

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

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

For the quarterly period ended **September 30, 2020**

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
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 of Securities Registered	Trading Symbol	Name of Each Exchange on which Securities are Registered
Common Stock, par value \$0.0001 per share	PLRX	The Nasdaq Global Select Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" 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 November 7, 2020, the registrant had 35,479,853 shares of common stock, \$0.0001 par value per share, outstanding.

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Pliant Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)

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

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 55,224	\$ 85,807
Short-term investments	238,776	16,966
Accounts receivable	7,131	7,052
Tax credit receivable	83	333
Prepaid expenses and other current assets	6,515	1,742
Total current assets	307,729	111,900
Property and equipment, net	4,144	4,079
Other non-current assets	451	3,085
Total assets	<u>\$ 312,324</u>	<u>\$ 119,064</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 3,140	\$ 1,250
Accrued liabilities (Note 5)	7,886	6,922
Total current liabilities	11,026	8,172
Other long-term liabilities (Note 5)	952	912
Total liabilities	11,978	9,084
Commitments and Contingencies (Note 13)		
Preferred stock, \$0.0001 par value; 10,000,000 shares and 0 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares issued and outstanding at September 30, 2020 and December 31, 2019;	—	—
Series A redeemable convertible preferred stock, \$0.0001 par value; 0 and 56,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 and 56,000,000 shares issued and outstanding, at September 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$62,468 at September 30, 2020 and December 31, 2019, respectively;	—	62,468
Series B redeemable convertible preferred stock, \$0.0001 par value; 0 shares and 49,501,221 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 49,501,221 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$75,860 at September 30, 2020 and December 31, 2019, respectively;	—	75,860
Series C redeemable convertible preferred stock, \$0.0001 par value; 0 shares and 44,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 26,360,745 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$47,947 at September 30, 2020 and December 31, 2019, respectively;	—	47,947
Stockholders' equity (deficit)		
Common stock, \$0.0001 par value; 300,000,000 and 181,000,000 shares authorized at September 30, 2020 and December 31, 2019; and 35,465,715 and 1,846,024 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively;	3	1
Additional paid-in capital	399,162	—
Accumulated deficit	(98,801)	(76,295)
Accumulated other comprehensive loss	(18)	(1)
Total stockholders' equity (deficit)	300,346	(76,295)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 312,324</u>	<u>\$ 119,064</u>

* The condensed balance sheet as of December 31, 2019 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue — related party	\$ 4,814	\$ —	\$ 37,352	\$ —
Operating expenses:				
Research and development	(16,884)	(10,779)	(48,339)	(35,626)
General and administrative	(4,591)	(2,583)	(11,642)	(7,827)
Total operating expenses	(21,475)	(13,362)	(59,981)	(43,453)
Loss from operations	(16,661)	(13,362)	(22,629)	(43,453)
Interest income	72	148	392	701
Other income (expense), net	55	(41)	(269)	(48)
Net loss	\$ (16,534)	\$ (13,255)	\$ (22,506)	\$ (42,800)
Accretion to redemption value and cumulative dividends on redeemable convertible preferred stock	—	(1,375)	—	(4,078)
Net loss attributable to common stockholders	\$ (16,534)	\$ (14,630)	\$ (22,506)	\$ (46,878)
Net loss per share, attributable to common stockholders:				
Basic	\$ (0.47)	\$ (8.53)	\$ (1.36)	\$ (30.03)
Diluted	\$ (0.47)	\$ (8.53)	\$ (1.36)	\$ (30.03)
Shares used in computing net loss per share attributable to common stockholders:				
Basic	35,445,504	1,714,285	16,592,746	1,561,242
Diluted	35,445,504	1,714,285	16,592,746	1,561,242
Comprehensive loss:				
Net loss	\$ (16,534)	\$ (13,255)	\$ (22,506)	\$ (42,800)
Net unrealized gain (loss) on short-term investments	\$ 12	\$ (10)	\$ (17)	\$ 1
Total other comprehensive income (loss)	12	(10)	(17)	1
Comprehensive loss	\$ (16,522)	\$ (13,265)	\$ (22,523)	\$ (42,799)

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

Pliant Therapeutics, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)

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

	Redeemable Convertible Preferred Stock						Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Series A		Series B		Series C		Shares	Amount				
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	56,000,000	\$ 62,468	49,501,221	\$ 75,860	26,360,745	\$ 47,947	1,846,024	\$ 1	\$ —	\$ (1)	\$ (76,295)	\$ (76,295)
Issuance of Series C redeemable preferred stock, net of issuance costs of \$167	—	—	—	—	28,527,313	52,038	—	—	—	—	—	—
Vesting of founders' common stock and restricted stock awards	—	—	—	—	—	—	52,093	—	4	—	—	4
Option exercises	—	—	—	—	—	—	8,252	—	26	—	—	26
Stock-based compensation expense	—	—	—	—	—	—	—	—	425	—	—	425
Net unrealized gain on short-term investments	—	—	—	—	—	—	—	—	—	60	—	60
Net income	—	—	—	—	—	—	—	—	—	—	11,029	11,029
Balance at March 31, 2020	56,000,000	\$ 62,468	49,501,221	\$ 75,860	54,888,058	\$ 99,985	1,906,349 *	\$ 1	\$ 455	\$ 59	\$ (65,266)	\$ (64,751)
Issuance of common stock upon initial public offering, net of issuance costs	—	—	—	—	—	—	10,350,000	1	148,399	—	—	148,400
Issuance of common stock upon private placement	—	—	—	—	—	—	625,000	—	10,000	—	—	10,000
Vesting of founders' common stock and restricted stock awards	—	—	—	—	—	—	40,102	—	1	—	—	1
Option exercises	—	—	—	—	—	—	73,719	—	177	—	—	177
Conversion of Series A, B, C convertible preferred stock to common stock	(56,000,000)	(62,468)	(49,501,221)	(75,860)	(54,888,058)	(99,985)	22,432,029	1	238,292	—	—	238,293
Stock-based compensation expense	—	—	—	—	—	—	—	—	786	—	—	786
Net unrealized loss on short-term investments	—	—	—	—	—	—	—	—	—	(89)	—	(89)
Net loss	—	—	—	—	—	—	—	—	—	—	(17,001)	(17,001)
Balance, June 30, 2020	—	\$ —	—	\$ —	—	\$ —	35,427,199	\$ 3	\$ 398,110	\$ (30)	\$ (82,267)	\$ 315,816
Additional issuance costs related to initial public offering	—	—	—	—	—	—	—	—	(123)	—	—	(123)
Vesting of founders' common stock and restricted stock awards	—	—	—	—	—	—	38,058	—	3	—	—	3
Option exercises	—	—	—	—	—	—	458	—	3	—	—	3
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,169	—	—	1,169
Net unrealized gain on short-term investments	—	—	—	—	—	—	—	—	—	12	—	12
Net loss	—	—	—	—	—	—	—	—	—	—	(16,534)	(16,534)
Balance, September 30, 2020	—	\$ —	—	\$ —	—	\$ —	35,465,715	\$ 3	\$ 399,162	\$ (18)	\$ (98,801)	\$ 300,346

* Common stock share amounts do not add up due to rounding.

