor developed by Pliant to target metabolic dysfunction-associated steatohepatitis, or MASH, and an additional \$29.0 million upon the achievement of specified research and development milestones. As part of a broad strategic realignment, Novartis has discontinued clinical development in MASH and, as a result,

discontinued development of PLN-1474. In February 2023, Novartis issued a termination notice for the collaboration and license agreement, and returned global rights to Pliant for PLN-1474.

Following termination of the Novartis Agreement, we are no longer eligible to receive additional milestone or royalty payments under the arrangement; however, we continued to earn research and development services revenues through the effective termination date of April 18, 2023. We recognized nil and **\$1.3 million** **\$0.2 million** in revenues for performing research and development activities associated with PLN-1474 and integrin research targets in the three months ended **March 31, 2024** **June 30, 2024** and 2023, respectively.

Operating Expenses

Research and Development

Our research and development expenses consist of expenses incurred in connection with the development of our product candidates. Research and development expenses include:

- employee-related expenses, which include salaries, benefits and stock-based compensation for our research and development personnel;
- expenses incurred under agreements with third-party contract organizations for pre-clinical studies, clinical trials and consultants that conduct research and development activities on our behalf;
- costs associated with the manufacture of supplies to support research and development, preclinical studies and clinical trials;
- depreciation of laboratory equipment and costs of equipment and supplies;
- costs associated with technology and intellectual property licenses; and
- facilities and other allocated expenses, which include expenses for rent and other facility related costs and other supplies.

General and Administrative

Our general and administrative expenses consist primarily of salaries, benefits and stock-based compensation for our general and administrative personnel, allocated facilities costs, insurance and other expenses for outside professional services, including legal, marketing, investor relations, human resource and accounting services.

Interest and Other Income (Expense), net

Our interest and other income (expense), net consists of interest, accretion income and amortization expense on cash and cash equivalents, and short-term investments, and realized gains and losses on investments.

Interest Expense

Our interest expense is derived from a term loan under the Oxford Loan Agreement that we entered into in May 2022. On March 11, 2024, we entered into an Amended and Restated Loan and Security Agreement (the "Amended Loan Agreement") with the Lender to borrow up to \$150.0 million. Borrowings under the Amended Loan Agreement bear interest at a rate per annum equal to 1-month term Secured Overnight Financing Rate (SOFR) plus 5.25%, subject to an agreed upon floor of 8.75%.

Financial Operations Overview

Comparison of the three months ended **March 31, 2024** **June 30, 2024** and 2023 (in thousands)

		Three Months Ended March 31,				Three Months Ended June 30,			
		2024	2023	\$ Change	2024	2023	\$ Change		
Revenue									
Operating expenses:									
Research and development									
Research and development									
Research and development									
General and administrative									
Total operating expenses									
Loss from operations									

Interest and other income (expense), net
Interest expense
Net loss

Revenue

The decrease in revenue of \$1.3 million \$0.2 million is attributable to the termination of the Novartis Agreement that went into effect in April 2023.

Research and development expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2024 June 30, 2024 and 2023 (in thousands):

	2024	2023	\$ Change	2024	2023	\$ Change
Employee-related expenses						
Outside and consulting services for preclinical studies and research and development activities by third-party contract organizations						
Clinical trials expenses						
Depreciation of lab equipment and costs of equipment and supplies						
Facilities and other allocated expenses						
Technology and intellectual property licenses						
Total research and development expenses						

Research and development expenses for the three months ended March 31, 2024 June 30, 2024 increased \$7.9 million \$12.6 million, primarily due to BEACON-IPF, a Phase 2b study of bexotegrast in patients with IPF, and employee-related expenses, driven by increased headcount. These costs were partially offset by a decrease in preclinical related manufacturing costs associated with activities that were substantially complete in 2023, activities.

We do not allocate our costs by product candidates or by preclinical programs as these are in early stages of clinical trials or development, and our internal expenses are not allocated between product candidates and programs. Although external third-party costs are allocable between product candidates and programs, we do not perform this allocation. We expect our research and development expenses to increase for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates and our preclinical programs and as they advance into later stages of development.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2024 June 30, 2024 increased \$1.1 \$0.4 million, primarily due to a marginal increase in professional service expenses.

We expect our general and administrative expenses to increase for the foreseeable future as we continue to build our administrative function to support our growth in operations.

Interest and Other Income (Expense), net

Interest and other income (expense), net increased \$0.8 million, attributable to higher interest income due to increased yields on short-term investments.

Interest Expense

Interest expense for the three months ended June 30, 2024 increased \$0.5 million due to additional borrowings under the Amended Loan Agreement executed March 11, 2024.

Comparison of the six months ended June 30, 2024 and 2023 (in thousands)

	Six Months Ended June 30,		
	2024	2023	\$ Change
Revenue	\$ —	\$ 1,580	\$ (1,580)
Operating expenses:			
Research and development	(82,763)	(62,275)	(20,488)
General and administrative	(30,268)	(28,728)	(1,540)
Total operating expenses	(113,031)	(91,003)	(22,028)
Loss from operations	(113,031)	(89,423)	(23,608)
Interest and other income (expense), net	11,535	11,313	222
Interest expense	(1,313)	(630)	(683)
Net loss	\$ (102,809)	\$ (78,740)	\$ (24,069)

Revenue

The decrease in revenue of \$1.6 million is attributable to the termination of the Novartis Agreement that went into effect in April 2023.

Research and development expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		
	2024	2023	\$ Change
Employee-related expenses	\$ 24,682	\$ 23,275	\$ 1,407
Outside and consulting services for preclinical studies and research and development activities by third-party contract organizations	8,015	8,844	(829)
Clinical trials expenses	39,461	22,066	17,395
Depreciation of lab equipment and costs of equipment and supplies	2,978	2,864	114
Facilities and other allocated expenses	7,620	5,172	2,448
Technology and intellectual property licenses	7	54	(47)
Total research and development expenses	\$ 82,763	\$ 62,275	\$ 20,488

Research and development expenses for the six months ended June 30, 2024 increased \$20.5 million, primarily due to BEACON-IPF, a Phase 2b study of bexotegrist in patients with IPF, employee-related expenses driven by increased headcount, and an increase in depreciation of lab equipment and costs of equipment and supplies. These costs were partially offset by a decrease in preclinical manufacturing costs associated with activities that were substantially complete in 2023, and the Phase 2a clinical trial of bexotegrist in patients with primary sclerosing cholangitis (PSC) has reached its close-out stage in the first quarter of 2024.

We do not allocate our costs by product candidates or by preclinical programs as these are in early stages of clinical trials or development, and our internal expenses are not allocated between product candidates and programs. Although external third-party costs are allocable between product candidates and programs, we do not perform this allocation. We expect our research and development expenses to increase for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates and our preclinical programs and as they advance into later stages of development.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2024 increased \$1.5 million, primarily attributable to employee-related costs, driven by increased headcount.

We expect our general and administrative expenses to increase for the foreseeable future as we continue to build our administrative function to support our growth in operations.

Interest and Other Income (Expense), net

Interest and other income (expense), net increased \$1.0 million, \$0.2 million, attributable to higher interest income due to increased yields and an increase in short-term investments due to current year financing activities.

Interest Expenses

Our interest expense is derived from a term loan under an Amended and Restated Loan and Security Agreement (the "Oxford Loan Agreement") with Oxford Finance LLC (the "Lender"), which amended and restated, in its entirety, for the Loan and Security Agreement, dated as of May 4, 2022 (as amended, restated, supplemented or otherwise modified prior six months ended June 30, 2024 increased \$0.7 million due to the Effective Date, the "Prior Agreement") with the Lender and which permits us borrow a series of term loans up to an aggregate principal amount of \$150.0 million (the "Term Loans"), of which \$50.0 million is subject to the Lender's sole discretion. Borrowings additional borrowings under the Oxford Amended Loan Agreement bear interest at a rate per annum equal to 1-month term Chicago Mercantile Exchange ("CME") Term Secured Overnight Financing Rate ("SOFR") plus 5.25%, subject to an agreed upon floor of 8.75% executed March 11, 2024.

Liquidity and Capital Resources

Overview

As of March 31, 2024 June 30, 2024, we had \$483.9 million \$438.1 million of cash, cash equivalents and short-term investments. Our short-term investments consist of U.S. Treasury securities, U.S. Government agency securities and highly rated, investment-grade corporate debt securities.

In March 2024 we entered into the Oxford Loan Agreement with Oxford Finance LLC the (or the "Lender" or "Oxford") which upsized our existing term loan facility to a total size of \$150.0 million of available non-dilutive capital. Pursuant to the Oxford Loan Agreement, we drew an additional Term Loan of \$20.0 million and may borrow up to \$70.0 million at our option upon the satisfaction of certain conditions related to the development of bexotegrist. A further \$50.0 million may be made available to us at the sole discretion of Lender. See Note 7 to the Notes to our condensed financial statements of this Report for more information.

In January 2023, we completed an underwritten public offering of 9,583,334 shares of common stock, including the exercise in full of the underwriters' option to purchase 1,250,000 additional shares of common stock. The shares were offered at a price to the public of \$30.00 per share, resulting in aggregate proceeds of approximately \$269.8 million, net of underwriting discounts, commissions and offering expenses.

We believe that our existing capital resources, together with the funds available to us under the Amended Loan Agreement, will be sufficient to fund our anticipated operating expenses and capital expenditure requirements for the next 12 months and through 2026, beyond. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned.

During the third quarter of 2021, we entered into a Controlled Equity OfferingsSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may issue and sell shares of common stock in an "at-the-market" offering. In March 2023, we filed a prospectus registering the offer and sale of up to \$150.0 million of shares of common stock from time to time pursuant to the Sales Agreement. As of the date of this Report, we have not issued any shares pursuant to any at-the-market offerings, including pursuant to the Sales Agreement, but may do so at a future date date.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to conduct and complete the clinical trials, which may be impacted by health epidemics and pandemics, such as COVID-19, or other geopolitical conditions;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, and other comparable foreign regulatory authorities including but not limited to the European Medicines Agency (EMA), the U.K. Medicines and Healthcare products Regulatory Agency (MHRA);
- whether we enter into any collaboration agreements and the terms of any such agreements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending any intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost and timing of achieving favorable pricing and reimbursement agreements with the pricing authorities in each market of interest, including of securing a positive recommendation after undergoing a health technology assessment by health technology authorities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the cost of operating as a public company and the financial impact of current and future laws, regulations and ordinances.

Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures. If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations and other licensing or royalty arrangements. If we raise capital through additional debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, licensing or royalty arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

Cash Flows

Comparison of the three six months ended March 31, 2024 June 30, 2024 and 2023

The following summarizes our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,			Six Months Ended June 30,	
	2024	2024	2023	2024	2023
Net cash used in operating activities					
Net cash used in (provided by) investing activities					
Net cash provided by (used in) investing activities					
Net cash provided by financing activities					
Net increase in cash and cash equivalents					

Cash Used in Operating Activities

Net cash used in operating activities was consistent year over year. While we experienced increased \$20.5 million compared to the six months ended June 30, 2023, driven by an increase in net loss of \$9.4 million \$24.1 million, this which was wholly partially offset by changes in our operating assets and liabilities plus the receipt of accreted value associated with maturities on our short-term investment portfolio during the quarter, six months ended June 30, 2024.

Cash Used in (Provided by) Provided by (Used in) Investing Activities

Net cash used in provided by investing activities increased over the same period of prior year over year was primarily due to purchase as maturities of marketable securities exceeding exceeded related purchases during the six months ended June 30, 2024, while purchases exceeded maturities during the quarter, six months ended June 30, 2023 as a result of the public offering of common stock in January 2023.

Cash Provided by Financing Activities

Net cash provided by financing activities decreased \$251.5 million \$251.0 million primarily due to net proceeds of \$270.3 million from the Company's January 2023 underwritten public offering, which was partially offset by additional Term Loans entered into during the current quarter six months ended June 30, 2024 associated with the Amended Loan agreement.

Contractual Obligations and Other Commitments

Except as mentioned below, there have been no material changes to our contractual obligations and other commitments as of **March 31, 2024** **June 30, 2024**, as compared to those disclosed in **our Annual Report on Form 10-K for the fiscal year ended December 31, 2023**, **2023 10-K**.

At **March 31, 2024** **June 30, 2024**, we had various non-cancelable operating leases for office space and equipment, which expire between **March 31, 2024** **June 30, 2024** and **March** **June** 2031. Refer to Note 13 and 14 in the notes to condensed unaudited financial statements of this Report for a discussion of material obligations and commitments.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements or holdings in any variable interest entities.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. 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 the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from those described in "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2023 10-K.

Recent Accounting Pronouncements

See Note 2 to the Notes to Condensed Unaudited Financial Statements of this Report for more information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We had cash and cash equivalents and short-term investments of **\$483.9 million** **\$438.1 million** as of **March 31, 2024** **June 30, 2024** which consisted of bank deposits, highly liquid money market funds and short-term investments in U.S. treasury securities, U.S. government agency securities and corporate debt securities. Under the Amended Loan Agreement, we had a \$30.0 million term loan outstanding as of **March 31, 2024** **June 30, 2024** which is subject to the movement in interest rates. Due to the short-term maturities of our cash equivalents and short-term investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents or short-term investments.

To minimize the risk, we maintain our portfolio of cash equivalents and short-term investments in institutional market funds that are composed of U.S. Treasury and U.S. Treasury-backed repurchase agreements or short-term U.S. Treasury securities, U.S. Government agency securities and highly rated, investment-grade corporate debt securities. We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein. A hypothetical 10% change in interest rates during the periods presented would not have had a material impact on our condensed financial statements.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of **March 31, 2024** **June 30, 2024**, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation 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. Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of **March 31, 2024** **June 30, 2024**, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended **March 31, 2024** **June 30, 2024** that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

As of the date of this filing, we are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this Report. The risks and uncertainties described below are not the only ones facing us. There may be additional risks faced by our business.

Other events that we do not currently anticipate or that we currently deem immaterial also may adversely affect our financial condition or results of operations.

RISK FACTORS

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception and have financed our operations principally through equity and debt financing and our prior collaboration with Novartis. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss was ~~\$47.0 million~~ ~~\$55.9 million~~ and ~~\$37.5 million~~ ~~\$41.2 million~~ for the three months ended ~~March 31, 2024~~ ~~June 30, 2024~~ and 2023, respectively. Our net loss was ~~\$161.3 million~~ ~~\$102.8 million~~ and ~~\$123.3 million~~ ~~\$78.7 million~~ for the ~~years~~ ~~six months~~ ended ~~December 31, 2023~~ ~~June 30, 2024~~ and ~~2022, 2023~~, respectively. As of ~~December 31, 2023~~ ~~June 30, 2024~~, we had an accumulated deficit of ~~\$499.7 million~~ ~~\$602.6 million~~. We have devoted substantially all of our resources and efforts to research and development, and we expect that it will be at least several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for and commercialize one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to further develop and, if approved, market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we:

- advance our lead product candidate, bexotegast, and our other product candidates through clinical development, and, if successful, later-stage clinical trials;
- discover and develop new product candidates;
- advance our preclinical development programs into clinical development;
- further develop manufacturing processes and manufacture our product candidates;
- experience delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third-party service providers on whom we rely, or our supply chain due to the effects of health epidemics and pandemics, such as COVID-19;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize bexotegast, our other product candidates and any future product candidates, if approved;
- increase the amount of research and development activities to identify and develop product candidates;
- hire additional clinical development, quality control, scientific and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- maintain, expand and protect our intellectual property portfolio;
- invest in or in-license other technologies or product candidates; and
- continue to build out our organization to engage in such activities.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing, and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant 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. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.