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

Pliant Therapeutics, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)

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

	Redeemable Convertible Preferred Stock						Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Total Stockholders' Deficit
	Series A		Series B		Series C		Shares	Amount				
	Shares	Amount	Shares	Amount	Shares	Amount						
Balance at December 31, 2018	56,000,000	\$ 61,516	49,501,221	\$ 70,587	—	\$ —	1,363,000	\$ 1	\$ —	\$ —	\$ (71,470)	\$ (71,469)
Vesting of founders' common stock and restricted stock awards	—	—	—	—	—	—	126,057	—	8	—	—	8
Accretion to redemption value and cumulative dividends on redeemable convertible preferred stock	—	—	—	1,344	—	—	—	—	(320)	—	(1,024)	(1,344)
Stock-based compensation expense	—	—	—	—	—	—	—	—	312	—	—	312
Net unrealized gain on short-term investments	—	—	—	—	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	—	—	—	—	(14,023)	(14,023)
Balance at March 31, 2019	56,000,000	\$ 61,516	49,501,221	\$ 71,931	—	\$ —	1,489,057	\$ 1	\$ —	\$ 3	\$ (86,517)	\$ (86,513)
Vesting of founders' common stock and restricted stock awards	—	—	—	—	—	—	139,363	—	9	—	—	9
Option exercises	—	—	—	—	—	—	21,940	—	132	—	—	132
Accretion to redemption value and cumulative dividends on redeemable convertible preferred stock	—	—	—	1,359	—	—	—	—	(647)	—	(712)	(1,359)
Stock-based compensation expense	—	—	—	—	—	—	—	—	506	—	—	506
Net unrealized gains on short-term investments	—	—	—	—	—	—	—	—	—	8	—	8
Net loss	—	—	—	—	—	—	—	—	—	—	(15,522)	(15,522)
Balance at June 30, 2019	56,000,000	\$ 61,516	49,501,221	\$ 73,290	—	\$ —	1,650,360	\$ 1	\$ —	\$ 11	\$ (102,751)	\$ (102,739)
Vesting of founders' common stock and restricted stock awards	—	—	—	—	—	—	116,865	—	7	—	—	7
Option exercises	—	—	—	—	—	—	6,774	—	14	—	—	14
Accretion to redemption value and cumulative dividends on redeemable convertible preferred stock	—	—	—	1,375	—	—	—	—	(501)	—	(874)	(1,375)
Stock-based compensation expense	—	—	—	—	—	—	—	—	480	—	—	480
Net unrealized loss on short-term investments	—	—	—	—	—	—	—	—	—	(10)	—	(10)
Net loss	—	—	—	—	—	—	—	—	—	—	(13,255)	(13,255)
Balance at September 30, 2019	<u>56,000,000</u>	<u>\$ 61,516</u>	<u>49,501,221</u>	<u>\$ 74,665</u>	<u>—</u>	<u>\$ —</u>	<u>1,773,999</u>	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ 1</u>	<u>\$ (116,880)</u>	<u>\$ (116,878)</u>

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

Pliant Therapeutics, Inc.
Condensed Statements of Cash Flows
(Unaudited)

(In thousands)	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (22,506)	\$ (42,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	963	823
Stock-based compensation expense	2,380	1,298
Changes in operating assets and liabilities:		
Tax credit receivable	250	(20)
Accounts receivable	(79)	—
Prepaid expenses and other current assets	(4,774)	(1,321)
Other non-current assets	(70)	(88)
Accounts payable	1,826	212
Accrued liabilities	1,228	2,357
Other long-term liabilities	(4)	45
Net cash used in operating activities	(20,786)	(39,494)
Cash flows from investing activities		
Purchase of short-term investments	(267,818)	(34,751)
Maturity of short-term investments	45,997	27,023
Accretion of short-term investments	(6)	(242)
Purchase of property and equipment	(945)	(780)
Net cash used in investing activities	(222,772)	(8,750)
Cash flows from financing activities		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs	150,751	—
Proceeds from issuance of common stock upon completion of private placement	10,000	—
Proceeds from issuance of Series C preferred stock, net of issuance costs	52,019	—
Proceeds from exercise of stock options	205	—
Proceeds from issuance of restricted common stock	—	146
Payment of deferred offering costs	—	(1,438)
Net cash provided by/(used) in financing activities	212,975	(1,292)
Net decrease in cash and cash equivalents	(30,583)	(49,536)
Cash and cash equivalents at beginning of period	85,807	60,949
Cash and cash equivalents at end of period	\$ 55,224	\$ 11,413
Supplemental disclosures of noncash investing and financing activities:		
Purchase of property and equipment in accounts payable and accrued liabilities	\$ 242	\$ —
Reclassification of restricted stock awards from liabilities to common stock upon vesting	\$ 9	\$ 24
Accretion to redemption value and cumulative dividends on redeemable convertible preferred stock	\$ —	\$ 4,078
Deferred offering costs in accounts payable and accrued liabilities	\$ —	\$ 1,152
Net unrealized (loss) gain on short-term investments	\$ (17)	\$ 1

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”) is a clinical 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.

Reverse Stock Split

On May 22, 2020, the Company implemented a 1-for-7.15 reverse stock split of the Company’s common stock. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. All share and per share data shown in the accompanying financial statements and related notes have been retroactively revised to reflect the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company’s Preferred Stock were proportionately reduced and the respective conversion prices were proportionately increased. As of June 3, 2020, all outstanding preferred stock have been converted into common stock.

Initial Public Offering

On June 3, 2019, the Company’s registration statement on Form S-1 was declared effective by the United States Securities and Exchange Commission (“SEC”), for its initial public offering (“IPO”) of its common stock. The Company’s shares of common stock started trading on the Nasdaq Select Global Market on June 3, 2020 and the transaction closed on June 5, 2020. In connection with the IPO, the Company sold an aggregate of 10,350,000 shares of common stock, which included 9,000,000 shares of common stock and 1,350,000 shares of common stock sold pursuant to the underwriters’ exercise of their option to purchase additional shares, at a public offering price of \$16.00 per share. The aggregate net proceeds received by the Company from the offering were \$148.3 million, net of underwriting discounts, commissions and offering expenses of \$5.7 million, of which \$2.6 million were paid in 2019 and \$3.1 million paid in the current year. Upon the closing of the IPO, 160,389,279 shares of the Company’s outstanding convertible preferred stock were automatically converted to common stock on a 7.15:1 basis and the related carrying amount of \$238.3 million was reclassified to common stock and additional paid-in capital within stockholders’ equity (deficit).

Concurrent with the completion of the IPO, the Company also issued 625,000 shares of its common stock to Novartis (“Novartis”), a strategic partner and existing stockholder of the Company, in a private placement at a price of \$16.00 per share for proceeds of \$10.0 million, which resulted in Novartis owning approximately 6.1% of the Company’s outstanding shares of common stock (Note 6).

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

The accompanying condensed balance sheet as of September 30, 2020, condensed statements of operations and comprehensive loss, condensed statements of cash flows, and the condensed statements of redeemable convertible preferred stock and stockholders’ equity (deficit) for the three and nine months ended September 30, 2020 and 2019, are unaudited. The balance sheet as of December 31, 2019 was derived from audited financial statements as of and for the year ended December 31, 2019. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements as of and for the year ended December 31, 2019, and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company’s financial position as of September 30, 2020, and the results of its operations and its cash flows for the three and nine months ended September 30, 2020 and 2019. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2020 and 2019, are also unaudited.

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, useful lives assigned to property and equipment, the fair values of common and redeemable convertible preferred stock, stock-based compensation expense, accruals 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.

Revenue Recognition

The Company accounts for its total revenue under Accounting Standards Update or ASU, ASU 2014-09, Topic 606 *Revenue from Contracts with Customers* (“Topic 606”), which was adopted by the Company using the full retrospective transition method. ASU 2014-09 provides a single, comprehensive revenue recognition model for all contracts with customers. This standard contains principles for the determination of the measurement of revenue and the timing of when such revenue is recognized. Revenue recognition will reflect the transfer of goods or services to customers at an amount that is expected to be earned in exchange for those goods or services. Subsequently, the FASB has issued the following guidance to amend ASU 2014-09: ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*; ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*; ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*; ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*; and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606*, which clarifies narrow aspects of Topic 606 or corrects unintended application of the guidance. The Company adopted ASU No. 2015-14, ASU No. 2016-08, ASU No. 2016-10, ASU No. 2016-12, and ASU No. 2016-20 with ASU No. 2014-09, which are referred to collectively as the “Topic 606”.

The FASB issued ASU No. 2018-18, “Collaborative Arrangements (Topic 808)” issued in November 2018. The Company assessed and concluded that they are not under Topic 808 and as the Novartis Agreement is not considered a collaboration under its provisions.

To date all revenue has been generated from the Company’s Collaboration and License Agreement with Novartis (the “Novartis Agreement”).

The Company’s revenue is generated solely from the Novartis Agreement. The Company’s licensing agreement includes upfront signing fees, cost reimbursements, research and development services, milestone payments and royalties on future licensee’s product sales. The Company has both fixed and variable consideration. Non-refundable upfront fees are considered fixed, while funding of research and development activities and milestone payments are identified as variable consideration. A contract liability is an obligation to transfer goods or services for which the Company has received consideration, or for which an amount of consideration is due from the customer. A contract asset is a right to consideration in exchange for goods or services that the Company has transferred to a customer when that right is conditional on something other than the passage of time. A receivable will be recorded on the balance sheet when the Company has unconditional rights to consideration (i.e., only the passage of time is required before payment becomes due). Receivables cannot be netted against contract liabilities and are presented separately from contract assets. Contract assets and contract liabilities are netted at the contract level and are then aggregated and presented separately each reporting period.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the contract with a customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. The Company’s performance obligations include providing the worldwide license rights to compound PLN-1474, provide research and development services for PLN-1474 through Phase 1 of its development and provide research and development services on initial candidate targets, which services are combined with a non-exclusive license to the initial candidate targets. The Company concluded that the worldwide license was distinct because the customer can benefit from the license on its own or together with other resources that are readily available, and the research and development services are not transformative in nature. The Company concluded the research and development services on initial candidate targets were not distinct from a non-exclusive license for the initial candidate targets, primarily as a result of (i) Pliant being unable to benefit on its own or together with other resources that are readily available as the license and (ii) the research and development services, including manufacturing in support of such services, were expected to significantly modify the initial license. Therefore, the promised goods and services were considered a single performance obligation. Significant management judgment is required in the identification of performance obligations and to determine the level of effort required under an arrangement and the period over which the Company expects to complete our performance obligations under the arrangement. If the Company cannot reasonably estimate when the performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. The Company estimates the transaction price and records revenue in the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, we re-evaluate the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. The estimated period of performance and project costs are reviewed quarterly and adjusted, as needed, to reflect the Company’s current assumptions regarding the timing of our deliverables.

As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The Company has never sold the performance obligations separately; therefore, an observable stand-alone selling price does not exist. Accordingly, the Company estimates a stand-alone selling price through maximizing the use of observable inputs such as market data, project cost estimates, and targeted margins. The Company determined that each of the performance obligations is priced and delivered at the stand-alone selling price. Therefore, no reallocations are needed since there is no material right and the license and services are provided at the stand-alone selling price.

During the three and nine months ended September 30, 2020, the entirety of the Company's revenue—related party is related to the Collaboration and License Agreement with Novartis. The Company did not have any prior revenue agreements and did not recognize revenue during the three and nine months ended September 30, 2019. Receivables from collaborations are typically unsecured and are concentrated in the biopharmaceutical industry. Accordingly, the Company may be exposed to credit risk generally associated with biopharmaceutical companies or specific to the Novartis Agreement. An allowance on the receivables will be recorded if circumstances indicate collection is doubtful for a particular receivables balance. To date, the Company has not experienced any losses related to these receivables.

Fair Value Measurements

The Company defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities which are required to be recorded at fair value, the Company considers the principal or most advantageous market in which to transact and the market-based risk. Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. The carrying amount of the Company's financial instruments, including cash and cash equivalents, short-term investments, tax credit receivable, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short-term maturities.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, short-term investments and accounts receivable. The Company invests in money market funds, treasury bill and notes, government notes and corporate debt securities. The Company limits its credit risk associated with its cash and cash equivalents by placing them with banks and institutions it believes are highly credit worthy and in highly rated investments. The Company performs credit evaluations of its customer, and the risk with respect to accounts receivable is further mitigated by the short duration of customer payment terms, generally within 60 days, and the pedigree of the customer base. During the three and nine months ended September 30, 2020, Novartis accounted for 100% of the Company's revenue—related party and accounts receivable.

The Company's future results of operations involve several other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's product candidates, uncertainty of market acceptance of the Company's product candidates, competition from substitute products, including those that may be developed or marketed by larger companies, securing and protecting intellectual property, strategic relationships and dependence on key individuals and sole source suppliers.

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

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing novel therapies for fibrotic diseases. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in the United States of America.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in Money Market Funds, United States ("U.S.") treasury securities, U.S. government agency securities and corporate debt securities and are stated at fair value.

Short-Term Investments

The Company's short-term investments consist of U.S. Treasury securities, U.S. government agency securities and corporate debt securities with remaining 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. As of September 30, 2020 and December 31, 2019, all of the Company's short-term investments were classified as available-for-sale and were carried at fair market value with unrealized losses or income recorded in "other comprehensive income and loss" ("OCI") in the statements of operations and comprehensive loss. See Note 3 for further details.

Short-term investments are considered impaired when a decline in fair value is judged to be other-than-temporary. The Company consults with its investment managers and considers available quantitative and qualitative evidence in evaluating potential impairment of its short-term investments on a quarterly basis. If the cost of an individual investment exceeds its fair value, the Company evaluates, among other factors, general market conditions, the duration and extent to which the fair value is less than cost and its intent and ability to hold the investment. Once a decline in fair value is determined to be other-than-temporary, an impairment charge will be recorded to other expense, net, in the statements of operations and comprehensive loss and a new cost basis in the short-term investment will be established. As of September 30, 2020, the Company had not recorded any impairment related to other-than-temporary declines in the fair value of short-term investments.

Property and Equipment, Net

Property and equipment are recorded at cost net of accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. The useful lives of property and equipment are as follows:

Laboratory equipment	5 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Upon retirement or sale of the assets, the cost and related accumulated depreciation and amortization are removed from the balance sheets and the resulting gain or loss is recorded to the statements of operations and comprehensive loss. Repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There was no impairment of long-lived assets during the three and nine months ended September 30, 2020 and 2019.

Redeemable Convertible Preferred Stock

All preferred stock was automatically converted into common stock upon the Company's IPO in June 2020. Prior to this conversion, the Company classified redeemable convertible preferred stock outside of stockholders' equity (deficit) because, upon the occurrence of certain change in control events that were outside the Company's control, including liquidation, sale or transfer of the Company's assets, holders of the redeemable convertible preferred stock could have caused redemption for cash. At any time on or after December 19, 2024, the holders of a majority of the outstanding redeemable convertible preferred stock could also have required the Company to redeem the redeemable convertible preferred stock by providing the Company a written notice requesting such redemption. The Company recognized changes in the redemption value immediately as they occurred, for example changes in fair value of preferred stock, and adjustments in the carrying amount of the redeemable convertible preferred stock to equal the redemption value at the end of each reporting period up through December 19, 2019, when the Company entered into the Series C Preferred Stock Purchase Agreement. See Note 9 for further details. In the absence of retained earnings these accretion charges were recorded against additional paid in capital, if any, and then to accumulated deficit. The Company analyzed all embedded derivatives and beneficial conversion features for its redeemable convertible preferred stock and concluded that none required bifurcation.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of personnel costs for the Company's research and product development employees. Also included are non-personnel costs such as fees paid to consultants and third parties for preclinical and clinical studies, research and development services, laboratory supplies and equipment maintenance costs, license costs, contract manufacturing costs and allocations of facility related costs.