We will require substantial additional capital to fund our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our planned clinical trials of bexotegast and any future product candidates that we may develop, seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of ~~March 31, 2024~~ ~~June 30, 2024~~, we had approximately ~~\$483.9 million~~ ~~\$438.1 million~~ in cash, cash equivalents, and short-term investments. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses and capital expenditure requirements ~~through 2026, for the next 12 months and beyond~~. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, marketing, and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to conduct and complete the clinical trials, including any increased costs due to disruptions caused by marketplace conditions, including the effects of health epidemics and pandemics, such as COVID-19, or other geopolitical conditions;
- the cost and capital commitments required for developing manufacturing processes for our product candidates and manufacturing our product candidates at clinical and commercial scales;

- the number and characteristics of product candidates that we develop;
 - the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
 - whether we are able to enter into future collaboration agreements and the terms of any such agreements;
 - the ability to and timing of achieving a favorable pricing and reimbursement decision by the pricing authorities in the markets of interest;
 - the ability to secure a position recommendation following the health technology assessment by the health technology bodies in the relevant market;
 - the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
 - the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
 - the effect of competing technological and market developments;
 - the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to our Oxford Loan Agreement, or potentially pursuant to new arrangements with different lenders. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. However, we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In

addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility resulting from challenging financial markets factors, including the effects of health epidemics and pandemics, such as the COVID-19 pandemic, could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Covenants and other provisions in the Oxford Loan Agreement restrict our business and operations in many ways, and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the Oxford Loan Agreement.

Pursuant to the Oxford Loan Agreement, Oxford has been granted a security interest in substantially all of our assets, excluding intellectual property (but including the right to payments and proceeds of intellectual property) and such exclusion of intellectual property is subject to change per the terms of the Oxford Loan Agreement), and a negative pledge on substantially all of our intellectual property, subject to customary exceptions. If an event of default occurs under the Oxford Loan Agreement, Oxford may foreclose on its security interest and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, Oxford would have a prior right to substantially all of our assets to the exclusion of our general unsecured creditors. Only after satisfying the claims of Oxford and any unsecured creditors would any amount be available for our equity holders.

The pledge of these assets and other restrictions imposed in the Oxford Loan Agreement may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged to secure the Oxford Loan Agreement obligations, our ability to incur additional indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

In addition, if we are unable to comply with certain financial and operating restrictions in the Oxford Loan Agreement, we may be limited in our business activities and access to credit or may default under the Oxford Loan Agreement. Provisions in the Oxford Loan Agreement impose certain restrictions or require prior approval on our ability, and the ability of certain of our subsidiaries to, among other things:

- Incur additional debt;
 - Make certain investments and acquisitions;
 - Guarantee the indebtedness of others or our subsidiaries;
 - Create liens or encumbrances;
 - Engage in new lines of business;
 - Enter into transactions with affiliates;
- Pay cash dividends and make distributions;
 - Redeem or repurchase capital shares;
 - Sell, lease or transfer certain parts of our business or property, including equity interests of our subsidiaries;

- Prepay other indebtedness; and
- Acquire new companies and merge or consolidate.

The Oxford Loan Agreement also contains other customary covenants. We may not be able to comply with these covenants in the future. Our failure to comply with these covenants may result in the declaration of an event of default, which, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the Oxford Loan Agreement and would require us to pay all amounts outstanding. If the maturity of our indebtedness is accelerated, we may not have sufficient funds then available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us or at all. Our failure to repay our obligations under the Oxford Loan Agreement would result in Oxford foreclosing on all or a portion of our assets, which could force us to curtail or cease our operations.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

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

- 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 and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing 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;
- the cost of manufacturing our product candidates, which may vary depending on the difficulty of manufacture, quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as recessions or the effects of health epidemics and pandemics, such as COVID-19 pandemic;
- the changing and volatile U.S. and global economic and political environments; 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.

Risks Related to Research and Development and the Biopharmaceutical Industry

We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product candidates and our technology related to transforming growth factor beta, or TGF- β , signaling and integrin biology, medicinal chemistry, translational screening technologies, and clinical insights to discover and develop novel therapies for the treatment of fibrosis. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. We have not yet demonstrated the ability to progress any product candidate through clinical trials, obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. Consequently, we expect our operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control, and predictions 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 and commercializing drug products.

Our business is highly dependent on the success of our lead product candidate, bexotegragr and any other product candidates that we advance into the clinic. Our product candidates will require significant additional development before we may be able to seek regulatory approval for and launch a product commercially.

We are currently conducting a Phase 2b trial of bexotegragr in IPF and a Phase 2a trial in PSC and have no products that are approved for commercial sale and may never be able to develop marketable products. If bexotegragr or any of our other product candidates encounter safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

Before we can generate any revenue from sales of our lead product candidate, bexotegragr, or any of our other product candidates, we must undergo additional preclinical and clinical development, regulatory review, and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates.

We may experience setbacks that could delay or prevent regulatory approval of, or the extent of regulatory protection or our ability to commercialize, our product candidates, including:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by subjects in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling subjects in clinical trials, including due to operational challenges, competition with other clinical trials or the effects of health epidemics and pandemics, such as the COVID-19 pandemic;
- high drop-out rates or screening failures of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- challenges manufacturing our product candidates to regulatory requirements in a cost effective manner;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- failure to secure or maintain orphan designation in some jurisdictions;
- poor efficacy of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Our approach to drug discovery and development in the area of fibrotic diseases, with an initial focus on tissue-specific integrin modulation and TGF- β signaling inhibition, is unproven and may not result in marketable products.

Our approach is designed to discover and develop targeted treatments for fibrosis with an initial focus on the antagonism of tissue-specific TGF- β signaling through the inhibition of integrins known to mediate the release of activated TGF- β in fibrotic tissue. However, this mechanism has not been definitively proven to successfully treat fibrosis. Targeting integrins to treat fibrosis is a novel approach in a rapidly developing field, and there can be no assurance that we will not experience currently unknown problems or delays in developing our product candidates, that such problems or delays will not result in unanticipated costs, or that any such development problems can be solved. As a result, we may never succeed in developing a marketable product.

Clinical development involves a lengthy, complex, and expensive process, with an uncertain outcome.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or earlier stage clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A large number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of bexotegast or any of our other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- development of competing products in the same disease state;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical;
- failure or inability to perform by third party vendors, including vendors foreign jurisdictions including China; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Further, as we rely on novel technologies including sophisticated imaging technologies to generate data relating to our clinical endpoints, there is an increased risk that we may not properly measure, analyze or interpret this data. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, some of our trials are open label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open label clinical trials are aware when they are receiving treatment. In addition, open label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small molecule drug products, we are also commencing the development of biological products, including a potential candidate for muscular dystrophies, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government **regulations, regulations or changes in regulatory policy as a result of judicial challenges**. Examples of such regulations **and changes** include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

We must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, and if approved for marketing, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

For example, the new EU Clinical Trials Regulation (EU) No 536/2014 (CTR) has amended the system of approval for clinical trials in the EU and has established a new clinical trials portal and database for application for authorizations, called the Clinical Trials Information System (CTIS). The CTR provides a three-year transition period; by January 31, 2025 all ongoing clinical trials in the EU will be subject to the provisions of the CTR. In addition, on June 18, 2024, new CTIS transparency rules came into effect, requiring scheduled publication of certain key clinical trial information

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of bexotegast or any other product candidates.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize bexotegast or any other product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- additional delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- **we may fail to comply with the deadline for transition to CTIS under the new EU Clinical Trial Regulation**

- 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 to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Our product development costs will increase if we experience additional delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the timeframes we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.

In our clinical trials to date, bexotegrast has been generally well tolerated. However, if significant adverse events or other side effects are observed in any of our ongoing or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts altogether. In addition, in our ongoing Phase 2a clinical trials, we are evaluating bexotegrast administered with approved IPF agents. We have completed a Phase 1a study evaluating one-way interaction of bexotegrast on nintedanib or pirfenidone, concluding that clinical safety and pharmacokinetic data indicate that no dose adjustments are needed for nintedanib or pirfenidone when combined with bexotegrast. However, we may encounter unexpected drug-drug interactions in our planned trials, and may be required to further test these candidates, including additional drug-drug interaction studies, which may be expensive, time-consuming and result in delays to our programs.

Some potential therapeutics developed in the biopharmaceutical industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may 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 trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials;
- the proximity of patients to trial 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 and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating or other studies enrolling for similar diseases;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

For example, we are initially developing bexotegrast for the treatment of IPF and PSC, each of which is an orphan indication. In the United States, IPF is estimated to affect approximately 140,000 patients, while PSC is estimated to affect approximately 30,000 to 45,000 patients. As a result, we may encounter difficulties enrolling subjects in our clinical trials of bexotegrast due, in part, to the small size of these patient populations. Our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will 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.

Additionally, the FDA may modify or enhance trial requirements, which may affect enrollment. For example, in August 2023, the FDA published a guidance document, "Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors," which supersedes past guidance and finalizes draft guidance on informed consent. **The Further, in December 2023, FDA published a final rule, "Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations," which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects.** The FDA's new guidance **presents and rulemaking present** evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

The design or execution of our ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced.

Additionally, in some instances, there can be significant variability in safety or efficacy results between different trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout

among clinical trial participants. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. Further, requirements regarding clinical trial data may evolve. In June 2023, the FDA published draft guidance, which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements may cause the FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved.

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

Although we have received U.S. orphan drug designation for bexotegrast for IPF and PSC indications and EEA orphan drug designation for bexotegrast for IPF and for PSC, we may be unable to obtain and maintain orphan drug designation for our other product candidates and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA, may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In order to obtain orphan designation in the European Economic Area (EEA) and the U.K., the product must fulfill certain challenging criteria. Under Article 3 of Regulation (EC) 141/2000 in the EU, and Regulation 50G of the Human Medicines Regulation 2012 in the U.K, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (1) such product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either the prevalence of such condition must not be more than five in 10,000 persons in the territory of the EU or U.K. (as applicable) when the application is made, or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the EU/U.K. to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis,

prevention or treatment of such condition authorized for marketing in the EU/U.K. or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. In the EEA, the grant of the orphan designation does not mean that the product will be granted orphan status at the time it is assessed in parallel with the application for a marketing authorization. The authorities reassess then whether the product still fulfills the criteria for orphan status.

Although we have received U.S. orphan drug designation for bexotegrast for IPF and PSC and EEA orphan drug designation for bexotegrast for IPF and for PSC, the designation of any of our product candidates as an orphan drug does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities from approving another marketing application for a product that constitutes a similar medicinal product treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EEA. The ten-year period of market exclusivity in the EEA can be extended by a further two years if the product qualifies for a pediatric extension, but can be reduced to a period of six years if the orphan designation criteria are no longer met after the fifth year. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive replacing Directive 2001/83 on the Community Code relating to medicinal products for human use. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation and may make it more difficult to obtain orphan designation in the EEA.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition in the United States or EEA. Even after an orphan drug is approved, the FDA or EMA, as applicable, may subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the latter drug is not a similar medicinal product or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, results of operations, financial condition and prospects.

A Fast Track designation by the FDA, even if granted for other current or future product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Fast Track designation for one or more of our future product candidates. In April 2022, bexotegrast received Fast Track designation for the treatment of IPF. If a drug product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for our product candidates, but there is no assurance that the FDA will grant this designation to any of our proposed product candidates. Marketing applications submitted by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing licensure by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways and receiving a Fast Track designation does not provide assurance of ultimate FDA licensure. In

addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

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.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. Additionally, if we advance a biological candidate into IND-enabling studies, the manufacturing processes for biological products is more complex and expensive than with small molecule products and additional manufacturing suppliers may be needed to manufacture clinical supplies for these programs. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial, and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.

We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we seek to accelerate our development timelines, including by initiating certain clinical trials of our product candidates, including our adaptive trial, before earlier-stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later-stage trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable.

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing bexotegrist and any of our other product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain additional insurance for clinical trials as bexotegrast continues clinical development and as additional product candidates enter the clinic. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than us.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. 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.

There are a number of biopharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of fibrosis. Companies that we are aware of that are targeting the treatment of various fibrosis indications through inhibiting various parts of the TGF- β pathway include companies with significant financial resources such as AbbVie Inc., AstraZeneca plc, Bristol Myers Squibb Co., Corbus Pharmaceutical, Merck & Co., Inc., Morphic Therapeutics, Inc., Novartis AG, Scholar Rock, Inc., and Takeda Pharmaceutical Company.

Many of our current or potential competitors, either alone or with their strategic partners, 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 biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of fibrosis as well, which could give such products significant regulatory and market timing advantages over bexotegrast or other product candidates that we may identify. Our competitors also may obtain FDA or other regulatory 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. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to change, including due to judicial challenges.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

Risks Related to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if bexotegrast or any other product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients and third-party payors. In addition, the availability of coverage by third-party payors may be affected by existing and future healthcare reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- positive HTA assessment in jurisdictions where required;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement and a positive recommendation by health technology bodies; and

- the prevalence and severity of any side effects.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.

Coverage and reimbursement may be limited or unavailable or pricing unfavorable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and adequacy of reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and adequate reimbursement will be available for any product that we may develop and, if reimbursement is available, what the level of reimbursement will be.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor'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.

In the United States as well as foreign jurisdictions, no uniform policy of coverage and reimbursement for products exists among third-party payors.

Coverage and reimbursement for products may vary depending on the payor, the insurance plan, and other factors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

A primary trend in the United States and European health care industries is toward cost containment, as legislative bodies, government authorities, third-party payors, and others have attempted to control costs by limiting coverage, pricing and the amount of reimbursement available for certain treatments. Such third-party payers, including Medicare, may question the coverage of, and challenge or seek to lower the prices charged for medical products, and many third-party payers limit coverage and reimbursement for newly approved health care products. Moreover, reimbursement, if available, 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 or by future laws, regulations, or guidance seeking to limit prescription drug prices. If we are unable to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payers for any approved products that we develop, or if net prices are reduced

by mandatory discounts or rebates, there could be a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Changes to current healthcare laws and state and federal healthcare reform measures that may be adopted in the future that impact coverage and reimbursement for drug or biologic products may result in additional payment reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. For additional details regarding healthcare reform measures, see the discussion in the risk factor under the heading "Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations."

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. 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. 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 any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing, or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate 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 may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our relationships with healthcare providers, physicians, third-party payors, and other potential referral sources will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians, third-party payors, and other potential referral sources in the United States and elsewhere play a primary role in the distribution, recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, as detailed in Part I, Item 1 - Business - Government Regulation - Other Healthcare Laws of our Annual Report on Form 10-K for the year ended December 31, 2023. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, and certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs, remuneration provided to health care professionals and their affiliates, charitable donations, interactions with entities excluded from participation in government healthcare programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment. Ensuring business arrangements comply with applicable healthcare laws can be time- and resource-consuming.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, pharmacovigilance, and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with current Good Manufacturing Practice, or cGMP, and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategies, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA or any other foreign regulatory authority may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- voluntary or mandatory product recalls and related publicity requirements;
- total or partial suspension of production;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our ability to profitably sell any product candidates for which we obtain marketing approval or licensure. Changes in regulations, statutes or the interpretation of existing regulations governing the regulatory approval or licensure, manufacture, and marketing of regulated products or the pricing, coverage and reimbursement thereof could impact our business in the future by resulting in, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; (iv) more rigorous coverage criteria or additional downward pressure on the price that we receive for product candidates for which we obtain marketing approval; or (v) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs, as detailed in Part I, Item 1 – Business – Government Regulation – Current and Future Healthcare Reform Legislation of our

Annual Report on Form 10-K for the year ended December 31, 2023. For example, in August 2022, President Biden signed into law the IRA, which implements substantial changes to the Medicare program, including drug pricing reforms and changes to the Medicare Part D benefit design. Among other reforms, the IRA, imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap patient annual out-of-pocket spending at \$2,000, while imposing new discount obligations for pharmaceutical manufacturers and payors; and, beginning in 2026, establishes a “maximum fair price” for a fixed number of high spend pharmaceutical and biological products that are selected by the Centers for Medicare and Medicaid Services (CMS) and covered under Medicare Parts B and D following a price negotiation process with the Centers agency. For a drug product to be considered a qualifying single source drug that may be selected by CMS for Medicare and Medicaid Services, price negotiation under the “maximum fair price” program, at least seven years must have elapsed since the biological product was licensed by the FDA. For a biological product to be considered a qualifying single source drug that may be selected by CMS for price negotiation, at least eleven years must have elapsed since the biological product was licensed by the FDA.

The IRA explicitly excludes from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. Those drugs with multiple orphan designations are not excluded from drug price negotiation. As we are developing bexotegast in multiple orphan indications, this aspect of the IRA could have a negative impact on our ability to seek reimbursement in rely on the U.S. orphan drug exclusion to the “maximum fair price” program.