The Company estimates preclinical and clinical studies and research expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical and clinical studies and research services on its behalf. The Company estimates these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and are expensed as services are rendered.

Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred.

Tax Credit Receivable

The Company was eligible for federal and California research and development credits for its research and development activities performed within the United States and California, respectively. The Company was eligible to apply up to \$250,000 of the federal R&D credits to offset the Federal Insurance Contribution Act ("FICA") portion of its payroll taxes each year prior to fiscal year 2019. Starting in the fourth quarter of 2019, the Company was no longer eligible to apply its federal R&D credits to offset its FICA taxes as it generated revenue in excess of \$5 million of gross receipts during that year. The Company, however, is still eligible for future federal research and development credits for its research and development activities performed within the United States and California.

Stock-Based Compensation

The Company's stock-based equity awards include restricted stock awards, stock options and shares that will be issued under the Company's 2020 Employee Stock Purchase Plan ("ESPP"). Stock-based compensation for awards that are granted to employees is accounted at fair value on the award grant date and the expense is recognized over the period the employee is required to provide service in exchange for the award, which is generally on a straight-line basis over the vesting period of the award. The expense is recorded in either research and development or general and administrative expenses in the statements of operations and comprehensive loss based on the function to which the related services are provided. Forfeitures are accounted for as they occur.

The Black-Scholes option-pricing model, used to estimate fair value of stock-based awards, requires the use of the following assumptions:

- *Expected term*—The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for the Company's stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or simplified method. The expected term for the ESPP is the offering period.
- *Expected volatility*—Prior to the Company being public, the Company did not have any trading history for its common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their size, stage in the life cycle or area of specialty. As the Company went public in June 2020, we will continue to apply this process for stock options and ESPP awards until enough historical information regarding the volatility of its stock price becomes available.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected dividend*—The Company has never paid dividends on the common stock and has no plans to pay dividends on the common stock. Therefore, the Company used an expected dividend yield of zero.

Prior to our IPO, the fair value of our common stock has been determined using independent third-party valuations based on relevant valuation methodologies as outlined in the American Institute of Certified Public Accountants (AICPA) Practice Aid, "*Valuation of Privately-Held-Company Equity Securities Issued as Compensation*". The Company also considered the amount of time between the independent third-party valuation dates and the grant dates and used interpolation of the fair value between the two valuation dates to estimate common stock fair value at each grant date. This determination included an evaluation of whether the subsequent valuation indicated that any significant change in valuation had occurred between the previous valuation and the grant date. Following our IPO, we use our stock price traded on NASDAQ to determine its fair value.

Deferred Offering Costs

Deferred offering costs, consisting of direct legal, accounting, filing and other fees directly related to the Company's IPO were capitalized and reclassified to additional paid in capital upon completion of the IPO in June 2020. As of December 31, 2019, \$2.7 million in deferred offering costs were recorded as other non-current assets in the Balance Sheets.

Leases and Rent Expense

The Company records rent expense on a straight-line basis over the life of the lease. In cases where there is a free rent period or future fixed rent escalations, the Company records a deferred rent liability. Additionally, the receipt of any lease incentives is recorded as a deferred rent liability which is amortized over the lease term as a reduction of rent expense. Building improvements made with the lease incentives or tenant allowances are capitalized as leasehold improvements and included in property and equipment, net in the Balance Sheets.

Income Taxes

The Company provides for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax basis of assets and liabilities and net operating loss and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all the tax benefits will not be realized.

The Company accounts for uncertain tax positions in accordance with ASC No. 740-10, *Accounting for Uncertainty in Income Taxes*. The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

The Company includes any penalties and interest expense related to income taxes as a component of income tax expense, as necessary.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the three and nine months ended September 30, 2020, the Company had a \$12,000 net unrealized gain and a \$17,000 net unrealized loss, respectively, on short-term investments. For the three and nine months ended September 30, 2019, the Company had a \$10,000 net unrealized loss and a \$1,000 net unrealized gain, respectively, on short-term investments.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss attributed to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock.

Prior to the conversion of our preferred stock in our IPO, net loss or income per share attributable to common stockholders was calculated using the two-class method, which is based on an earnings allocation formula that determines net loss or income per share for the Company's common stockholders and holders of participating securities. The holders of preferred stock were entitled to receive dividends prior and in preference to any declaration or payment of any dividend on the common stock. Under this method, net loss or income is increased or reduced by the amount of any dividends earned and accretion of redeemable convertible preferred stock to its redemption value, if any, during the period. The undistributed earnings are allocated to common stock and each series of redeemable convertible preferred stock to the extent that each preferred security may share in the earnings as if all of the earnings for the period had been distributed. Net loss or income attributable to common stockholders and participating preferred shares are allocated to each share on an as-converted basis as if all the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded. Diluted net loss or income per share is computed using the more dilutive of (a) the two-class method or (b) the as-converted method. The Company allocated earnings first to redeemable convertible preferred shares stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of shares of common stock included in the computation of diluted net loss or income gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and preferred stock.

Common stock equivalent shares are excluded from the computation of diluted net loss or income per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is antidilutive. The Company reported a net loss attributable to common stockholders for the three and nine months ended September 30, 2020 and 2019.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) No. 2016-02, *Leases (“Topic 842”)*, which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. For public entities, ASU No. 2016-02 is effective for fiscal years beginning after December 15, 2018. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU No. 2016-02 is effective for the Company in the fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022, with early adoption permitted. The Company is currently in the process of evaluating the impact of the adoption of ASU No. 2016-02 on the Company’s financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The new standard amends guidance on measuring and reporting credit losses for financial assets held at amortized cost basis, including accounts receivable and investments classified as available for sale, such as our debt securities. This ASU requires a new forward-looking model based on expected credit losses rather than the current one based on incurred losses. In November 2019, the FASB issued ASU 2019-10, which deferred the effective date for certain ASUs including ASU 2016-13. This standard is effective for the Company’s fiscal year beginning after December 15, 2022. Early adoption is permitted for all entities. The Company is currently in the process of evaluating the impact of the adoption of ASU 2016-13 on the Company’s financial statements.

In December 2019, the FASB issued Accounting Standards Update 2019-12 (“ASU 2019-12”), *Income Taxes (topic 740): Simplifying the Accounting for Income Taxes*. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 removes the exception for intraperiod tax allocations when there is a loss from continuing operations and income or a gain from other items (other comprehensive income). ASU 2019-12 is effective beginning on January 1, 2021. Early adoption of the amendments is permitted. The Company has early adopted the new standard effective January 1, 2020, and its adoption did not have a material impact on our condensed financial statements.

3. Financial Instruments

The Company’s short-term investments consist of U.S. Treasury securities, U.S. Government agency securities and corporate debt securities with remaining 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 losses or income recognized in other comprehensive income (loss).

Assets and liabilities recorded at fair value on a recurring basis in the Balance Sheets and assets and liabilities measured at fair value on a non-recurring basis or disclosed at fair value, are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

- *Level 1*—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;
- *Level 2*—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- *Level 3*—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company's cash equivalent Money Market Funds are classified as Level 1 because they are valued using quoted 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, 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. These Level 2 instruments require more management judgment and subjectivity compared to Level 1 instruments which include determining which instruments are most similar to the instrument being priced, determining whether the market is active and determining which model-derived valuations are to be used when calculating fair value. The Company performs its analysis with the assistance of investment advisors.

The following tables show the Company's cash and cash equivalents, Money Market Funds and short-term investments by significant investment category as of September 30, 2020 and December 31, 2019 (in thousands):

	As of September 30, 2020			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value
Level 1:				
Money Market Funds	\$ 20,292	\$ —	\$ —	\$ 20,292
Level 2:				
U.S. Treasury securities included in short-term investments	101,106	5	—	101,111
U.S. government agency securities included in cash and cash equivalents and short-term investments	66,998	6	(2)	67,002
Corporate debt securities included in cash and cash equivalents and short-term investments	85,338	0	(27)	85,311
Total financial assets	\$ 273,734	\$ 11	\$ (29)	\$ 273,716
	As of December 31, 2019			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value
Level 1:				
Money Market Funds	\$ 16,366	\$ —	\$ —	\$ 16,366
Level 2:				
U.S. Treasury securities included in short-term investments	2,998	—	—	2,998
U.S. government agency securities included in short-term investments	34,204	1	(2)	34,203
Total financial assets	\$ 53,568	\$ 1	\$ (2)	\$ 53,567

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 September 30, 2020 and December 31, 2019. There have been no transfers between fair value measurement levels during the nine months ended September 30, 2020 and 2019. In addition, there were no assets or liabilities measured at fair value on a non-recurring basis as of September 30, 2020 and December 31, 2019.

As of September 30, 2020, the Company had not recorded any impairment related to other-than-temporary declines in the fair value of short-term investments. Short-term investments are considered impaired when a decline in fair value is judged to be other-than-temporary. The Company consults with its investment managers and considers available quantitative and qualitative evidence in evaluating potential impairment of its short-term investments on a quarterly basis. If the cost of an individual investment exceeds its fair value, the Company evaluates, among other factors, general market conditions, the duration and extent to which the fair value is less than cost and its intent and ability to hold the investment.

The Company records interest income and accretion income earned on Money Market Funds and U.S. Treasury, U.S. government agency and corporate debt securities to interest income in its statement of operations and comprehensive loss.

4. Property and Equipment, net

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

	As of September 30, 2020	As of December 31, 2019
Computer equipment and software	\$ 22	\$ 22
Laboratory equipment	6,251	5,580
Leasehold improvements	701	657
Construction-in-progress	320	8
Total property and equipment, gross	7,294	6,267
Less: Accumulated depreciation	(3,150)	(2,188)
Total property and equipment, net	<u>\$ 4,144</u>	<u>\$ 4,079</u>

Depreciation expense for the three months ended September 30, 2020 and 2019 was \$0.3 million. Depreciation expense for the nine months ended September 30, 2020 and 2019 was \$1.0 million and \$0.8 million, respectively.

5. Accrued Liabilities and Other Long-Term Liabilities

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	As of September 30, 2020	As of December 31, 2019
Accrued compensation and benefits	\$ 2,889	\$ 2,971
Accrued research and development expenses	3,970	2,624
Other accrued liabilities	1,014	1,263
Deferred rent	13	64
Total accrued liabilities	<u>\$ 7,886</u>	<u>\$ 6,922</u>

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

Other Long-Term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	As of September 30, 2020	As of December 31, 2019
Deferred rent	\$ 565	\$ 458
Leasehold incentive obligation	384	444
Other liabilities — deposits	3	10
Total other long-term liabilities	<u>\$ 952</u>	<u>\$ 912</u>

6. Novartis Agreement

In October 2019, the Company entered into a Collaboration and License Agreement with Novartis (the “Novartis Agreement”), for the development and commercialization of our preclinical product candidate, PLN-1474 and up to three additional integrin research targets. PLN-1474 is an internally discovered small molecule selective inhibitor of integrin $\alpha_v\beta_1$, currently being developed for the treatment of liver fibrosis associated with nonalcoholic steatohepatitis (“NASH”). In accordance with the Novartis Agreement, on December 7, 2019, Novartis paid to Pliant an upfront non-refundable license fee of \$50.0 million for the worldwide exclusive license to PLN-1474.

Novartis will fund the Company’s research and development services for PLN-1474 through Phase 1 after which Novartis will assume responsibility for all future development, manufacturing and commercialization costs of PLN-1474. Novartis will also fund the research and development services associated with integrin research targets as outlined in the Novartis Agreement. The Company is scheduled to receive up to \$19.6 million in funding for PLN-1474 development services through Phase 1 of its development, which is expected to go through 2020. The Company is initially obligated to perform research and development services on the integrin research targets for sixty days. Novartis has the option to continue the research and development services through 2022, with the option to terminate the services with 60 days’ notice. If any of the targets achieves target validation and are deemed a research target, Novartis holds the rights to exercise its license options to obtain

an exclusive license for those deemed research targets on a research target-by-research target basis by paying an option exercise fee for each target (up to three in total), including all license compounds that are the subject of the applicable research program. Novartis will also pay the Company a certain specified target validation fee of \$4.0 million for each candidate target that achieves target validation and is deemed a research target, for up to three candidate targets. Upon exercise of an option, Novartis will be responsible for global clinical development and commercialization of each licensed research target.

Under the Novartis Agreement, the Company is eligible for developmental, regulatory and commercial milestone payments related to PLN-1474 and the integrin research targets of up to \$416.0 million if defined development and commercialization milestones are achieved and tiered royalties ranging from the mid-single digits to low teens on product sales upon commercialization.

Upon execution of the Novartis Agreement, Pliant also entered into a Financing Side Letter with Novartis (the “Financing Side Letter”), whereby Novartis committed to provide up to \$30.0 million in equity financing of which \$20.0 million was satisfied by the issuance of 10,928,962 shares of Series C Redeemable Convertible Preferred Stock on December 19, 2019 and the remaining \$10.0 million was satisfied by the issuance of shares of common stock through a concurrent private placement with the Company’s IPO. The Company determined that the Novartis Agreement and the Financing Side Letter are separate agreements and should not be combined as they were not entered into for a single commercial objective and the consideration in each agreement are tied to separate and different types of obligations. The Series C Redeemable Preferred Stock was issued to Novartis at fair value of \$1.83 per share in conjunction with its issuance to other investors at the same price. In addition, the contingent issuance of shares upon an Initial Public Offering would also be at fair value. Further, Novartis became a related party to the Company following its purchase of 10.9 million shares of our Series C Redeemable Convertible Stock on December 19, 2019, representing holdings of 6.1% and 7.4% of our outstanding shares of common stock on a fully diluted basis as of September 30, 2020 and December 31, 2019, respectively. See Notes 9 and 14 to these financial statements for additional information.

The Company evaluated the Novartis Agreement under the revenue standard Topic 606 and concluded that Novartis is a customer. The Company identified the following performance obligations at the inception of the contract.

- Provide Novartis worldwide license rights to PLN-1474.
- Provide research and development services for PLN-1474 through Phase 1 of its development.
- Provide non-exclusive license rights to integrin research targets and research and development services on integrin research targets, together as a single performance obligation.

The Company determined the transaction price at inception of the Novartis Agreement is the \$69.6 million consisting of the license fee of \$50.0 million and research and development funding of \$19.6 million payment to be allocated to the various performance obligations. The Novartis Agreement includes variable consideration for the funding of research and development services and potential future milestones and royalties that were contingent on future success factors for development programs. The Company used the “most likely” method to determine the variable consideration. None of the regulatory or development milestones were included in the transaction price. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

The Company considered the license to PLN-1474 as functional intellectual property, as when control of the license was transferred to Novartis at the inception of the Novartis Agreement, Novartis had the right to access its technology and it was functional. The Company determined the \$50.0 million was the standalone selling price PLN-1474 license and was recognized as revenue when control of the license transferred to Novartis, which was at or near inception of the Novartis Agreement.