Since its enactment, the Centers for Medicare and Medicaid Services, or CMS, has taken steps to implement various drug pricing provisions of the IRA. This includes, without limitation, issuing new guidance on June 30, 2023 detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the “maximum fair price” provision that would become effective in 2026 and, on August 29, 2023, releasing the initial list of 10 drugs subject to price negotiations. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry (including orphan drug or small molecule development), several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services (HHS), the Secretary of HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA’s drug price negotiation provisions. We cannot predict whether the IRA, or any of its component parts, will be overturned, repealed, replaced, or amended nor can we predict the likelihood, nature, or extent of other health reform initiatives that may arise from future legislation, administrative, or other action. However, we expect these initiatives to increase pressure on drug pricing. Further, certain broader legislation that is not targeted to the healthcare industry may nonetheless adversely affect our profitability. If we or any third parties we may engage 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.

Inadequate funding for the FDA, the SEC 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 drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, 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.

Drug marketing and reimbursement regulations may materially affect our ability to market and secure reimbursement for our products.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. **From January 2025, Regulation No 2021/2282 on Health Technology Assessment (HTA Regulation) will become applicable in the EU. The HTA Regulation intends to foster cooperation among EU member states in assessing health technologies and provide the basis for cooperation at EU level for joint clinical assessments.** In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Furthermore, in many European countries (including the U.K.), effective access to the market depends on whether the product obtains a positive recommendation from the relevant health technology assessment body. In

addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to induce or reward improper performance generally to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and in respect of the U.K. (which is no longer a member of the EU), the Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe, recommend, use, procure or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the U.K. despite its departure from the EU.

Payments made to physicians in certain EU Member States and more generally throughout Europe (including the U.K.) and other countries must be publicly disclosed under applicable transparency provisions. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including those within the EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement are the prerogative of the Member States and vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow or maintain favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business entity from paying, offering, authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and healthcare providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, contract 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 in time. We plan to engage third parties for clinical trials

and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and 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.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business will depend in large part on obtaining and maintaining patent, IP regulatory rights (such as data exclusivity, marketing exclusivity and patent extensions) trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, 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, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications, we hold 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. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we were the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights or will design around the claims of patents that may issue that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- we may not be able to extend the patent term in some jurisdictions;

- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents or regulatory intellectual property rights such as our data protection, orphan market exclusivity and others;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

We may enter into license or other collaboration agreements that may impose certain obligations on us. If we fail to comply with our obligations under such agreements with third parties, we could lose license rights that may be important to our future business.

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements pertaining to the in-license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance, or other obligations on us, subject to antitrust law restrictions. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

Moreover, 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 product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the 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 product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that

could prevent legal recourse by us. For example, our clinical development strategy includes the testing of live tissue samples, and our techniques for preserving and testing these samples are proprietary and confidential. If one or more third parties obtain or are otherwise able to replicate these techniques, an important feature and differentiator of our clinical development strategy will become available to potential competitors. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed by or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies, or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition, and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

Our collaborators may assert ownership or commercial rights to inventions they develop from research we support or that we develop from our use of the tissue samples or other biological materials, which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, universities, medical centers, physicians, and researchers in scientific matters and expect to continue to enter into additional collaboration agreements. In certain cases, we do not have written agreements with these collaborators, or the written agreements we have do not cover intellectual property rights. Also, we rely on numerous third parties to provide us with tissue samples and biological materials that we use to conduct our research activities and develop our product candidates. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates, intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability

to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract 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 price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development 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 substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently, and these rights may be held by others. We may develop products containing our compounds and pre-existing biopharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. 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. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

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

Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office.

The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor

were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there 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 substantial adverse effect on the price of our common stock.

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 on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. 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. Noncompliance 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 certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO (or foreign patent offices).

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2037 through 2044, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO, EPO or other relevant foreign patent offices will grant any of these patent applications.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. 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. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has

created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, the USPTO, and courts or legislative bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

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

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

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

At the EU level, the CJEU has recently narrowed the availability of patent term extension for second medical use therefore affecting the scope of patent protection available.

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

Depending upon the timing, duration, and specifics of any FDA or foreign marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent 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. However, we may not be granted an extension 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 applicable time period or the scope of patent protection afforded could be less than we request. In addition, within the EU, regulatory protections afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extensions are currently under review and is likely to be curtailed in future years. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive replacing Directive 2001/83 on the Community Code relating to medicinal products for human use. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation and will affect the existing period of regulatory protection afforded to medicinal products in the European Union and Northern Ireland. If we are unable to obtain patent term extension or the term of any such extension is less than we request, or if data exclusivity or other regulatory protections are reduced, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. It should be noted that the European Commission's new proposed legislation, if implemented, will also affect the current EU legal framework of pediatric medicines as well as the framework applicable to patent term extension, also called Supplementary Protection Certificates (SPCs).

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. 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 for name recognition by potential partners or customers in our markets of interest. 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.

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 drug 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 may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our drug candidates, drug products or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and/or infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets;
- other parties may independently develop the technology covered by our trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We depend upon third parties to conduct certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if due to federal or state orders or absenteeism due to global conditions, including health epidemics and pandemics, they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties for tissue samples and other materials required for our research and development activities, and if we are unable to reach agreements with these third parties our research and development activities would be delayed.

We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of tissue samples and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. While we currently have agreements in place with the institutions from which we receive our tissue samples, we do not have any exclusive arrangements with such sources and there is no guarantee that we will be able to maintain or renew such agreements on commercially reasonable terms, if at all. If we were unable to maintain or renew such agreements, we would be forced to seek new arrangements with new hospitals, clinics or health institutions. If so, we may not be able to reach agreements with alternative partners or do so on terms acceptable to us. If we are unable to enter into such agreements, our research and development activities will be delayed and possibly impaired.

Because we rely on third-party manufacturing and supply vendors, including single-source vendors and vendors in foreign jurisdictions, including China, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture our product candidates for preclinical studies and clinical trials. We do not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices, including due to challenging macroeconomic conditions, including the effects of health epidemics and pandemics, such as COVID-19. In addition, we rely on vendors in foreign jurisdictions, including China for our clinical drug supply for bexotegast. If this supply is interrupted for business or geopolitical reasons, the development of bexotegast could be materially delayed. In particular, any replacement of our manufacturers could require significant time, effort and expertise because there may be a limited number of qualified replacements and the process to transfer technology and initiate manufacturing is complex and time consuming.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. 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 components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the 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 reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture 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 our product candidates. If we 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. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for bexotegast or any other product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

We rely on a sole supplier for the manufacture of bexotegast. If this sole supplier is unable to supply to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. We also do not have long-term supply agreements with any of our suppliers. Our current contracts with certain suppliers may be canceled or not extended by such suppliers and, therefore, do not afford us with protection against a reduction or interruption in supplies. Moreover, in the event any of these suppliers breach their contracts with us, our legal remedies associated with such a breach may be insufficient to compensate us for any damages we may suffer.

In addition, we contract with fill and finishing providers with the appropriate expertise, facilities and scale to meet our needs. Failure to maintain cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current fill and finish contractor is operating in accordance with cGMP, but we can give no assurance that FDA or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business. In the future, if we advance a biological product candidate into IND-enabling studies, we will need to identify and contract with suppliers who are able to produce biological product candidates and adhere to additional cGMP compliance obligations required for biologicals.

If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to selectively evaluate partnerships in indications and geographies where we believe partners can add significant commercial and/or development capabilities. Further, we have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have in the past and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology.

Any future collaborations we enter into may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;

- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction 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;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates 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;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates;
- disagreements with collaborators, including disagreements over 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 maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates or if a future collaborator terminates its agreement with us, we may not receive any research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Report also apply to the activities of our therapeutic collaborators.

We face significant competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully establish a collaboration for one or more of our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. 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. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Our suppliers and any future collaborators may need assurances that our financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with us.

Our suppliers and any future collaborators may need assurances that our financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with us. If these parties are not satisfied with our financial resources and stability, it could have a material adverse effect on our ability to develop our drug candidates, enter into licenses or other agreements and on our business, financial condition or results of operations.

Risks Related to Managing Our Business and Operations

Global health pandemics, including the effects of health epidemics and pandemics, such as COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

The outbreak of COVID-19 and government measures taken in response thereto had a significant impact, both direct and indirect, on businesses and commerce. As a result of COVID-19, we experienced disruptions that negatively impacted our business, preclinical studies and clinical trials.

Any resurgences of COVID-19 or other pandemics may result in renewed travel restrictions and social distancing in the United States and other countries, business closures or business disruptions. Any such disruptions could have a material adverse impact on our business, financial condition or results of operations.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of **March 31, 2024** **June 30, 2024**, we had **158** **166** full-time employees. As our clinical development and commercialization plans and strategies develop, we will need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for bexotegrast and any other product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert 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 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 bexotegrast or any other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management, scientific and medical personnel, including key members of our senior management and executive team. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facility in South San Francisco, California. This region is headquarters to many other biopharmaceutical companies, biotechnology companies and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our key employees are at-will employees, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our operations are located in our facilities in South San Francisco, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations 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 our research facilities or 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.

As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

Our employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators, and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws

will increase significantly, and our costs associated with compliance with such laws will also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing, and education programs. We adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, 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, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals, which are generally handled by third parties. We are subject to foreign, federal, state, and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products such as human tissue samples that may have the potential to transmit diseases. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and 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, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

The Animal Welfare Act, or AWA, is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment, and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering, and shipping conditions. Third parties with whom we contract are subject to registration, inspections, and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2023, we had net operating loss carryforwards for U.S. federal and state income tax purposes of \$241.5 million and \$397.6 million, respectively, some of which will begin to expire in 2035. As of December 31, 2023, we also had available tax credit carryforwards for U.S. federal income tax purposes of \$31.5 million, which begin to expire in 2036, and state income tax purposes of \$7.1 million, which can be carried forward indefinitely. Under Section 382 of the Internal Revenue Code, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50 percentage points within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. We have performed an analysis under Internal Revenue Code Sections 382 and 383 to determine the amount of our net operating loss carryforwards and research and development credit carryforwards that will be subject to annual limitation. This analysis concluded that we have experienced one or more such ownership changes prior to December 31, 2023, and the Company's net operating losses and tax credit carryforwards generated prior to the identified ownership changes are subject to no permanent limitation under Sections 382 or 383. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in our stock ownership. Any such limitation could have a material adverse effect on our results of operations in future years. Our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us. Net operating losses generated after December 31, 2017 are not subject to expiration, but may not be carried back to prior taxable years, except that net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in any taxable year beginning after December 31, 2020.

Risks Related to Our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Report, these factors include:

- the commencement, enrollment or results of our current Phase 2a and Phase 2b clinical trials of bexotegrast and any other clinical trials for our product candidates conducted by us or our collaborators;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings for bexotegrast or our other product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of bexotegrast or any other product candidate;
- changes in laws or regulations applicable to bexotegrast or any other product candidate, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- failure to secure a positive health technology assessment recommendation;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of bexotegrast or any other product candidate;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including as a result of effects of health epidemics and pandemics, such as COVID-19, geopolitical events, such as the Russian invasion of Ukraine, the Israel-Hamas conflict and related global escalation of geopolitical tensions, and rising inflationary pressures. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

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

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the development, operation and growth of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our executive officers, directors and their affiliates and our principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and our principal stockholders beneficially hold a significant portion of our voting stock. These stockholders, acting together, may be able to significantly influence matters requiring stockholder approval. For example,

these stockholders would be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.

Shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market as they become vested. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Additionally, the number of shares of our common stock reserved for issuance under our 2020 Stock Option and Incentive Plan will automatically increase on January 1 of each year by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors or compensation committee. Moreover, the number of shares of our common stock reserved for issuance under our 2020 Employee Stock Purchase Plan, or ESPP, will automatically increase on January 1 of each year by the lesser of 700,000 shares of common stock, 1% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors or compensation committee. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

Effective December 31, 2023, we became a large accelerated filer and no longer qualify as a smaller reporting company, which increases our costs and demands on management.

Based on the market value of our common stock held by our non-affiliates as of June 30, 2023, we are no longer considered a smaller reporting company and are considered a "large accelerated filer" effective as of December 31, 2023. Thus, we are subject to accelerated filing deadlines as well as the requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, which require our independent registered public accounting firm to formally attest to the effectiveness of our internal control over financial reporting. We have devoted, and expect to continue to devote, significant time and effort to implement and comply with the additional standards, rules and regulations that apply to us. Compliance with the additional requirements of being a large accelerated filer will also increase our legal, accounting and financial compliance costs.

Further, due to the complexity and logistical difficulty of implementing the standards, rules and regulations that now apply to our business, there is an increased risk that we may be found to be in non-compliance with such standards, rules and regulations or to have significant deficiencies or material weaknesses in our internal controls over financial reporting. Any failure to maintain effective disclosure controls and internal control over financial reporting could materially and adversely affect our business, results of operations and financial condition, and could cause a decline in the trading price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing or cause us to take other corporate actions our stockholders desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws designate certain courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Pursuant to our bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim

governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware forum provision. This exclusive forum provision will not apply to any causes of action

arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the federal forum provision. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware forum provision and the federal forum provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware forum provision and the federal forum provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the State of California. In addition, these forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control, including as a result of any identified material weakness, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public reporting company, we are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of 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 an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to continue to grant equity awards to employees, directors, and consultants under our stock incentive plans. In July 2022 and

January 2023, we completed underwritten public offerings of our common stock. In July 2021, we entered into the Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may issue and sell shares of common stock from time to time. On March 27, 2023, we filed a registration statement on Form S-3 (File No. 333-270862) which included a sales agreement prospectus registering the offer and sale of up to \$150.0 million of shares under the Sales Agreement (the Sales Agreement Prospectus). As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

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 depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules

subsequently adopted by the SEC and the Nasdaq Stock Market, or Nasdaq, to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

Numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information or personal information. In the course of performing our business we obtain personally identifiable information (PII), including health-related information. Such laws and regulations relating to privacy, data protection, and consumer protection are evolving and subject to potentially differing interpretations. These requirements may be interpreted and applied in a manner that varies from one jurisdiction to another and/or may conflict with other laws or regulations. HIPAA establishes national privacy and security standards for the protection of individually identifiable health information, including protected health information (PHI) for certain covered entities, including healthcare providers that submit certain covered transactions electronically, as well as their "business associates." Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly depending on the failure and could include civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. The HHS Office for Civil Rights (OCR) has recently increased its enforcement efforts on compliance with HIPAA, including the security regulations (Security Rule), bringing actions against entities which have failed to implement security measures sufficient to reduce risks to electronic protected health information or to conduct an accurate and thorough risk analysis, among other violations. HIPAA enforcement actions may lead to monetary penalties and costly and burdensome corrective action plans. Moreover, compliance with state laws related to health privacy may cause additional compliance costs. For instance, Washington State recently passed the "My Health My Data Act" which regulates "consumer health data" which is defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data Act" provides exemptions for personal data used or shared in research, including data subject to 45 C.F.R. Parts 46, 50, and 56. Nevada also recently enacted a consumer health data privacy bill, and additional states may adopt health-specific privacy laws that could impact our business activities depending on how they are interpreted.

We may encounter vendors that engage in information blocking practices that may inhibit our ability to access the relevant data on behalf of clients or impose new or additional costs. In 2020, the U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services promulgated final rules to support access, exchange, and use of electronic health information (EHI). Specifically, the information blocking rules were implemented as part of the 21st Century Cures Act, and are primarily designed to facilitate technology interoperability and enable the free flow of healthcare information for healthcare treatment, payment or operation purposes. On June 27, 2023, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) published its final rule implementing information blocking penalties for "actors," which is supplemented by ONC's January 9, 2024 final rule enhancing certain blocking requirements. HHS-OIG may impose penalties for information blocking that has occurred after September 1, 2023, and ONC and HHS proposed a rule on November 1, 2023 listing certain disincentives for actors that conduct information blocking. The impact on the information blocking rules to our business is currently unclear.