The Company estimated the standalone selling price of each research program based on internal and external costs to perform the research plus a reasonable profit margin. The total estimated cost of the research and development services reflects the nature of the services to be performed and the Company’s best estimate of the length of time required to perform the services. The Company selected an input method of costs incurred to measure progress toward complete satisfaction of its performance obligation to provide research and development services as such method faithfully depicts the Company’s performance in transferring control of the research and development service to Novartis. Changes in estimates of total internal and external costs expected to be incurred are recognized in the period of change as a cumulative catch-up adjustment. There have been no changes to the Company’s estimates to date.

During the three and nine months ended September 30, 2020, the Company recognized revenue—related party of \$4.8 million and \$37.4 million, respectively. Revenue-related party for the three months ended September 30, 2020 consists of \$4.8 million generated from research and development services performed during the period. Revenue-related party for the nine months ended September 30, 2020, consists of \$25.0 million of revenue from the achievement of the first patient dosing milestone of the Novartis agreement in the first quarter of 2020 and \$12.4 million of revenue generated from research and development services performed during the nine months ended September 30, 2020. The Company recognized no revenue during the three and nine months ended September 30, 2019.

As of September 30, 2020 and December 31, 2019, there is a receivable of \$7.1 million related to the Novartis Agreement. There were no contract assets or contract liabilities as of September 30, 2020 and December 31, 2019.

7. License Agreements

UC Regents

In August 2015, the Company entered into an exclusive, worldwide license agreement (the “UC Agreement”) with the Regents of the University of California (the “UC Regents”) relating to the use of certain patents and technology relating to $\alpha_v\beta_1$ compound in fibrosis indications. Pursuant to the UC Agreement, the Company is obligated to (i) make a non-refundable upfront license fee payment of \$0.4 million and annual license maintenance fee payments of \$10,000 per year beginning on the first anniversary of the UC Agreement escalating to \$25,000 per year thereafter (ii) make royalty payments to the UC Regents of 3% of net sales of a therapeutic licensed product or 1% of net sales of a method of use licensed product, subject to an annual minimum of \$1.0 million, (iii) make milestone payments up to an aggregate of \$18.2 million to the UC Regents upon the occurrence of certain events, (iv) make a milestone payment based on the number of outstanding shares and a price per share as defined in the UC Agreement within 30 days of the closing of an IPO or change of control, and (v) reimburse the UC Regents for prosecution and maintenance expenses of the licensed patents without limitation. As a result of the IPO on June 3, 2020, the Company made a \$2.4 million milestone payment to the UC Regents. The Company will expense any payments for milestones to research and development expenses prior to receiving FDA approval for any of its product candidates. These costs will be capitalized when FDA approval is obtained for any products being selected for commercialization and amortized over the remaining life of the patent. If the Company sublicenses its rights under the UC Agreement, it is obligated to pay the UC Regents a percentage of the total gross proceeds received in consideration of the grant of the sublicense, which total amount would be first reduced by the aggregate amount of certain research and development related expense incurred by the Company.

The UC Agreement can be terminated at any time upon the material breach of contract terms by either party to the agreement. The Company has the right to terminate the agreement at any time upon providing written notice to the UC Regents. Unless terminated early, the UC Agreement will remain in effect from the effective date until the later of (i) the expiration or abandonment of the patent rights licensed under the UC Agreement, or (ii) ten years from the date of the first commercial sale of the first licensed product under the agreement.

8. Research Agreement

Adimab Development and Option Agreement

In October 2018, the Company and Adimab LLC (“Adimab”) entered into a development and option agreement (the “Adimab Agreement”) for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Agreement, the Company will select biological targets against which Adimab will use its proprietary platform technology to research and develop antibody proteins using a mutually agreed upon research plan.

Upon the Company’s selection of a target, the Company and Adimab will initiate a research plan and the discovery term begins. During the discovery term, Adimab will grant the Company a non-exclusive, non-sublicensable license under its technology with respect to the target, to research, design and preclinically develop and use antibodies that were modified or derived using Adimab technology, solely to evaluate such antibodies, perform the Company’s responsibilities under the research plan and use such antibodies for certain diagnostic purposes. The Company will also grant to Adimab a non-exclusive, non-sublicensable and non-transferable license with respect to the target under the Company’s technology that covers or relates to such target, solely to perform its responsibilities under the research plan during the discovery period. The Company is required to pay Adimab at an agreed upon rate for its full-time employees during the discovery period while Adimab performs research on each target under the applicable research plan.

Adimab granted the Company an exclusive option to obtain a worldwide, royalty-bearing, sublicensable license under Adimab platform patents and other Adimab technology to research, develop and commercialize up to twenty-four antibodies selected by the Company (the “Program Antibodies”) against specific biological targets (the “Commercialization Option”). Upon the exercise of a Commercialization Option, and payment of the applicable option fee to Adimab, Adimab will assign the patents that cover the Program Antibodies to Company. The Company will be required to use commercially reasonable efforts to develop, seek market approval of, and commercialize at least one antibody against the target covered by the Commercialization Option in specified markets upon the exercise of a Commercialization Option.

Pursuant to the Adimab Agreement, the Company is obligated to (i) make a nonrefundable upfront license fee payment for access to Adimab’s technology; (ii) pay Adimab at an agreed upon rate for each full-time employee (“FTE”) during the research period; (iii) make additional payments upon the Company making other research related elections; (iv) pay up to a dollar amount in the low double digit millions for the achievement of certain research and development milestones for each research target program which can vary by target type; (v) make royalty payments to Adimab on Company net sales of its products covered under the Adimab Agreement, subject to varying royalty payments on certain product types. Currently, no product types have been selected by the Company.

During the three and nine months ended September 30, 2020, the Company recognized research and development expenses under the Adimab Agreement of \$0.1 million related to FTE costs.

During the three and nine months ended September 30, 2019, the Company recognized research and development expense under the Adimab Agreement of nil and \$0.4 million, respectively, related to antibody discovery fees and FTE costs.

9. Redeemable Convertible Preferred Stock

Under the Company's Amended and Restated Certificate of Incorporation ("Certificate of Incorporation"), the Company is authorized to issue two classes of shares: preferred 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. As a result of the IPO in June 2020, in which all convertible preferred stock was converted into common shares of the Company, there was no outstanding redeemable convertible preferred stock as of September 30, 2020. The following is a summary of the Company's redeemable convertible preferred stock as of December 31, 2019 (in thousands except share amounts):

	Preferred Shares Authorized	Shares Issued and Outstanding	Redemption Value/ Liquidation Preference	Carrying Value
Series A	56,000,000	56,000,000	\$ 62,468	\$ 62,468
Series B	49,501,221	49,501,221	75,860	75,860
Series C	44,000,000	26,360,745	47,947	47,947
	<u>149,501,221</u>	<u>131,861,966</u>	<u>\$ 186,275</u>	<u>\$ 186,275</u>

Series A Preferred

In August 2015, the Company entered into a Series A Preferred Stock Purchase Agreement (the "Series A Purchase Agreement") pursuant to which it agreed to sell, and the purchasers agreed to purchase up to \$45.0 million of Series A Redeemable Convertible Preferred Stock ("Series A Preferred") in three anticipated tranches based on the achievement of defined performance milestones. The Series A Preferred stockholders may not assign the rights to purchase shares of Series A Preferred at any future milestone closing tranches separately without a transfer of already purchased shares. The Company determined that these future tranche obligations did not meet the definition of a freestanding financial instrument because, while separately exercisable, they were not legally detachable. Further, the Company determined that the embedded future tranche obligation did not require bifurcation for accounting purposes as it was clearly and closely related to the economic characteristics and risks of the Series A Preferred and would not meet the definition of a derivative on a standalone basis.