California passed the California Consumer Protection Act of 2018, or the CCPA, which went into effect in January 2020 and provides data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. Failure to comply with the CCPA risks regulatory fines, and the CCPA grants a private right of action and statutory damages for an unauthorized access and exfiltration, theft, or disclosure of certain types of personal information resulting from the company's violation of a duty to maintain reasonable security procedures and practices. The CCPA also provides authority to the California Attorney General to seek civil penalties for intentional violations of the CCPA. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. Additionally, this exception does not apply to the private cause of action afforded to individuals for information security incidents.

In addition, the CCPA was expanded on January 1, 2023, when the California Privacy Rights Act of 2020, or the CPRA, became operative. The CPRA, among other things, gives California residents the ability to limit use of certain sensitive personal information, further restricts the use of cross-contextual advertising, establishes restrictions on the retention of personal information, expands the types of data breaches subject to the CCPA's private right of action, provides for increased penalties for CPRA violations concerning California residents under the age of 16, and established a new California Privacy Protection Agency to implement the law through additional regulations and to enforce the law. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how it is interpreted. In the interim, the CPRA will require additional investment in compliance programs and potential modifications to business processes.

Multiple other states have followed California to legislate and enacted comprehensive privacy laws with data privacy rights. For example, on March 2, 2021, the Virginia Consumer Data Protection Act was signed into law, which went into effect on January 1, 2023, on May 10 2022, the Connecticut Data Privacy Act was signed into law, which went into effect on July 1, 2023, and on July 8, 2021, the Colorado Privacy Act, was signed into law, which went into effect on July 1, 2023. Multiple laws. Additionally multiple states have enacted or are considering similar legislation which will go into effect in the coming years, and Congress continues to consider federal privacy legislation. While these proposals and

new laws generally include exemptions for HIPAA-covered and clinical trial data, they add layers of complexity to compliance in the U.S. market, and could increase our compliance costs and adversely affect our business.

Additionally, the Federal Trade Commission (FTC) and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health-related and other personal information and in particular health information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. Additionally, the FTC published an advance notice of proposed rulemaking in 2022 on commercial surveillance and data security, and may implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive in the coming years.

Our business relies on secure and continuous processing of information and the availability of our Information Technology (IT) networks and IT resources, as well as critical IT vendors that support our technology and data processing operations. Security breaches, computer malware and computer hacking attacks have become more prevalent across industries and may occur on our systems or those of our third-party service providers. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. OCR, pursuant to legislation passed in 2021, issued guidance on recognized security practices for covered entities and business associates. OCR indicated that recognized security practices will not be an aggravating factor in OCR investigations, but that implementation of recognized security practices strengthen an organization's cybersecurity and regulatory posture, as well as possibly lessening enforcement penalties in a potential regulatory enforcement.

We regularly monitor, defend against and respond to attacks to our networks and other information security incidents. Despite our information security efforts, our facilities, systems, and data, as well as those of our third party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our IT support vendors, fail to comply with laws requiring the protection of sensitive personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, we may be subject to regulatory enforcement and fines as well as private civil actions. We may be required to expend significant resources in the response, containment, mitigation of cybersecurity incidents as well as in defense against claims that our information security was unreasonable or otherwise violated applicable laws or contractual obligations.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal data, we may seek to conduct clinical trials in the EEA and may become subject to additional EEA data privacy laws, regulations and guidelines.

In the EU, the processing of personal data (i.e., data which identifies an individual or from which an individual is identifiable) is governed by the EU General Data Protection Regulation 2016/679 (EU GDPR). The U.K. has implemented the EU GDPR as the U.K. GDPR (together with the EU GDPR, the GDPR) which sits alongside the U.K. Data Protection Act 2018. The GDPR has direct effect where an entity is established in the EEA or the U.K. (as applicable) and has extra-territorial effect where an entity established outside of the EEA or the UK processes personal data in relation to the offering of goods or services to individuals in the EEA and/or the UK or the monitoring of their behavior.

The GDPR imposes obligations on controllers, including, among others: (i) accountability and transparency requirements, requiring controllers to demonstrate and record compliance with the GDPR and to provide detailed information to individuals regarding the processing of their personal data (e.g., via ICFs); (ii) requirements to process personal data lawfully including specific requirements for obtaining valid consent where consent is the lawful basis for processing; (iii) obligations to consider data protection when any new products or services are developed and designed (including e.g., to limit the amount of personal data processed); (iv) obligations to comply with individuals' data protection rights; and (v) an obligation to report certain personal data breaches to the competent data protection authority and affected individuals.

In addition, the EU GDPR prohibits the international transfer of personal data from the EEA to jurisdictions that the European Commission does not recognize as having an 'adequate' level of data protection unless a data transfer mechanism has been put in place or a derogation under the EU GDPR can be relied on. In July 2020, the Court of Justice of the EU (CJEU) in its Schrems II judgement limited how organizations could lawfully transfer personal data from the EEA to the U.S. by invalidating the EU-U.S. Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (EU SCCs), including a requirement for companies to carry out a transfer privacy impact assessment (TIA). A TIA, among other things, assesses laws governing access to personal data in the recipient country. On 10 July 2023, the European Commission adopted its Final Implementing Decision granting the U.S. adequacy (Adequacy Decision) for EU-U.S. transfers of personal data for entities self-certified to the new Trans-Atlantic Data Privacy Framework

(DPF). Entities relying on EU SCCs for transfers to the U.S. are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U.S. national security safeguards and redress.

The U.K. GDPR also imposes similar restrictions on transfers of personal data from the U.K. to jurisdictions that the U.K. Government does not consider adequate, including the US. The U.K. Government has published its own form of the EU SCCs, known as the International Data Transfer Agreement and an International Data Transfer Addendum to the new EU SCCs. The U.K. Information Commissioner's Office (ICO) has also published its own version of the TIA. Further, on September 21, 2023, the U.K., Secretary of State for Science, Innovation and Technology established a UK-U.S. data bridge (i.e., a U.K. equivalent of the Adequacy Decision) and adopted UK regulations to implement the U.K.-U.S. data bridge (U.K. Adequacy Regulations). Personal data may now be transferred from the UK under the UK-U.S. data bridge through the UK extension to the DPF to organizations self-certified under the UK extension to DPF.

Data protection supervisory authorities have the power under the GDPR to (amongst other things) impose fines for serious breaches of up to the higher of 4% of the organization's annual worldwide turnover or €20m (under the EU GDPR) or £17.5m (under the U.K. GDPR). Individuals also have a right to compensation, as a result of an organization's breach of the GDPR which has affected them, for financial or non-financial losses (e.g., distress).

In the event we commence clinical trials in the EEA, the U.K. or Switzerland, applicable data protection laws may increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms and safeguards to ensure compliance, including as implemented by member states in the European Union. Compliance with data protection laws in the EEA, the U.K. and Switzerland is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. Further, as the EU GDPR may be implemented differently in national laws of member states of the European Union, we may face additional costs associated with complying with potentially varying data protection requirements in these member states.

If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or biopharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law. Such clients or biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

Following Brexit, legal, political and economic uncertainty surrounding the exit of the U.K. from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U.K. and pose additional risks to our business, revenue, financial condition and results of operations.

On January 31, 2020, the U.K. ceased being a Member State of the EU. The U.K. and the EU signed a EU-U.K. Trade and Cooperation Agreement, or TCA, which became effective on May 1, 2021. Such a withdrawal from the EU is unprecedented, and it is unclear how the restrictions on the U.K.'s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the U.K.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Since the regulatory framework in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our product candidates in the U.K., now that U.K. legislation may depart from EU legislation. For instance, now the transition period has expired, Great Britain will no longer be covered by the centralized procedure for obtaining an EEA-wide marketing authorization from the EMA and a separate process will be required for authorization of drug products covering the U.K. or Great Britain only. In addition, the MHRA has launched new procedures designed to accelerate the marketing authorization application process including the Innovative Licensing and Access Pathway (ILAP) and the International Recognition Procedure. The ILAP is an accelerated assessment procedure for marketing authorization applications facilitating the early interaction with pricing authorities and HTA bodies which aims to enable companies to enter the U.K. market faster. On January 1, 2024, the MHRA also launched a new International Recognition Procedure for Great Britain (England, Scotland and Wales) marketing authorization applications whereby the MHRA will, when considering such applications, recognize the approval of medicines by trusted reference regulators in Australia, Canada, Switzerland, Singapore, Japan, United States and EU following its own abbreviated assessment. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. and/or EU for our product candidates, which could significantly and materially harm our business.

The TCA allows for future deviation from the current regulatory framework and it is not known if and/or when any deviations may occur, which may have an impact on development, manufacture, marketing authorization, commercial sales and distribution of pharmaceutical products. **The On March 24, 2024, the U.K. Government and the EU recently adopted a new agreement, the "Windsor Framework," which will amend amended the Northern Ireland Protocol.** According to the Windsor Framework, medicinal products intended for the U.K. market, including Northern Ireland, will be authorized by the MHRA and will bear a "U.K. only" label. This means that medicinal products placed on the market in Northern Ireland will no longer need to be compliant with EU law. These new measures will be implemented on January 1, 2025. **The new U.K. Government, elected on July 4, 2024, has committed to implement the Windsor Framework.**

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

Our information systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our information systems and those of our current and any future collaborators, other contractors or consultants, and third-party suppliers (i.e. our supply chain) are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We exercise little or no direct control over how these third parties operate their networks, which increases our vulnerability to problems with their systems. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our information systems or those of our collaborators, vendors, contractors or consultants, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, as well as reputational harm and adverse legal and regulatory consequences. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We are also subject to cybersecurity risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release, exposure or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious code and viruses, supply chain attacks, phishing and other cyberattacks. The number and complexity of these threats continue to increase over time. While we have not experienced, to date, a cybersecurity threat, including as a result of any previous cybersecurity incidents, that has materially affected or is reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, we cannot guarantee that we will not experience such a threat or incident in the future. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged and we could be subject to adverse legal and regulatory consequences. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we

develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

In addition, while we maintain insurance policies that may cover certain liabilities in connection with a cybersecurity incident, we cannot be certain that the insurance coverage will be adequate for liabilities actually incurred, that insurance will continue to be available to us on commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims that exceed available insurance coverage, or the occurrence of changes in insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including its financial condition, results of operations and reputation.

Unfavorable global 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 economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials costlier to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, due to factors including the effects of health epidemics and pandemics, such as COVID-19, geopolitical events, such as the Russian invasion of Ukraine, the Israel-Hamas conflict and related global escalation of geopolitical tensions, rising inflationary pressures and rising interest rates could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None of the Company's directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the three months ended **March 31, 2024** **June 30, 2024**, as such terms are defined under Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's quarterly report on Form 10-Q (File No. 001-39303) filed on August 11, 2020).
3.2	Second Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-39303) filed on September 16, 2022).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-238146) filed on May 26, 2020).
10.1	Office Lease Agreement by and between the Registrant and HCP BTC, LLC, dated September 28, 2023 (incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-39303) filed on October 3, 2023).
10.2	Termination Agreement by and between the Registrant and Healthpeak OP, LLC, dated September 28, 2023 (incorporated herein by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-39303) filed on October 3, 2023).
10.3*	Amended and Restated Loan and Security Agreement, by and among the Registrant, the lenders from time to time party thereto and Oxford Finance LLC, dated March 11, 2024.
31.1*	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*(1)	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document - the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Document
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith

- (1) The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates them by reference.

Signatures

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

Date: **May 6, 2024** **August 7, 2024**

PLIANT THERAPEUTICS, INC.

By:	<u>/s/ Bernard Coulie</u> Bernard Coulie, M.D., Ph.D. President and Chief Executive Officer
By:	<u>/s/ Keith Cummings</u> Keith Cummings, M.D., M.B.A. Chief Financial Officer (Principal Financial Officer)

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AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT (as the same

may from time to time be amended, restated, amended and restated, supplemented or otherwise modified from time to time, this "Agreement") dated as of March 11, 2024 (the "Effective Date") among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, VA 22314 ("Oxford"), as collateral agent (in such capacity, "Collateral Agent"), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time, including Oxford in its capacity as a Lender, OXFORD FINANCE CREDIT FUND II LP, by its manager Oxford Finance Advisors, LLC, and OXFORD FINANCE CREDIT FUND III LP, by its manager Oxford Finance Advisors, LLC, each with an office located at 115 South Union Street, Suite 300, Alexandria, VA 22314 (each a "Lender" and collectively, the "Lenders"), and PLIANT THERAPEUTICS, INC., a Delaware corporation with offices located at 260 Littlefield Avenue, S San Francisco CA 94080 ("Borrower"), and provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders and amends and restates, in its entirety, that certain Loan and Security Agreement by and among the Collateral Agent, Lenders (as defined therein) and Borrower dated as of May 4, 2022 (as amended, restated, amended and restated, supplemented or otherwise modified prior to the date hereof, including without limitation by that certain First Amendment to Loan and Security Agreement by and between Collateral Agent, Lenders (as defined therein) and Borrower dated as of October 4, 2022, (collectively, the "Prior Agreement"). The parties agree as follows:

1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations shall be made in accordance with GAAP (except with respect to unaudited financial statements for the absence of footnotes and subject to year-end audit adjustments), provided, however, that if at any time any change in GAAP would affect the computation of any covenant or requirement set forth in any Loan Document, and either Borrower or any Lender shall so request, Borrower and the Lenders shall negotiate in good faith to amend such covenant or requirement to preserve the original intent thereof in light of such change in GAAP; provided, further, that, until so amended, (i) such covenant or requirement shall continue to be computed in accordance with GAAP prior to such change therein and (ii) Borrower shall provide the Lenders financial statements and other documents required under this Agreement or as reasonably requested hereunder setting forth a reconciliation between calculations of requirement made before and after giving effect to such change in GAAP; provided, further, that (x) all obligations of any Person that are or would have been treated as operating leases for purposes of GAAP prior to the issuance by the Financial Accounting Standards Board on February 25, 2016 of an Accounting Standards Update (the "ASU") shall continue to be accounted for as operating leases for purposes of all financial definitions, calculations and covenants for purpose of this Agreement (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with the ASU (on a prospective or retroactive basis or otherwise) to be treated as Capital Lease Obligations in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "Dollars" or "\$" are United States Dollars, unless otherwise noted.

2. LOANS AND TERMS OF PAYMENT

1.1 **Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and

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unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

1.1 Term Loans.

(a) Availability.

(i) Subject to the terms and conditions of the Prior Agreement, prior to the Effective Date, Oxford made a term loan to Borrower in an aggregate principal amount of Ten Million Dollars (\$10,000,000.00) (the, "Original Term A Loan").

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, on the Effective Date, as follows:

(1) The secured promissory note issued by Borrower evidencing the Original Term A Loan made by Oxford on May 4, 2022 in an aggregate principal amount equal to Ten Million Dollars (\$10,000,000.00), shall be replaced with an amended and restated

secured promissory note in the same amount; and

(2) The Lenders shall make term loans to Borrower in an aggregate principal amount equal to Twenty Million Dollars (\$20,000,000.00) ratably according to each Lender's respective Term A Loan Commitment (after giving effect to the Original Term A Loan) as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "New Term A Loan", and collectively as the "New Term A Loans"; the Original Term A Loan, as well as each New Term A Loan is hereinafter referred to singly as a "Term A Loan" and collectively as the "Term A Loans"). After repayment, no Term A Loan may be re-borrowed.

(iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term B Draw Period, to make term loans to Borrower in an aggregate principal amount up to Thirty-Five Million Dollars (\$35,000,000.00) to be disbursed in a single advance equal to or greater than Twenty Million Dollars (\$20,000,000) on the Funding Date of the initial Term B Loan, ratably according to each Lender's respective Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "Term B Loan", and collectively as the "Term B Loans"). After repayment, no Term B Loan may be re-borrowed. If the Term B Draw Period terminates on December 31, 2025 (other than as the result of an Event of Default), up to Fifteen Million Dollars (\$15,000,000) of the remaining amount of the Term B Loan Commitment on December 31, 2025 shall be added to the Term C Loan Commitment (such additional amount, the "Additional Term C Loan Commitment Amount") effective as of January 1, 2026 on a pro rata basis in accordance with the Commitment Percentage for the Term C Loans.

(iv) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term C Draw Period, to make term loans to Borrower in an aggregate principal amount equal to Thirty-Five Million Dollars (\$35,000,000.00), plus the Additional Term C Loan Commitment Amount, if any, and disbursed during the Term C Draw Period ratably according to each Lender's respective Term C Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "Term C Loan", and collectively as the "Term C Loans"). After repayment, no Term C Loan may be re-borrowed.

(v) Subject to the terms and conditions of this Agreement, the Lenders may, in their sole discretion upon Borrower's request, agree to make term loans to Borrower prior to the

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Amortization Date in an aggregate principal amount equal to Fifty Million Dollars (\$50,000,000.00) disbursed in a single advance and, if made, according to a commitment schedule to be provided by the Lenders prior to the Funding Date of such term loans (such term loans are hereinafter referred to singly as a "Term D Loan", and collectively as the "Term D Loans"; each Term A Loan, Term B Loan, Term C Loan or Term D Loan is hereinafter referred to singly as a "Term Loan" and the Term A Loans, the Term B Loans, the Term C Loans and the Term D Loans are hereinafter referred to collectively as the "Term Loans"). After repayment, no Term D Loan may be re-borrowed.

(b) Repayment.

(i) Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the first full calendar month to occur after the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the last calendar day of the calendar month in which such Funding Date occurs.

(ii) Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to Collateral Agent, for the account of the Lenders (payable to each Lender in accordance with its Pro Rata Share), as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to nine (9) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Collateral Agent, for the account of the Lenders (payable to each Lender in accordance with its respective Pro Rata Share), an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through such

prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loans.

(d) **Permitted Prepayment of Term Loans.**

(i) Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) Business Days (or such shorter period as Collateral Agent may agree in its sole discretion) prior to such prepayment, and (ii) pays to the Collateral Agent, for the account of the Lenders, on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due

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amounts. The Lenders hereby agrees to waive the Prepayment Fee (as defined in the Prior Agreement) with respect to the Original Term A Loan owed under the Previous Agreement.

(ii) Notwithstanding anything herein to the contrary, Borrower shall also have the option to prepay part of Term Loans advanced by the Lenders under this Agreement, provided Borrower

(i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) Business Days (or such shorter period as Collateral Agent may agree in its sole discretion) prior to such prepayment, (ii) prepays such part of the Term Loans in a denomination that is a whole number multiple of Five Million Dollars (\$5,000,000.00) (or such lesser amount as is acceptable to Collateral Agent in its sole discretion), and (iii) pays to the Collateral Agent, for the account of the Lenders, on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment, and (C) all other Obligations that are then due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts, (D) the applicable Prepayment Fee with respect to the portion of such Term Loans being prepaid, and (E) without duplication, any fee that would have otherwise been required to be paid pursuant to Section 2.2(d)(i). For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under Section 2.2(b) on a pro-rata basis.

1.2 Payment of Interest on the Credit Extensions.

(a) **Interest Rate.** Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan and monthly thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) **Default Rate.** Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "Default Rate"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) **360-Day Year.** Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

(d) **Debit of Accounts.** Collateral Agent and each Lender may debit (or ACH) the Designated Deposit Account (or, if funds in the Designated Deposit Account are insufficient or if an Event of Default has occurred and is continuing, any other account of a Loan Party which is subject to a Control Agreement in favor of Collateral Agent), for principal and interest payments or any other amounts Borrower owes Collateral Agent or the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) **Payments.** Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to Collateral Agent (and Collateral Agent shall then make the payments to the respective Lender to which such payments are owed), at Collateral Agent's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or

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interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

1.2 Secured Promissory Notes. The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as **Exhibit D** hereto (or in the case of the Original Term A Loan, an Amended and Restated Promissory Note; each a "**Secured Promissory Note**"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence, absent manifest error, of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note with a customary indemnification with respect such lost, stolen, destroyed or mutilated Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

1.3 Fees. Borrower shall pay to Collateral Agent, for the account of the Lenders (payable to each Lender in accordance with its Pro Rata Share):

(a) **Amendment Fee.** A non-refundable amendment fee (the "**Amendment Fee**") to be paid to Oxford Finance LLC in its capacity as a Lender, equal to Fifty Thousand Dollars (\$50,000.00) which shall be fully earned due and payable on the Effective Date;

(b) **Final Payment.** The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(c) **Prepayment Fee.** The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares. For the sake of clarity, for purposes of the determination of the Prepayment Fee, the Funding Date of each Term A Loan, which such Term A Loans are in the original aggregate principal amount of Thirty Million Dollars (\$30,000,000.00), is the Effective Date; and

(d) **Lenders' Expenses.** All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

1.4 Withholding. Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower shall be permitted to make such withholding and deduction and hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or

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deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. The amount by which a payment is required to be increased pursuant to the prior sentence is referred to hereafter as the **"Withholding Tax Indemnity Amount."** Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which adequate reserves have been set aside on its books in accordance with GAAP. The agreements and obligations of Borrower contained in this **Section 2.6** shall survive the termination of this Agreement. On the date of this Agreement, each Lender shall deliver, and upon a Lender Transfer, the applicable successor or assign shall deliver, to Borrower, a complete and properly executed IRS Form W-9 or Form W-8, as applicable, or any similar or successor certificate designated by the IRS (a **"Tax Certificate"**). Notwithstanding anything to the contrary in this **Section 2.6**, so long as no Event of Default has occurred and is continuing, if a Lender fails to deliver a Tax Certificate, Borrower shall not be required to pay the Withholding Tax Indemnity Amount, if any, unless and until such Lender delivers the Tax Certificate.

3. **CONDITIONS OF LOANS**

1.1 Conditions Precedent to Initial Credit Extension. Each Lender's obligation to make the initial Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

- (a) Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;
- (b) a duly executed Control Agreement with respect to the Designated Deposit Account;
- (c) duly executed original Amended and Restated Secured Promissory Note in favor of Oxford in the amount of Ten Million Dollars (\$10,000,000) in respect of the Original Term A Loan;
- (d) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan Commitment Percentage in respect of the Term A Loans made by such Lender on the Effective Date;
- (e) Collateral Agent shall have received an Officer's Certificate, (A) certifying as to (i) the Operating Documents of each Loan Party (which, to the extent filed with a Governmental Authority, shall be certified as of a recent date by such Governmental Authority), (ii) the resolutions of the governing body of each Loan Party and (iii) the incumbency (including specimen signatures) of the responsible officers of each Loan Party and (B) attaching certificates of the good standing, existence or its equivalent of each Loan Party, which shall be as of a date no earlier than thirty (30) days (or such earlier date as the Collateral Agent may agree in its sole discretion) prior to the Effective Date;
- (f) a duly executed Perfection Certificate from Borrower (which covers Borrower and each of its Subsidiaries);
- (g) the Annual Projections, for the fiscal year ending December 31, 2024;

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- (h) that certain termination of side letter agreement, duly executed by Borrower;
- (i) certified copies, dated as of date no earlier than thirty (30) days (or such later date as the Collateral Agent may agree in its sole discretion) prior to the Effective Date, of financing statement searches, as Collateral Agent shall reasonably request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;
- (j) a duly executed customary legal opinion of counsel to Borrower with respect to the Loan Documents, dated as of the Effective Date;
- (k) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by **Section 6.5** hereof are in full force and effect, together with certificates of insurance policies naming Collateral Agent as loss payee and additional insured; and

(l) payment of the fees and Lenders' Expenses then due and payable as specified in [Section 2.5](#) hereof.

1.2 Conditions Precedent to all Credit Extensions. The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Disbursement Letter in the form of [Exhibit B](#) attached hereto;

(b) the representations and warranties in [Section 5](#) hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension shall be deemed to be Borrower's representation and warranty on that date that the representations and warranties in [Section 5](#) hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender's sole discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the Annual Projections of Borrower presented to and accepted by Collateral Agent and each Lender;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date;

(e) solely with respect to any Term B Loan, Borrower's delivery to Collateral Agent and Lenders of evidence, reasonably satisfactory to Collateral Agent and Lenders in their sole discretion, that as of the Funding Date of such Term B Loan (i) the Phase 2b trial of PLN-74809 in IPF (Idiopathic

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Pulmonary Fibrosis) remains ongoing and (ii) if a Phase 3 trial of PLN-74809 in IPF (Idiopathic Pulmonary Fibrosis) has been initiated, then such Phase 3 trial must also be ongoing; and

(f) payment of the fees and Lenders' Expenses then due as specified in [Section 2.5](#) hereof.

1.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

1.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon Eastern time five (5) Business Days (or such later date as the Collateral Agent may agree in its sole discretion) prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its ratable portion of the Term Loan to be advanced on such Funding Date in accordance with its Commitment Percentage.

4. CREATION OF SECURITY INTEREST

1.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower, shall promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower. If any Collateral shall be sold, transferred or otherwise disposed of by any Loan Party (other than to a Loan Party or any Subsidiary) in a transaction permitted by this Agreement, then Collateral Agent, at the request and sole expense of such Loan Party, shall promptly execute and deliver to such Loan Party such documents as such Loan Party may reasonably request to evidence the release of such item of Collateral from the security interest granted hereunder.

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1.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any Transfer of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

1.3 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) Business Days (or such longer period as the Collateral Agent may agree in its sole discretion) of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to (i) exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof; provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms and (ii) receive and retain any and all cash dividends, payments or other distributions made in respect of the Shares (other than stock dividends and other dividends constituting Collateral which are addressed hereinabove) to the extent they are not prohibited by the Loan Documents. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

1.1 Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified, except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, the Borrower has delivered to Collateral Agent on the Effective Date a duly executed perfection certificate, dated on or about the date hereof (as amended, restated, amended and restated, supplemented or otherwise modified from time to time in accordance with this Section 5.1 and any additional perfection certificate for any Subsidiary which is formed or acquired after the Closing Date to the extent requested by Collateral Agent, each a "Perfection Certificate" and collectively, the "Perfection Certificates"). Borrower represents and warrants that

(a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on the Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on the

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Perfection Certificate; (c) the Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) the Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years prior to the Effective Date, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries is accurate and complete in all material respects (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); provided that such updates to the Perfection Certificate are subject to the review and approval of Collateral Agent, unless such facts, events or circumstances being updated first arose or occurred after the Effective Date and do not constitute a breach, default or Event of Default under this Agreement or any other Loan Document. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by each Loan Party of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any Loan Party's organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate, in any material respect, any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which any Loan Party, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect or are being obtained pursuant to [Section 6.1\(b\)](#)), or (v) constitute an event of default under any material agreement by which any Loan Party, or their respective properties, is bound. No Loan Party is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

1.2 Collateral.

(a) Borrower and each Guarantor has good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any Guarantor or any of their respective Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect of which each Loan Party has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein, in each case, to the extent required by [Section 6.6](#). The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate, (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral with an aggregate value in excess of Five Hundred Thousand Dollars (\$500,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to [Section 6.11](#).

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(c) All Inventory is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiaries' interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent within ten

(10) Business Days of Borrower or any of its Subsidiaries entering into or becoming bound by any material license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

1.1 Litigation. Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with [Section 6.9](#) hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries

which if could reasonably be expected to result in damages or costs to Borrower or such Subsidiaries in excess of Five Hundred Thousand Dollars (\$500,000.00).

1.2 No Material Deterioration in Financial Condition; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries as of the dates and for the periods set forth therein, and the consolidated results of operations of Borrower and its Subsidiaries. There has not been a Material Adverse Change nor any event or circumstance since December 31, 2021 that could reasonably be expected to have a Material Adverse Change.

1.3 Solvency. Borrower is Solvent, and Borrower and its Subsidiaries, taken as a whole, are Solvent.

1.4 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is required to register as an "investment company" under the Investment Company Act of 1940, as amended (furthermore, strictly as of the Funding Date of each Term Loan, neither Borrower nor any of its Subsidiaries is "controlled" by an "investment company" that is required to register under the Investment Company Act of 1940, as amended). Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

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None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' controlled Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower, and any of their controlled Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

1.5 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

1.6 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed (or timely filed extensions to file) all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, material state, and material local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless (a) such taxes are being contested in accordance with the following sentence or (b) in the case of material state and material local taxes, assessments, deposits and contributions owed do not, individually or in the aggregate, exceed One Hundred Thousand Dollars (\$100,000.00). Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien." Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiaries' prior tax years which could result in additional taxes in excess of One Hundred Thousand Dollars (\$100,000.00) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

1.7 Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

1.8 Shares. Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, as of the Effective Date, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

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1.9 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given in connection with the Loan Documents to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, in each case, as such information may have heretofore been modified or supplemented by other information so furnished, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading in any material respect in light of the circumstances under which such statements were made (after giving effect to all supplements and updates thereto) (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results, and such difference may be material).

1.10 "Know Your Customer" Information. All materials and information provided to Collateral Agent and Lenders in connection with applicable "know your customer" and Anti-Terrorism Laws are true and correct in all material respects.

1.11 Definition of "Knowledge." For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

6. AFFIRMATIVE COVENANTS

Each Loan Party shall do all of the following:

1.1 Government Compliance.

(a) Maintain its and, except as permitted by the second sentence of Section 7.3, all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly notify Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries and, upon Collateral Agent's request, provide copies of such Governmental Approvals to Collateral Agent.

1.2 Financial Statements, Reports, Certificates.

(a) Deliver to Collateral Agent:

(i) as soon as available, but no later than forty-five (45) days (or such later date as Collateral Agent may agree in its sole discretion) after the last day of the first three (3) fiscal quarters of the Borrower's fiscal year, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such fiscal quarter, all in reasonable detail and prepared in accordance with GAAP, certified by a

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Responsible Officer and in a form reasonably acceptable to Collateral Agent (it being agreed that the financial statements delivered by the Borrower to the Collateral Agent prior to the Effective Date are in a form acceptable to the Collateral Agent), of Borrower as fairly presenting the financial condition of Borrower and its Subsidiaries in all material respects, subject only to normal year-end audit adjustments and the absence of footnotes;

(ii) as soon as available, but no later than ninety (90) days (or such later date as Collateral Agent may agree in its sole discretion) after the last day of Borrower's fiscal year or within five (5) Business Days (or such later date as the Collateral Agent may agree in its sole discretion) of filing with the Securities and Exchange Commission, audited consolidated financial statements all in reasonable detail and prepared in accordance with GAAP, audited and accompanied by a report and opinion of an independent certified public accountant of nationally recognized standing reasonably acceptable to Collateral Agent (it being understood and agreed that Deloitte Touche Tohmatsu Limited is acceptable), which report and opinion shall be prepared in accordance with generally accepted auditing standards and shall not be subject to any "going concern" or like qualification or exception or any qualification or exception as to the scope of such audit, other than a going concern exception or explanatory note resulting (a) solely from the Maturity Date occurring within one year of such audit report or (b) a going concern qualification typical for a venture capital backed company similar to Borrower;

(iii) as soon as available after approval thereof by Borrower's Board of Directors, but no later than thirty (30) days (or such later date as the Collateral Agent may agree in its sole discretion) after the last day of each fiscal year of Borrower, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's Board of Directors, which such annual financial projections shall be set forth in a quarter-by-quarter format (such annual financial projections as delivered to Collateral Agent and the Lenders are referred to herein as the "Annual Projections"; provided that, any revisions of the Annual Projections approved by Borrower's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) Business Days of delivery, copies of all non-ministerial statements, reports and notices made available to Borrower's security holders or holders of Subordinated Debt, in such holders' capacities as security holders or holders of Subordinated Debt;

(v) within five (5) Business Days of filing, all reports on Form 10 K, 10 Q and 8 K filed with the Securities and Exchange Commission;

(vi) prompt notice of (y) in the event that Borrower is no longer subject to reporting requirements under the Securities Exchange Act of 1934, as amended, any material change to the capitalization table of Borrower, and (z) any amendments of the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days (or such later date as the Collateral Agent may agree in its sole discretion) after the last day of each month, copies of the month end account statements for each Collateral Account maintained by Borrower or its Subsidiaries which statements may be provided to Collateral Agent by Borrower or directly from the applicable institution(s);

(ix) no later than ten (10) Business Days after any Key Person ceases to be actively engaged in the management of Borrower, written notice of such change;

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(x) promptly, after Borrower or any its Subsidiaries obtains knowledge thereof, notice of any Liens which have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits; and

(xi) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the Securities and Exchange Commission) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in [Section 6.2\(a\)\(i\)-\(ii\)](#) above, deliver to Collateral Agent, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once per calendar year; provided, that when an Event of Default exists Collateral Agent (or any of its respective representatives or independent contractors) may do any of the foregoing at the expense of Borrower at any time during normal business hours and without advance notice.