Under the Series A Purchase Agreement, as part of the initial closing, the Company issued 6.5 million shares of Series A Preferred at \$1.00 per share in exchange for cash proceeds of \$6.4 million and the conversion of convertible promissory notes in the amount of \$0.1 million representing outstanding principal and accrued interest.

In April 2016, the Company issued 5.0 million shares of Series A Preferred at \$1.00 per share in exchange for cash proceeds of \$5.0 million in an additional closing of the first tranche. The final closing of the first tranche occurred in September of 2016, when the Company issued 5.0 million additional shares of Series A Preferred at \$1.00 per share in exchange for cash proceeds of \$5.0 million.

In February 2017, the Company issued 8.0 million shares of Series A Preferred at \$1.00 per share in exchange for cash proceeds of \$8.0 million in a closing of the second tranche.

In July 2017, the Company issued 12.0 million shares of Series A Preferred at \$1.00 per share in exchange for cash proceeds of \$12.0 million in an initial closing of the third tranche.

In January 2018, the Company issued 8.5 million shares of Series A Preferred at \$1.00 per share in exchange for cash proceeds of \$8.5 million in an additional closing of the third tranche.

In March 2018, based on the amendment to the Series A Purchase Agreement, the Company issued 11.0 million additional shares of Series A Preferred at \$1.00 per share in exchange for cash proceeds of \$11.0 million in the final closing of the third tranche.

Series B Preferred

In July 2018, the Company entered into a Series B Preferred Stock Purchase Agreement (the "Series B Purchase Agreement") in which it agreed to sell, and the purchasers agreed to purchase, up to \$70.0 million of Series B Redeemable Convertible Preferred Stock ("Series B Preferred"). Under the Series B Purchase Agreement, the Company initially issued 45.1 million shares of Series B Preferred at \$1.3767 per share in exchange for cash proceeds of approximately \$62.1 million.

In November 2018, the Company issued 4.4 million additional shares of Series B Preferred at \$1.3767 per share in exchange for cash proceeds of approximately \$6.0 million.

Series C Preferred

In December 2019, the Company entered into a Series C Preferred Stock Purchase Agreement (the “Series C Purchase Agreement”) in which it agreed to sell, and the purchasers agreed to purchase, up to \$80.5 million of Series C Redeemable Convertible Preferred Stock (“Series C Preferred”). Under the Series C Purchase Agreement, the Company initially issued 26.4 million shares of Series C Preferred at \$1.83 per share in exchange for aggregate cash proceeds of \$48.2 million. Novartis purchased 10.9 million shares of this allotment of Series C Preferred at \$1.83 per share for cash proceeds of \$20.0 million. Novartis became a related party following its purchase of 10.9 million shares of our Series C Preferred. Novartis holdings represent of 6.1% and 7.4% of our outstanding shares of common stock on a fully diluted basis as of September 30, 2020 and December 31, 2019, respectively. See Note 14 for additional information.

In February 2020, the Company issued an additional 28.5 million additional shares of Series C Preferred at \$1.83 per share in exchange for gross cash proceeds of \$52.2 million and incurred \$0.2 of issuance costs.

The Series A Preferred, Series B Preferred and Series C Preferred (collectively, the “Preferred Stock”) had the following rights and privileges:

Voting

Each holder of shares of Preferred Stock were entitled to the number of votes equal to the number of shares of common stock into which such shares could have been converted and had voting rights and powers equal to the voting rights and powers of the common stock, and except as provided by law or by other provisions of the Company’s Certificate of Incorporation, as amended, could have voted together with the common stock as a single class on an as-converted basis on all matters as to which holders of common stock have the right to vote.

The holders of Series A Preferred, voting separately as a single class, were entitled to elect two members of the Company’s board of directors. At any time when at least 12.5 million shares of Series B Preferred were outstanding, the holders of Series B Preferred were entitled to elect one member of the Company’s board of directors. The holders of shares of common stock, voting separately as a single class, were entitled to elect one member of the Company’s board of directors. All remaining members of the Company’s board of directors were elected by the holders of the common stock and Preferred Stock voting together as a single class.

Conversion

Shares of the Preferred Stock were convertible at any time at the option of the holder into such number of shares as is determined by dividing the original issuance price by the conversion price in effect at the time. The conversion price was the original issuance price for each series of Preferred Stock, as adjusted for the 1-for-7.15 reverse stock split of the Common Stock. Following such adjustment, the per-share conversion price was \$7.15 for Series A Preferred, \$9.843405 for Series B Preferred and \$13.0845 for Series C Preferred, subject to certain adjustments.

All outstanding shares of Preferred Stock converted to shares of common stock upon the completion of the Company’s IPO.

Dividends

The holders of Series A Preferred were originally entitled to receive cumulative dividends from their respective dates of issuance at the rate of 8.0% on their original issue price. In July 2018, in conjunction with the execution of the Series B Purchase Agreement, the Series A Preferred accreted dividends were cancelled.

Under the Series B Purchase Agreement, the holders of both shares of Series A and Series B Preferred were entitled to receive cumulative dividends commencing on July 10, 2018, the issuance date of Series B Preferred, at an annual rate of 8.0% on their original issuance price. The Series A Preferred and Series B Preferred dividends accrue from day-to-day, whether declared or not, and were payable only when and if declared by the Company’s board of directors. As such, the Company recorded accretion charges to adjust the carrying values of the Series A Preferred and Series B Preferred to their redemption values up until the date the Series C Purchase Agreement was executed. In December 2019, in conjunction with the execution of the Series C Purchase agreement, the Series A preferred and Series B preferred accreted dividends were cancelled.

Under the Series C Purchase Agreement, the holders of Series A, Series B and Series C Preferred were entitled to receive non-cumulative dividends commencing on December 19, 2019 at an annual rate of 8.0% on their original issuance price. The Series A, Series B and Series C Preferred dividends accrue from day-to-day, whether declared or not, and were payable only when and if declared by the Company's board of directors. Since inception, the Company has never declared or paid any dividends.

Liquidation Preferences

The holders of all shares of preferred stock were entitled to receive dividends prior and in preference to any declaration or payment of any dividend on the common stock.

Upon liquidation, dissolution, or winding up of the Company or a deemed liquidation event as defined in the Company's Certificate of Incorporation, the holders of shares of Series C and Series B Preferred Stock were entitled to receive, on a pari passu basis, a per share amount equal to the Series C purchase price of \$1.83 (plus any declared but unpaid dividends) and equal to the original Series B purchase of \$1.3767 (plus any declared but unpaid dividends), collectively (the "Series C and Series B Liquidation Preference") or such amount per share as would have been payable had all shares of Series C and Series B been converted into common stock immediately prior to such liquidation event. The payment of Series C and Series B Liquidation Preference was to be made before any payment made to the holders of Series A Preferred Stock and Common Stock. Thereafter, the Series A Preferred holders were entitled to receive their liquidation preference before any distributions were made to common stockholders, a per share amount equal to \$1.00 (plus any declared but unpaid dividends) (the "Series A Liquidation Preference") or such amount per share as would have been payable had all shares of Series A had been converted into common stock immediately prior to such liquidation event. After payments of the full liquidation preferences of the Series C and Series B Liquidation Preference and the Series A Liquidation Preference described above, any remaining assets of the Company would have been distributed to the holders of the common stock in proportion to the number of shares of common stock that they held.