1.3 Inventory; Returns. Keep all Inventory of the Loan Parties and their Subsidiaries in good and marketable condition, free from material defects except for Inventory for which adequate reserves have been made. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date. Borrower shall promptly notify Collateral Agent of all returns, recoveries, disputes and claims that involve more than Five Hundred Thousand Dollars (\$500,000.00) individually or in the aggregate in any calendar year.

1.4 Taxes; Pensions. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, material state, and material local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of [Section 5.8](#) hereof, and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans; provided that, as used herein, "material state, and material local Taxes, assessments, deposits and contributions" mean those, individually or in the aggregate, equal to or exceed One Hundred Thousand Dollars (\$100,000.00).

1.5 Insurance. Keep Borrower and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. Subject to the Post-Closing Letter, all of the Loan Parties' property policies shall have a lender's loss payable endorsement showing

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Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, subject to the Post-Closing Letter, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to One Million Dollars (\$1,000,000.00) with respect to any loss, but not exceeding One Million Dollars (\$1,000,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this [Section 6.5](#) or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this [Section 6.5](#), and take any action under the policies Collateral Agent or such Lender deems prudent.

1.6 Operating Accounts.

(a) Maintain all of Borrower's and its Subsidiaries' Collateral Accounts at the banks and financial institutions as disclosed in the Perfection Certificates delivered on the Effective Date; provided that if Borrower desires to establish a Collateral Account with any bank or financial institution that is not disclosed in the Perfection Certificate delivered on the Effective Date, (i) such Person shall be acceptable to Collateral Agent in its reasonable discretion (except for a new Excluded Account as Collateral Agent will not need to approve the bank or financial institution at which such new Excluded Account is maintained) and (ii) Borrower shall be in compliance with the requirements of [Section 6.6\(b\)](#); provided further that, subject to the Post-Closing Letter, such Loan Parties' Collateral Accounts (other than the Excluded Accounts) shall at all times be subject to a Control Agreement or other appropriate instrument under applicable law in favor of

Collateral Agent with respect to any such Collateral Accounts to perfect Collateral Agent's Lien in such Collateral Accounts in accordance with the terms hereunder and provide Collateral Agent with the ability to assert control with respect thereto. Notwithstanding the foregoing, until all Collateral Accounts (other than Excluded Accounts) in existence on the Effective Date are subject to a Control Agreement in favor of the Collateral Agent in accordance with the terms of this Section 6.6 and the Post Closing Letter, the Designated Deposit Account shall maintain funds of not less than an amount equal to the aggregate principal amount of Term Loans which have been funded.

(b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account, other than Excluded Accounts, at or with any Person following the Effective Date. In addition, for each Collateral Account that a Loan Party at any time maintains, such Loan Party shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument under applicable law with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder and provide Collateral Agent with the ability to assert control with respect thereto prior to the establishment of such Collateral

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Account, which Control Agreement or other appropriate instrument under applicable law may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to Excluded Accounts.

(c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

1.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall:

(a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly, after Borrower or any of its Subsidiaries obtains knowledge thereof, advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

1.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

1.9 Notices of Litigation and Default. Borrower will give prompt written notice to Collateral Agent of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Five Hundred Thousand Dollars (\$500,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

1.10 Financial Covenant.

(a) **Minimum Cash.** Upon the occurrence of the Minimum Cash Trigger Event, and at all such times thereafter when Borrower's Market Capitalization is not equal to or greater than Eight Hundred Million Dollars (\$800,000,000.00), Borrower shall, subject to the immediately succeeding paragraph, maintain unrestricted cash, in Collateral Accounts subject to a Control Agreement in favor of Collateral Agent, in an amount equal to or greater than fifty percent (50%) the aggregate principal amount of Term Loans at any time currently outstanding.

Notwithstanding the foregoing, if promptly following (and in no event later than two (2) Business Days thereafter) the occurrence of the Minimum Cash Trigger Event, Borrower prepays fifty percent (50%) of the aggregate principal amount of Term Loans then currently outstanding (and in accordance with Section 2.2(d) hereof), then the aforementioned "Minimum Cash" covenant shall not apply.

(b) **Intellectual Property Lien.** No later than the date on which the aggregate original principal amount of Term Loans advanced by the Lenders outstanding under this Agreement is greater than Fifty Million Dollars (\$50,000,000.00) (or such later date as the Collateral Agent may agree in its sole

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discretion), Borrower shall have executed and delivered to Collateral Agent and the Lenders an amendment to this Agreement, intellectual property security agreement, and any other documentation reasonably requested by Collateral Agent, in each case, to effect the grant of such lien in Borrower's Intellectual Property.

1.11 Landlord Waivers; Bailee Waivers. In the event that any Loan Party, after the Effective Date, adds any new offices or business locations, including warehouses, or otherwise stores any portion of the Collateral with, or delivers any portion of the Collateral to, a bailee, in each case in accordance with Section 7.2, then such Loan Party will promptly notify Collateral Agent in writing and, in the event that the new location is the chief executive office of a Loan Party or the Collateral at any such new location is valued in excess of Five Hundred Thousand Dollars (\$500,000.00) in the aggregate, such Loan Party shall use commercially reasonable efforts to cause such bailee or landlord, as applicable, to execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent within thirty (30) days of the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

1.12 Creation/Acquisition of Subsidiaries. In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary (including, without limitation, pursuant to a Division), Borrower shall provide prior written notice to Collateral Agent of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent (if any) to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares of each such newly created Subsidiary. Notwithstanding anything to the contrary herein, the parties hereto agree that so long as the Loan Parties are in compliance with Section 7.12, (i) Pliant Belgium shall not be required to become a co-Borrower or provide a guarantee of the Obligations, (ii) Pliant Belgium shall not be required to grant a security interest in any of its assets and (iii) no Loan Party shall be required to provide a perfected security interest in the Shares of Pliant Belgium under the laws of Belgium or take any other actions in Belgium with respect to such Shares.

1.13 Use of Proceeds. Use the proceeds of the Credit Extensions for working capital purposes, to fund its general business requirements in accordance with the provisions of this Agreement, and to fund cost and expenses incurred in connection with the execution, delivery and performance by the Loan Parties of the Loan Documents; provided that the Credit Extensions shall not be used for personal, family, household or agricultural purposes.

1.14 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.

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7. NEGATIVE COVENANTS

The Loan Parties shall not:

1.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers:

(a) of Inventory in the ordinary course of business;

(b) of worn out or obsolete Equipment;

(c) of cash and Cash Equivalents in connection with transactions not prohibited hereunder to the extent such transactions are in the ordinary course of business;

(d) in connection with Permitted Liens, Permitted Investments and Permitted Licenses;

(e) other Transfers in the ordinary course of business not exceeding Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any fiscal year of Borrower so long as no Event of Default has occurred and is then continuing or could reasonably be expected to result therefrom;

(f) Transfers to Borrower's contract manufacturers to facilitate product manufacturing; provided that the fair market value of the assets or property sold or otherwise transferred pursuant to this clause (g) shall not exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any period of twelve (12) consecutive months;

(g) the cancellation of intercompany Indebtedness owing between Loan Parties or by Loan Parties to Subsidiaries that are not Loan Parties; and

(h) Transfers of equipment or real property to the extent that (A) such property is exchanged for credit against the purchase price of similar replacement property or (B) the proceeds of such Transfer are reasonably promptly applied to the purchase price of such replacement property.

1.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower or any of its Subsidiaries as of the Effective Date or reasonably related or incidental thereto or constituting a reasonable extension thereof; (b) liquidate or dissolve; or (c) permit a Change of Control. Borrower shall not, without at least ten (10) Business Days' (or such shorter period as the Collateral Agent may agree in its sole discretion) prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (i) contain less than Five Hundred Thousand Dollars (\$500,000.00) in assets or property of Borrower or any of its Subsidiaries and (ii) are not Borrower's or its Subsidiaries' chief executive office); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

1.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person (including, without limitation, pursuant to a Division). A Subsidiary may merge or consolidate (i) into any one or more other Subsidiaries of Borrower, provided that when any Loan Party is merging with another Subsidiary of a Loan Party that

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is not a Loan Party, such Loan Party shall be the continuing or surviving Person or (ii) with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result thereof.

1.15 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

1.16 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" herein.

1.17 Maintenance of Collateral Accounts. Maintain any Collateral Account except as permitted pursuant to the terms of Section 6.6 hereof.

1.18 Distributions; Investments.

(a) Pay any dividends or make any distribution or payment or redeem, retire or purchase any capital stock except:

(i) dividends with respect to Borrower's capital stock payable solely in additional capital stock that constitute common stock (or the equivalent);

(ii) Borrower's purchase, redemption, retirement, or other acquisition of its capital stock with the proceeds received from a substantially concurrent issue of new shares of its capital stock, provided that (x) no Event of Default has occurred and is continuing or would result therefrom and

(y) the aggregate amount of all such dividends or other distributions permitted under this clause (ii) shall not exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any fiscal year of Borrower;

(iii) dividends paid by any Subsidiary to any other Loan Party;

(iv) Borrower may make dividends or other distributions pursuant to and in accordance with restricted stock agreements, stockholder rights plans, director or consultant stock option plans or other similar plans for management or employees of Borrower and its Subsidiaries or in connection with the satisfaction of withholding tax obligations; provided that the aggregate amount of all such dividends or other distributions permitted under this clause (iv) shall not exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any fiscal year of Borrower;

(v) Borrower may pay cash in lieu of the issuance of fractional shares in an amount not to exceed Fifty Thousand Dollars (\$50,000) in any fiscal year, provided that no Event of Default has occurred and is continuing or could result therefrom;

(vi) Borrower may honor any non-cash conversion requests in respect of any convertible securities of Borrower permitted under this Agreement into capital stock of Borrower pursuant to the terms of such convertible securities;

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(vii) Borrower may honor any exercise request in respect of warrants to purchase capital stock of Borrower pursuant to the terms of such warrants, and so long as such exercise does not result in a payment of any cash by Borrower (other than cash in lieu of fractional shares which shall be subject to the cap set forth in clause (v) above), provided that no Event of Default has occurred and is continuing or would result therefrom; and

(viii) Borrower may agree to pay and accrue dividends on its capital stock payable so long as Borrower does not make actual payment of any such dividend until (x) all Obligations have been paid in full (other than unasserted indemnification and expense reimbursement Obligations) and (y) this Agreement has been terminated;

(b) directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary) other than Permitted Investments.

1.4 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for:

(a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person;

(b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries;

(c) Permitted Investment and Permitted Indebtedness;

(d) transactions among the Borrower and its Subsidiaries in respect of transfer pricing and cost-plus arrangements;

(e) normal and reasonable compensation and reimbursement of expenses of officers and directors entered into in the ordinary course of business and approved by Borrower's Board of Directors to the extent required by Borrower's organizational documents;

(f) transactions between and among Loan Parties;

(g) employment, compensation and benefits arrangements in the ordinary course of business with current or former officers, employees, directors, managers and consultants and transactions pursuant to stock option, stock appreciation rights, stock incentive or other equity compensation plans and employee benefit plans and arrangements in the ordinary course of business and approved by Borrower's Board of Directors to the extent required by Borrower's organizational documents; and

(h) transactions permitted by Sections 7.1(g), 7.3 and 7.7 hereof.

1.5 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except as permitted under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the principal amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

1.6 Compliance. Become required to register as an "investment company" under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending

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credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

1.7 Compliance with Anti-Terrorism Laws. Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any controlled Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any controlled Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

1.8 Pliant Belgium. (a) Permit the aggregate amount of cash and the value of assets held or maintained by Pliant Belgium to exceed Five Hundred Thousand Dollars (\$500,000.00) at any time or (b) permit Pliant Belgium to own or license any Intellectual Property.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

1.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date unless such failure is caused by Collateral Agent's failing to auto debit Borrower's Designated Deposit Account when sufficient funds were contained therein of the Obligations when due, (b) in the event Collateral Agent fails to auto debit Borrower's Designated Deposit Account when sufficient funds were contained therein of the Obligations when due, pay any Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof) or (c) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date

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or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period).

1.2 Covenant Default.

(a) Any Loan Party fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.9 (Notice of Litigation and Default) or 6.12 (Creation/Acquisition of Subsidiaries) or Borrower violates any covenant in Section 7; or

(b) Any Loan Party fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within fifteen (15) Business Days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (15) Business Day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to the covenants set forth in subsection (a) above;

1.3 Material Adverse Change. A Material Adverse Change occurs.

1.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within fifteen (15) Business Days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any fifteen (15) Business Day cure period; and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business.

1.1 Insolvency. (a) Borrower is or becomes Insolvent, or Borrower and its Subsidiaries, taken as a whole, are or become Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower is, or Borrower and its Subsidiaries, taken as a whole, are, Insolvent and/or until any Insolvency Proceeding is dismissed);

1.2 Other Agreements. There is a default under any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an aggregate principal amount in excess of Five Hundred Thousand Dollars (\$500,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by

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the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Collateral Agent or any Lender has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document, and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower;

1.3 Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars (\$500,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance

carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of fifteen (15) Business Days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

1.4 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement of fact made by or on behalf of Borrower or any of its Subsidiaries herein or in any other any Loan Document delivered in writing to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement of fact shall be incorrect in any material respect when made;

1.5 Subordinated Debt. (a) Any document, instrument, or agreement evidencing any Subordinated Debt shall for any reason be revoked or invalidated or otherwise cease to be in full force and effect, in each case, other than in accordance with the terms thereof; (b) the Borrower or any Subsidiary shall be in breach thereof or contest in any manner the validity or enforceability thereof or deny that it has any further liability or obligation thereunder, or (c) the Obligations shall for any reason be subordinated or shall not have the priority contemplated by this Agreement or any applicable subordination or intercreditor agreement;

1.6 Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect (other than in accordance with its terms); (b) any Guarantor does not perform any material obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the liquidation, winding up, or termination of existence of any Guarantor;

1.7 Governmental Approvals. Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term and such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change;

1.8 Lien Priority. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any material portion of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement; provided that such circumstance is not due to Collateral Agent's failure to file an appropriate continuation financing statement, amendment financing statement or initial financing statement;

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1.9 Delisting. The shares of common stock of Borrower are delisted from NASDAQ Global Select Market because of failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed on any other nationally recognized stock exchange in the United States having listing standards at least as restrictive as the NASDAQ Global Select Market.

9. RIGHTS AND REMEDIES

1.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license

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to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, each Loan Party's labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, each Loan Party's rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of any Loan Party; and

(vii) subject to Sections 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "Exigent Circumstance" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of any Loan Party after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

1.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney in fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse any Loan Party's name on any checks or other forms of payment or security; (b) sign any Loan Party's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney in fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder.

Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

1.3 Protective Payments. If any Loan Party fails to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which any Loan Party is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

1.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default,

(a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of any Loan Party of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

1.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

1.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

1.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which any Loan Party is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile or electronic mail transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address, facsimile number, or email address by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:	PLIANT THERAPEUTICS, INC. Keith Cummings (CFO) 260 Littlefield Avenue South San Francisco, CA 94080
with a copy (which shall not constitute notice) to:	SIDLEY AUSTIN LLP Sharon Flanagan 555 California Street, Suite 2000 San Francisco, CA 94104

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If to Collateral Agent:	OXFORD FINANCE LLC 115 South Union Street Suite 300 Alexandria, VA 22314 Attention: Legal Department
with a copy (which shall not constitute notice) to:	DLA PIPER LLP (US) 500 8th Street, NW Washington, DC 20004 Attention: Eric Eisenberg

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER, AND JUDICIAL REFERENCE

California law governs the Loan Documents without regard to principles of conflicts of law. Each party hereto submits to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Collateral Agent or any Lender and any Loan Party may respond action or proceeding or assert counterclaims relating thereto in such jurisdiction. Each party hereto expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and each party hereto hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Each party hereto hereby

waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to such Person at the address set forth in, or subsequently provided by such Person in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of such Person's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, EACH PARTY HERETO WAIVES THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR

RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a

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jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure §§ 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure § 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

12. GENERAL PROVISIONS

1.1 Successors and Assigns.

(a) This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "Lender Transfer") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided, however*, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "Approved Lender"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (i) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (ii) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

(b) Collateral Agent, acting as a non-fiduciary agent of Borrower (solely for tax purposes), shall maintain (a) a copy (or electronic equivalent) of the documentation for each Lender Transfer delivered to it, and (b) a register for recordation of the names, addresses, Term Loan Commitments of and Obligations owing to, each Lender. Entries in the register shall be conclusive, absent manifest error.

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and Borrower, Collateral Agent and Lenders shall treat each Person recorded in such register as a Lender for all purposes under the Loan Documents, notwithstanding any notice to the contrary. The register shall be available for inspection by Borrower or any Lender, from time to time upon reasonable notice.

(c) Each Lender that sells a participation shall, acting as a non-fiduciary agent of Borrower (solely for tax purposes), maintain a register in which it enters the participant's name, address and interest in Term Loan Commitments and Obligations (the "**Participant Register**"). Entries in the Participant Register shall be conclusive, absent manifest error, and such Lender shall treat each Person recorded in the register as the owner of the participation for all purposes, notwithstanding any notice to the contrary. No Lender shall have an obligation to disclose any information in such Participant Register, except to the extent necessary to establish that a participant's interest is in registered form under the U.S. Internal Revenue Code and Section 5f.103-1(c) of the U.S. Treasury Regulations. Collateral Agent (in its capacity as Collateral Agent) shall have no responsibility for maintaining a Participant Register.

1.1 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable and documented out-of-pocket attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including reasonable and documented fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct. This Section 12.2 with respect to taxes other than any taxes that represent losses, claims, damages, etc. arising from any non-tax claim.

1.2 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

1.3 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

1.4 Correction of Loan Documents. Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties, so long as Collateral Agent and Lenders provide Borrower with written notice of such correction and allows Borrower at least ten (10) Business Days to object to such correction. In the event

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of such objection, such correction shall not be made except by an amendment signed by Borrower and requisite Lenders, in accordance with Section 12.6 hereof.

1.5 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement;

(G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(b) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(c) Other than as expressly provided for in Section 12.6(a)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

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(d) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

1.6 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

1.7 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

1.8 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or

Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose relating to the administration of this Agreement, including, without limitation, for the development of client databases, reporting purposes, and market analysis, in each case on an aggregated basis without identifying information regarding the Borrower or its Subsidiaries. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this [Section 12.9](#) supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this [Section 12.9](#).

1.9 Public Announcement. Notwithstanding anything else herein to the contrary, Borrower hereby agrees that Collateral Agent and each Lender may make a public announcement of the transactions contemplated by this Agreement, and may publicize the same on its company website, in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames, logos, and any information related to the transactions to the extent such information is not confidential.

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1.10 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

1.11 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Term Loan to an assignee in accordance with [Section 12.1](#), (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of [Section 12.9](#), Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

1.12 Effect of Amendment and Restatement. This Agreement is intended to and does completely amend and restate, without novation, the Prior Agreement and the terms and provisions of the Prior Agreement shall be superseded by this Agreement. All security interests granted by Borrower under the Prior Agreement are hereby confirmed and ratified and shall continue to secure all Obligations under this Agreement. Without limiting the foregoing, all other Loan Documents issued in connection with the Prior Agreement (to the extent not yet exercised, terminated or amended and restated in connection with this Agreement) shall remain in full force and effect.

13. DEFINITIONS

1.1 Definitions. As used in this Agreement, the following terms have the following meanings: **"1-Month CME Term SOFR"** is the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website.

"Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

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"Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members. For purposes of this definition, the term "control" means, in respect of a particular Person, the possession, directly or indirect, of the power to direct or cause the direction of the management or policies of such Person, whether through the ability to exercise voting power, by contract, or otherwise.

"Agreement" is defined in the preamble hereof. **"Amendment Fee"** is defined in [Section 2.5](#).

"Amortization Date" is July 1, 2028; provided that, if Borrower achieves the Interest-Only Extension Milestone, then, upon Borrower written request to Collateral Agent therefor prior to July 1, 2028 and within thirty (30) days after the later of (i) achievement of the Interest-Only Extension Milestone and (ii) April 11, 2025, **"Amortization Date"** shall be July 1, 2029. **"Annual Projections"** is defined in [Section 6.2\(a\)](#).

"Anti-Terrorism Laws" are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Approved Fund" is any (a) Person, investment company, fund, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business and that is administered or managed by (i) a Lender, (ii) an Affiliate of a Lender, or (iii) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender, or (b) any Person (other than a natural person) which temporarily warehouses loans, or provides financing or securitizations, in each case, for any Lender or any entity described in the preceding clause (a).

"Approved Lender" is defined in [Section 12.1](#).

"Basic Rate" is with respect to each Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to (a) the greater of (i) the 1-Month CME Term SOFR on the last Business Day of the month that immediately precedes the month in which the interest will accrue and (ii) three and one-half percent (3.50%), plus (b) five and one-quarter percent (5.25%). Notwithstanding the foregoing, (i) in no event shall the Basic Rate for any Term Loan be less than eight and three-quarters percent (8.75%), and (ii) upon the occurrence of a Benchmark Transition Event, Collateral Agent may, in good faith and with reference to the margin above such interest rate in this definition, amend this Agreement to replace the Benchmark with a replacement interest rate and replacement margin above such interest rate that results in a substantially similar interest rate floor and total rate in effect immediately prior to the effectiveness of such replacement interest rate and replacement margin, and any such amendment shall become effective at 5:00 p.m. Eastern time on the third Business Day after Collateral Agent has notified Borrower of such amendment, and (iii) the Basic Rate for the Term Loan for the period from the Effective Date through and including March 31, 2024 shall be ten and fifty-seven hundredths of one percent (10.57%). Any determination, decision or election that may be made by Collateral Agent pursuant hereto will be conclusive and binding absent manifest error and may be made in Collateral Agent's sole discretion (except as set forth above) and without consent from any other party.

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"Benchmark" is, initially, the 1-Month CME Term SOFR; provided, that if a Benchmark Transition Event has occurred with respect to the 1-Month CME Term SOFR or the then-current Benchmark, then "Benchmark" means the applicable replacement rate that has replaced the immediately preceding benchmark rate pursuant to the defined term "Basic Rate".

"Benchmark Transition Event" means the occurrence of one or more of the following events with respect to the then-current Benchmark:

(a) a public statement or publication of information by or on behalf of the administrator for such Benchmark announcing that such Person has ceased or will cease to provide such Benchmark, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Benchmark;

(b) a public statement or publication of information by the regulatory supervisor for the administrator for such Benchmark, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the administrator for such Benchmark, a resolution authority with jurisdiction over the administrator for such Benchmark or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark, which states that the

administrator for such Benchmark has ceased or will cease to provide such Benchmark permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Benchmark; or

(c) a public statement or publication of information by the regulatory supervisor for the administrator for such Benchmark announcing that such Benchmark is no longer representative or in compliance with the International Organization of Securities Commissions Principles for Financial Benchmarks.

"Blocked Person" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Borrower" is defined in the preamble hereof.

"Borrower's Books" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, and state tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

"Capital Lease" means any lease that has been or is required to be, in accordance with GAAP, recorded, classified and accounted for as a capitalized lease or financing lease.

"Capital Lease Obligation" means, as to any Person, any obligation of such Person to pay rent or other amounts under a lease of (or other agreement conveying the right to use) real or personal property, which obligations are required to be classified and accounted for as a Capital Lease on a balance sheet of

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such Person under GAAP and, for purposes of this Agreement, the amount of any such obligation shall be the capitalized amount thereof, determined in accordance with GAAP.

"Cash Equivalents" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an **"Auction Rate Security"**).

"Change of Control" means an event or series of events by which: any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, but excluding any employee benefit plan of such person or its subsidiaries, and any person or entity acting in its capacity as trustee, agent or other fiduciary or administrator of any such plan) becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Securities Exchange Act of 1934, except that a person or group shall be deemed to have "beneficial ownership" of all securities that such person or group has the right to acquire, whether such right is exercisable immediately or only after the passage of time (such right, an "option right")), directly or indirectly, of forty-nine percent (49%) or more of the equity securities of Borrower entitled to vote for members of the board of directors or equivalent governing body of Borrower on a fully-diluted basis (and taking into account all such securities that such "person" or "group" has the right to acquire pursuant to any option right).

"Claims" are defined in Section 12.2.

"CME Term SOFR Administrator" is CME Group Benchmark Administration Limited, as administrator of the forward-looking term SOFR, or any successor administrator.

"CME Term SOFR Administrator's Website" is the website of the CME Group Benchmark Administrator at <http://www.cmegroup.com>, or any successor source.

"Code" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

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"Collateral" is any and all properties, rights and assets of Borrower described on [Exhibit A](#).

"Collateral Account" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

"Collateral Agent" is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

"Commitment Percentage" is set forth in [Schedule 1.1](#), as amended from time to time.

"Commodity Account" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"Communication" is defined in [Section 10](#).

"Compliance Certificate" is that certain certificate in the form attached hereto as [Exhibit C](#).

"Contingent Obligation" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation, in each case, directly or indirectly guaranteed, endorsed or sold with recourse by such Person, or for which such Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"Control Agreement" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

"Copyrights" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"Credit Extension" is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower's benefit.

"Default Rate" is defined in [Section 2.3\(b\)](#).

"Deposit Account" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"Designated Deposit Account" is Borrower's deposit account, account number ending in 5062, maintained with Silicon Valley Bank.

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"Disbursement Letter" is that certain form attached hereto as [Exhibit B](#).

"Division" means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.

"Dollars," "dollars" and "\$" each mean lawful money of the United States. **"Effective Date"** is defined in the preamble of this Agreement.

"Eligible Assignee" is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars (\$5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower's Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form reasonably satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

"Equipment" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"ERISA" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"Event of Default" is defined in [Article 8](#).

"Excluded Accounts" means any Deposit Account that is solely used for purposes of funding payroll, payroll taxes or employee wage and benefit payments, escrow accounts or other fiduciary accounts of such Person maintained solely for such purpose in the ordinary course of business.

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"Final Payment" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to [Section 2.2\(c\)](#) or (d), equal to the original principal amount of such Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

"Final Payment Percentage" is five and one-half percent (5.50%); provided that, if the Amortization Date is extended to July 1, 2029, then the **"Final Payment Percentage"** shall automatically, upon election to extend the Amortization Date, be increased to seven and one-quarter percent (7.25%).

"Funding Date" is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

"GAAP" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

"General Intangibles" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"Good Faith Deposit" is defined in [Section 2.6](#).

"Governmental Approval" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"Guarantor" is any Person providing a Guaranty in favor of Collateral Agent.

"Guaranty" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Indebtedness" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) Capital Lease Obligations, and (d) Contingent Obligations.

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"Indemnified Person" is defined in [Section 12.2](#).

"Insolvency Proceeding" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"Insolvent" means not Solvent.

"Intellectual Property" means all of Borrower's or any Subsidiary's right, title and interest in and to the following:

- (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;
- (c) any and all proprietary source code;
- (d) any and all design rights which may be available to Borrower;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
- (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"Interest-Only Extension Milestone" means Borrower's delivery to Collateral Agent and Lenders of evidence, reasonably satisfactory to Collateral Agent and Lenders in their sole discretion, that Borrower has received approval for its new drug application of PLN-74809 in IPF (Idiopathic Pulmonary Fibrosis).

"Inventory" shall have the meaning given to such term under GAAP.

"Investment" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, or capital contribution to any Person.

"Key Person" is each of Borrower's (i) Chief Executive Officer, who is Bernard Coulie, MD, PhD, as of the Effective Date, (ii) Chief Financial Officer, who is Keith Cummings, MD, MBA, as of the Effective Date, (iii) Chief Business Officer, who is Hans Hull as of the Effective Date and (iv) Chief Medical Officer, who is Eric LeFebvre as of the Effective Date.

"Lender" is any one of the Lenders.

"Lenders" are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"Lenders' Expenses" are all reasonable, documented out-of-pocket audit fees and expenses, costs, and expenses (including reasonable and documented out-of-pocket attorneys' fees and expenses, as well as reasonable and documented out-of-pocket appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or

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Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

"Lien" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"Loan Documents" are, collectively, this Agreement, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the Post Closing Letter, any subordination agreements, any note, or notes or any Guaranty, and any other present or future agreement entered into by any Loan Party for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

"Loan Party" means Borrower and any Guarantor.

"Material Adverse Change" is (a) a material impairment in the perfection or priority of Collateral Agent's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or of Borrower and its Subsidiaries taken as a whole; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"Maturity Date" is (a) March 1, 2029, if the Amortization Date is July 1, 2028; or (b) March 1, 2030, if the Amortization Date is July 1, 2029.

"Minimum Cash Trigger Event" means the occurrence of both (a) the aggregate original principal amount of Term Loans advanced by the Lenders under this Agreement exceeding Thirty Million Dollars (\$30,000,000.00) and (b) Borrower's delivery to Collateral Agent and Lenders of evidence, reasonably satisfactory to Collateral Agent and Lenders in their sole discretion, that PLN-74809 either (i) demonstrates negative Phase 2b or Phase 3 data in IPF (Idiopathic Pulmonary Fibrosis) or (ii) has been issued a complete response letter by the FDA for its IPF (Idiopathic Pulmonary Fibrosis) new drug application submission.

"Obligations" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, or arising from, out of or under, this Agreement and the other Loan Documents, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents.

"OFAC" is the U.S. Department of Treasury Office of Foreign Assets Control.

"OFAC Lists" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Operating Documents" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws

in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

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"Patents" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Payment Date" is the first (1st) calendar day of each calendar month, commencing on May 1, 2024.

"Perfection Certificate" and **"Perfection Certificates"** is defined in Section 5.1.

"Permitted Indebtedness" is:

- (a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;
- (e) Indebtedness consisting of Capital Lease Obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);
- (f) Indebtedness that also constitutes a Permitted Investment;
- (g) Guarantees by any of Borrower's Subsidiaries in respect of Indebtedness of Borrower otherwise permitted hereunder;
- (h) Indebtedness in respect of any cash management services, corporate credit cards, netting services, automatic clearinghouse arrangements, overdraft protections, employee credit card programs and other cash management and similar arrangements in the ordinary course of business and not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate at any time;
- (i) Indebtedness consisting of obligations in respect of performance, bid, appeal and surety bonds and performance and completion guarantees and similar obligations provided by Borrower or any of its Subsidiaries, in each case in the ordinary course of business and not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate at any time;
- (j) Indebtedness incurred by the Borrower or any of its Subsidiaries in respect of letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments issued or created in the ordinary course of business or consistent with past practice and not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate at any time;

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(k) Indebtedness with respect to Equipment rented or purchased in connection with advancing PLN-74809 into pivotal Phase 2b/3 PSC (Primary Sclerosing Cholangitis) clinical trials not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate at any time;

(l) Indebtedness to trade creditors incurred in the ordinary course of business;

(m) other unsecured Indebtedness not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate at any time; and

(n) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (n) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

"Permitted Investments" are:

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date and any modification, replacement, renewal or extension of any such Investment so long as no such modification, renewal or extension thereof increases the amount of such Investment except as otherwise permitted by this definition;

(b) (i) Investments consisting of cash and Cash Equivalents held in Borrower's Collateral Accounts that are maintained in accordance with Section 6.6, and (ii) any other Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent (it being understood and agreed that certain Investment Guidelines of Pliant Therapeutics, Inc., dated as of November 10, 2021, and delivered to the Collateral Agent prior to the Effective Date is approved);

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of, or held in, (i) Excluded Accounts or (ii) other Deposit Accounts or Securities Accounts, but in the case of this clause (ii), only to the extent that Collateral Agent has a perfected security interest in the amounts held in such accounts to the extent required pursuant to the terms of the Loan Documents;

(e) Investments to the extent permitted by Sections 7.1 and 7.4;

(f) Investments (i) by a Loan Party in any other Loan Party, (ii) by any Subsidiary that is not a Loan Party (x) in any other Subsidiary that is not a Loan Party or (y) in a Loan Party and (iii) by a Loan Party in any Subsidiary that is not a Loan Party in an aggregate amount, for purposes of this clause (iii) not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any fiscal year;

(g) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any fiscal year, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any fiscal year; and (iii) non-cash loans and advances to employees, officers, directors, managers and consultants relating to the purchase of equity securities of

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Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's board of directors;

(h) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (i) shall not apply to Investments of Borrower in any Subsidiary;

(j) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support; and

(k) other Investments in an aggregate amount not to exceed Five Hundred Thousand Dollars (\$500,000.00) per fiscal year of Borrower.

"Permitted Licenses" are (A) licenses of over-the-counter software that is commercially available to the public and (B) non-exclusive and exclusive licenses and sublicenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

"Permitted Liens" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on Borrower's Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) Liens securing Indebtedness permitted under clause (e) of the definition of **"Permitted Indebtedness,"** provided that (i) such Liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such Liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

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(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Five Hundred Thousand Dollars (\$500,000.00) (excluding from such cap, however, any location or arrangement to the extent Collateral Agent is a party to bailee waiver with respect to such location or arrangement pursuant to Section 6.11), and which are not delinquent or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the Indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the Indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Sections 8.4 or 8.7;

(j) Liens in favor of customs and revenue authorities arising as a matter of law to secure payments of custom duties in connection with the importation of goods;

(k) Liens on insurance proceeds securing the payment of financed insurance

premiums;

(l) Liens consisting of minor imperfections of title and easements, rights-of-way, covenants, consents, reservations, encroachments, variations and zoning and other similar restrictions, charges, encumbrances or title defects affecting real property which, in the aggregate, do not materially detract from the value of the property subject thereto or materially interfere with the conduct of the business conducted at the property subject to such encumbrance;

(m) deposits to secure the performance of bids, trade contracts and leases (other than Indebtedness), statutory obligations, surety and appeal bonds (other than bonds related to judgments or litigation), performance bonds and other obligations of a like nature, in each case in the ordinary course of business; provided however the aggregate amount of such deposits does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any given time;

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(n) Liens consisting of security deposits in connection with leases, utility services and similar transactions entered into in the ordinary course of business and in an aggregate amount not to exceed Five Hundred Thousand Dollars (\$500,000.00);

(o) Liens consisting of Permitted Licenses; and

(p) tax liens for unpaid property taxes provided that the Indebtedness associated with the same does not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any one time outstanding.

"Person" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Pliant Belgium" means Pliant Therapeutics Belgium BV, a wholly-owned Subsidiary of Borrower organized under the laws of Belgium.

"Post Closing Letter" is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

"Prepayment Fee" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, two percent (2.00%) of the principal amount of the Term Loans prepaid;

(iii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan through and including the third anniversary of the Funding Date of such Term Loan, one percent (1.00%) of the principal amount of the Term Loans prepaid; and

(iv) for a prepayment made after the third anniversary of the Funding Date of such Term Loan and prior to the Maturity Date, no Prepayment Fee shall be applicable.

"Pro Rata Share" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans (or Term Loan Commitments, as applicable) held by such Lender by the aggregate outstanding principal amount of all Term Loans (or all Term Loan Commitments, as applicable).

"Registered Organization" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"Required Lenders" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an **"Original Lender"**) have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100.00%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest

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in its Term Loan, Lenders holding at least sixty six percent (66.00%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"Requirement of Law" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"Responsible Officer" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

"Secured Promissory Note" is defined in [Section 2.4](#).

"Secured Promissory Note Record" is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

"Securities Account" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"Shares" is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower's Subsidiary, in any Subsidiary.

"Solvent" is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

"Subordinated Debt" is indebtedness incurred by any Loan Party subordinated to all Indebtedness of the Loan Parties to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Loan Parties, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

"Subsidiary" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"Term A Loan" is defined in [Section 2.2\(a\)\(ii\)](#) hereof.

"Term B Draw Period" is the period commencing, subject to satisfaction of the conditions set forth in [Section 3.2\(e\)](#) hereof, on October 1, 2025, and ending on the earliest of (i) December 31, 2025 and (ii) the occurrence of an Event of Default (which has not been waived by Collateral Agent and the Required Lenders in writing in their sole discretion); provided, however, that the Term B Draw Period shall not commence if on the proposed Funding Date of any such Term B Loan an Event of Default has occurred (unless and until such Event of Default has been waived by Collateral Agent and the Required Lenders in writing in their sole discretion explicitly for the purposes of the commencement and/or reinstatement of the Term B Draw Period); provided further that, for the avoidance of doubt, such Term B Draw Period shall

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automatically be reinstated with the same force and effect upon the waiver by the Collateral Agent and Required Lenders in writing in their sole discretion of such Event of Default explicitly for the purposes of the commencement and/or reinstatement of the Term B Draw Period.

"Term B Loan" is defined in [Section 2.2\(a\)\(iii\)](#) hereof.

"Term C Draw Period" is the period commencing on the date of the occurrence of the Term C Milestone, and ending on the earliest of (i) the date which is forty-five (45) days after the Term C Milestone is achieved, (ii) June 30, 2026 and (iii) the occurrence of an Event of Default (which has not been waived by Collateral Agent and the Required Lenders in writing in their sole discretion); provided, however, that the Term C Draw Period shall not commence if on the date of the occurrence of either clause (i) or (ii) of the Term C Milestone an Event of Default has occurred (unless and until such Event of Default has been waived by Collateral Agent and the Required Lenders in writing in their sole discretion explicitly for the purposes of the commencement and/or reinstatement of the Term C Draw Period); provided further that, for the avoidance of doubt, such Term C Draw Period shall automatically be reinstated with the same force and effect upon the waiver by the Collateral Agent and Required Lenders in writing in their sole discretion of such Event of Default explicitly for the purposes of the commencement and/or reinstatement of the Term C Draw Period.

"Term C Loan" is defined in Section 2.2(a)(iv), hereof.

"Term C Milestone" means Borrower's delivery to Collateral Agent and Lenders of evidence, reasonably satisfactory to Collateral Agent and Lenders in their sole discretion, that Borrower has achieved positive Phase 2b data of PLN-74809 in IPF (Idiopathic Pulmonary Fibrosis) sufficient to advance it into pivotal Phase 3 clinical trials.

"Term D Loan" is defined in Section 2.2(a)(v), hereof.

"Term Loan" is defined in Section 2.2(a)(v) hereof.

"Term Loan Commitment" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1.

"Term Loan Commitments" means the aggregate amount of such commitments of all Lenders.

"Trademarks" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"Transfer" is defined in Section 7.1.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

PLIANT THERAPEUTICS, INC.

By /s/ Keith Cummings

Name: Keith Cummings, M.D., MBA Title: Chief Financial Officer

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By /s/ Colette H. Featherly

Name: Colette H. Featherly

Its: Senior Vice President

LENDERS:

OXFORD FINANCE FUNDING XIII, LLC

By: Oxford Finance LLC, as servicer

By /s/ Colette H. Featherly

Name: Colette H. Featherly

Its: Senior Vice President

OXFORD FINANCE CREDIT FUND II LP
By: Oxford Finance Advisors, LLC, as manager

By /s/ Colette H. Featherly
Name: Colette H. Featherly
Its: Senior Vice President

OXFORD FINANCE CREDIT FUND III LP
By: Oxford Finance Advisors, LLC, as manager

By /s/ Colette H. Featherly
Name: Colette H. Featherly
Its: Senior Vice President

[Signature Page to Amended and Restated Loan and Security Agreement]

SCHEDULE 1.1

Lenders and Commitments**

Term A Loans		
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$15,500,000.00	51.67%
OXFORD FINANCE CREDIT FUND II LP	\$1,500,000.00	5.00%
OXFORD FINANCE CREDIT FUND III LP	\$3,000,000.00	10.00%
OXFORD FINANCE FUNDING XIII, LLC	\$10,000,000.00	33.33%
TOTAL	\$30,000,000.00	100.00%

Term B Loans		
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$35,000,000.00	100.00%
TOTAL	\$35,000,000.00	100.00%

Term C Loans		
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$35,000,000.00	100.00%
TOTAL	\$35,000,000.00	100.00%

Aggregate (all Term Loans A-C)		
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$85,500,000.00	85.50%
OXFORD FINANCE CREDIT FUND II LP	\$1,500,000.00	1.50%
OXFORD FINANCE CREDIT FUND III LP	\$3,000,000.00	3.00%
OXFORD FINANCE FUNDING XIII, LLC	\$10,000,000.00	10.00%
TOTAL	\$100,000,000.00	100.00%

** If the Term B Draw Period terminates on December 31, 2025 (other than as the result of an Event of Default), up to Fifteen Million Dollars (\$15,000,000) of the remaining amount of the Term B Loan Commitment on December 31, 2025 shall be added to the Term C Loan Commitment (such additional amount, the

"Additional Term C Loan Commitment Amount" effective as of January 1, 2026 on a pro rata basis in accordance with the Commitment Percentage for the Term C Loans.

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EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower's right, title and interest, whether now owned or existing or hereafter acquired or arising, in, to and under the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (excluding any Intellectual Property except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property and if a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) Excluded Accounts; and (iii) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Section 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral."

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property.

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EXHIBIT B

FORM OF DISBURSEMENT LETTER

[DATE]

The undersigned, being the duly elected and acting of PLIANT THERAPEUTICS, INC., a Delaware corporation with offices located at 260 Littlefield Avenue, S San Francisco CA 94080 ("**Borrower**"), does hereby certify, in such capacity and not individually, to **OXFORD FINANCE LLC** ("**Oxford**"), as collateral agent acting on behalf of the Lenders from time to time party to (as defined herein) the Loan Agreement (as defined below) (the "**Collateral Agent**") in connection with that certain Amended and Restated Loan and Security Agreement dated as of March 11, 2024, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement are true and correct in all material respects as of the date hereof; provided, however that such materiality qualifier is not applicable to any representations and warranties that already are qualified or modified by

materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date are true and correct in all material respects as of the date hereof.

2.As of the date hereof, no Event of Default has occurred and is continuing or will result from the Credit Extension.

3.Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.

4.All conditions referred to in Section [3.1/3.2] of the Loan Agreement to the making of the Term Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.

5. No Material Adverse Change has occurred.

6. The undersigned is a Responsible Officer.

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7. The proceeds of the Term [A][B][C] Loan shall be disbursed as follows:

Disbursement from Collateral Agent:

Loan Amount	\$
Plus:	
--Deposit Received	\$
Less:	
--Amendment Fee	(\$)
--Interim Interest	(\$)]
--Lender's Legal Fees	(\$)*

TOTAL TERM [A][B][C] LOAN NET PROCEEDS
FROM Collateral Agent \$

8.The Term [A][B][C] Loan shall amortize in accordance with the Amortization Table attached hereto as Annex 1.

9.The aggregate net proceeds of the Term Loans shall be transferred to the Designated Deposit Account as follows:

Account Name:
Bank Name:
Bank Address:
Account Number:
ABA Number:

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* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.

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Dated as of the date first set forth above.

BORROWER:

PLIANT THERAPEUTICS, INC.

By

Name:

Title:

COLLATERAL AGENT ON BEHALF OF LENDERS:

OXFORD FINANCE LLC

By

Name:

Title:

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[Signature Page to Disbursement Letter]

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ANNEX 1

AMORTIZATION TABLE

(Term [A][B][C] Loan) [see attached]

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EXHIBIT C

Compliance Certificate

TO: OXFORD FINANCE LLC, as Collateral Agent

FROM: PLIANT THERAPEUTICS, INC.

The undersigned authorized officer ("**Officer**") of PLIANT THERAPEUTICS, INC. ("**Borrower**"), hereby certifies, in such capacity and not individually, that in accordance with the terms and conditions of the Amended and Restated Loan and Security Agreement dated March 11, 2024 by and among Borrower, Collateral

Agent, and the Lenders from time to time party thereto (the “**Loan Agreement**,” capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement).

- (a) Borrower is in complete compliance for the period ending with all required covenants under the Loan Documents, except as noted below;
- (b) No Event of Default has occurred and is continuing as of date hereof, except as noted below;
- (c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date for the period described in clause (a) above; **provided, however**, that such materiality qualifier is not applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and **provided, further** that those representations and warranties expressly referring to a specific date are true and correct in all material respects as of such date;
- (d) Borrower, and each of Borrower’s Subsidiaries, has timely filed all (i) required tax returns and reports and timely pay and (ii) foreign, federal, material state, and material local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except as otherwise permitted pursuant to the terms of Section 6.4 of the Loan Agreement.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies, solely, in such capacity and not individually, that the attached financial statements are prepared in accordance with GAAP and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under “Complies” column.

Reporting Covenant	Requirement	Actual	Complies
Quarterly Financial Statements	Within 45 days of first three FQE		Yes/No/N/A

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Annual (CPA Audited) Financial Statements	Within 90 days after FYE		Yes/No/N/A
Annual Financial Projections	Annually (within 30 days of FYE), and when revised within 7 Business Days		Yes/No/N/A
8-K, 10-K and 10-Q Filings	Within 5 Business Days of filing		
Compliance Certificate	Concurrently with quarterly and annual financials		Yes/No/N/A
Month End Account Statements of each Borrower	Total amount of Borrower’s cash and cash equivalents at the last day of the measurement period	\$	
Month End Account Statements of each Subsidiary	Total amount of Borrower’s cash and cash equivalents at the last day of the measurement period	\$	

Deposit and Securities Accounts
(Please list all accounts; attach separate sheet if additional space needed)

Institution Name	Account Number	New Account?		Account Control Agreement in place?	
1)		Yes	No	Yes	No
2)		Yes	No	Yes	No
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3)		Yes	No	Yes	No
4)		Yes	No	Yes	No

Financial Covenants

Covenant	Requirement	Actual	Compliance
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1)	Section 6.10(a) Minimum Cash	\$	\$	Yes	No	N/A
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Other Matters

1)	Has any Key Persons departed since the last Compliance Certificate?	Yes	No
2)	Have there been any Transfers of Collateral or Intellectual Property prohibited by the Loan Agreement?	Yes	No
3)	Have there been any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Five Hundred Thousand Dollars (\$500,000.00) or more or which could reasonably be expected to have a Material Adverse Change?	Yes	No
4)	Have there been any amendments of the Operating Documents of Borrower or any of its Subsidiaries? If Borrower is no longer subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, has there been a material change to the capitalization table of Borrower? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No

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Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

PLIANT THERAPEUTICS, INC.

By Name: Title:

LENDER USE ONLY

Received by:

Date:

Verified by:

Date:

Compliance Status: Yes No

Date:

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SCHEDULE 1**Financial Statements**

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EXHIBIT D**FORM OF SECURED PROMISSORY NOTE
(Term [A][B][C] Loan)**

\$ Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, PLIANT THERAPEUTICS, INC., a Delaware corporation with offices located at 260 Littlefield Avenue, S San Francisco CA 94080 ("**Borrower**") HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") or its registered assigns the principal amount of [] MILLION DOLLARS (\$) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B][C] Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term [A][B][C] Loan, at the rates and in accordance with the terms of the Amended and Restated Loan and Security Agreement dated March 11, 2024 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term [A][B][C] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto as Annex 1 which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B][C] Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2(c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B][C] Loan, interest on the Term [A][B][C] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable and documented out-of-pocket fees and expenses, including, without limitation, reasonable and documented attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due, all in accordance with the Loan Agreement.

THE TERMS OF SECTION 11 (CHOICE OF LAW, VENUE, JURY TRIAL WAIVER AND JUDICIAL REFERENCE) ARE HEREBY INCORPORATED BY REFERENCE, *MUTATIS MUTANDIS*.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and

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stated interest on, this Note may be transferred only if (i) the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation and (ii) such transfer is made in accordance with Section 12.1 of the Loan Agreement. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

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IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

PLIANT THERAPEUTICS, INC.

By

Name:

Title:

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ANNEX 1

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By
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Exhibit 31.1

CERTIFICATION

I, Bernard Coulie, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pliant Therapeutics, 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 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 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 6, 2024 August 7, 2024

/s/ Bernard Coulie
Bernard Coulie, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Keith Cummings, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pliant Therapeutics, 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 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 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 6, 2024 August 7, 2024

/s/ Keith Cummings

Keith Cummings, M.D., MBA
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Bernard Coulie, Chief Executive Officer of Pliant Therapeutics, Inc. (the "Company"), and Keith Cummings, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024 June 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 6, 2024 August 7, 2024

/s/ Bernard Coulie

Bernard Coulie, M.D., Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

/s/ Keith Cummings

Keith Cummings, M.D., MBA

Chief Financial Officer

(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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