Redemption

The Series A Preferred were redeemable at any time on or after five years from August 19, 2015, the original issuance date of the 6.5 million shares of Series A Preferred, upon receipt of a written notice from the holders of a majority of the shares of Series A Preferred. The initial redemption price was the greater of (i) the Series A Preferred original issuance price per share, plus any accrued and unpaid dividends, whether or not declared by the board of directors, and (ii) the fair market value of Series A Preferred as mutually agreed upon by the Company and the holders of a majority of the shares of Series A Preferred then outstanding.

In July 2018, in conjunction with the execution of the Series B Preferred Purchase Agreement, the Series A Preferred redemption provision was amended as follows:

All outstanding shares of Preferred Stock shall be redeemed by the Company at a price equal to the original issuance price per share, plus any accrued and unpaid dividends, whether or not declared, together with any other dividends declared but unpaid in three annual installments commencing not more than sixty (60) days after receipt by the Company at any time on or after five years from the Series B Preferred original issuance date, July 10, 2018, a written notice from the holders of a majority of the shares of Preferred Stock.

The Company accounted for the changes in Series A Preferred redemption provision as a modification as there was no significant difference in Series A Preferred fair value before and after the modification.

In December 2019, in conjunction with the execution of the Series C Preferred Purchase Agreement, the Series A Preferred and Series B Preferred redemption provisions were modified as follows:

All outstanding shares of Preferred Stock shall be redeemed by the Company at a price equal to the original issuance price per share, plus any dividends declared but unpaid, in three annual installments commencing not more than sixty (60) days after receipt by the Company at any time on or after five years from the Series C Preferred original issuance date, December 19, 2019, a written notice from the holders of a majority of the shares of Preferred Stock.

The Company accounted for the changes in Series A Preferred redemption and Series B Preferred redemption provisions as a modification as there was no significant difference in Series A Preferred and Series B Preferred fair values before and after the modification.

10. Common Stock

The voting, dividend, and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers, and preferences of the holders of the Preferred Stock. As of September 30, 2020 and December 31, 2019, the Company had 300,000,000 and 181,000,000 authorized shares of common stock, respectively, 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 the Preferred Stock have been paid in accordance with their terms. No dividends have been declared or paid by the Company since its inception.

Liquidation

After payment of the respective liquidation preferences to the holders of shares of Preferred Stock, 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 or upon occurrence of a deemed liquidation event.

Shares reserved for future issuance

	As of September 30, 2020	As of December 31, 2019
Conversion of redeemable convertible preferred stock	—	18,442,233
Exercises of outstanding stock option awards	2,808,477	1,337,501
Shares of common stock available for future grants under the 2015 Equity Incentive Plan, as amended	—	567,110
Shares of common stock available for future grants under the 2020 Equity Incentive Plan	3,907,999	—
Shares of common stock available for future issuance under the 2020 ESPP	700,000	—
Total shares reserved for future issuance	<u>7,416,476</u>	<u>20,346,844</u>

Founders' Common Stock Awards

During 2015, the Company's board of directors granted common stock awards to the Company's founders in exchange for services provided to the Company. The purchase price of the common stock awards was the estimated fair value at the issuance date. The shares vest from one to four years and vesting could be accelerated upon a change in control. The vesting of certain performance-based grants of restricted stock awards were contingent upon the filing of an Investigational New Drug Application by the Company with the FDA.

If the holder of founders' common stock award terminates their relationship with the Company during the vesting period, the Company may repurchase any unvested restricted common stock held by these individuals at their original purchase price. During the vesting term, holders of founders' common stock awards are deemed to be common stockholders and have dividend and voting rights. The Company issued 745,244 shares of founders' common stock during 2015. No founders' common stock awards were granted in subsequent years. Total compensation expense was \$25,000 for these founders' common stock awards, which are recorded to operating expenses in the statements of operations over their respective vesting period. As of September 30, 2020 and December 31, 2019, all shares of founders' common stock awards were fully vested.

11. Equity Incentive Plans and Stock-Based Compensation

In May 2020, the board of directors adopted the 2020 Stock Options and Incentive Plan, (the "2020 Plan"), which 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 for the purchase of up to 4.2 million shares of the Company's common stock. In addition, to the extent that awards outstanding under the 2020 Plan or the 2015 Plan are cancelled, forfeited or held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the registrant prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) subsequent to May 2020, the shares of common stock reserved for issuance pursuant to such awards will become available for issuance as shares of common stock under the 2020 Plan. The 2020 Plan provides that an additional number of shares will automatically be added to the shares authorized for issuance under the 2020 Plan 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 administrator of the 2020 Plan, which is the compensation committee of the board of directors. As of September 30, 2020, 3.9 million shares remained available for issuance under the 2020 Plan.

Options under the 2020 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 10.0% shareholder shall not be less than 110.0% of the estimated 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.

In August 2015, the board of directors adopted the 2015 Equity Incentive Plan, as amended (the "2015 Plan"), which provides 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 for the purchase of up to 1.5 million shares of the Company's common stock. In July 2018, the 2015 Plan was amended to increase the number of shares reserved thereunder by 1.0 million shares. In January 2019, the Company's board of directors and stockholders voted to increase the number of shares reserved for issuance under the 2015 Equity Incentive Plan by 0.4 million shares. In March 2020, the Company's board of directors and stockholders voted to increase the number of shares reserved for issuance under the 2015 Plan by 1.4 million shares. In May 2020, the board of directors voted to adopt the 2020 Plan and not to issue any further grants under the 2015 Plan. As of September 30, 2020, 2.5 million shares remained available for issuance upon the exercise of previously granted stock options under the 2015 Plan.

Prior to the adoption of the 2020 Plan, options under the 2015 Plan could be granted for periods of up to 10 years and at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that the exercise price of an incentive stock option granted to a 10.0% shareholder could not be less than 110.0% of the estimated fair value of the shares on the date of grant and the option was not exercisable after the expiration of five years from the date of grant.

Restricted Common Stock Awards

The Company granted restricted stock awards under the 2015 Plan. The purchase price of the restricted common stock awards was the estimated fair value as determined by the board of directors at the issuance date. The shares vest from one to four years and vesting could be accelerated upon a change in control. A holder of an award may pay a total purchase price or a part of the purchase price for granted shares at any time during the vesting periods. Upon termination of employment, the Company has the right to repurchase any unvested restricted shares. The repurchase price for unvested shares of common stock will be the lower of (i) the fair market value on the date of repurchase or (ii) their original purchase price. During the vesting term, holders of restricted stock awards are deemed to be a common stock shareholder and have dividends and voting rights.

The Company accounted for restricted stock awards as early exercised options and recognized a liability in other liabilities when cash was received for the purchase of shares of restricted stock. As shares of restricted stock vested, the Company reclassified the liability to common stock and additional paid in capital. As of September 30, 2020 and December 31, 2019, the Company recorded a liability included in accrued expenses and other liabilities of \$13,000 and \$22,000, respectively.

There have been no grants of restricted stock awards granted for the nine months ended September 30, 2020 and 2019.

The following table summarizes restricted stock activity during the nine months ended September 30, 2020:

	Number of Shares	Weighted- Average Grant Date fair value
Outstanding and unvested, as of December 31, 2019	302,211	\$ 1.51
Issued	—	\$ —
Vested	(130,257)	\$ 1.24
Repurchases	(12,121)	\$ 1.22
Outstanding and unvested, as of September 30, 2020	159,833	\$ 1.79

The following table summarizes restricted stock activity during the nine months ended September 30, 2019:

	Number of Shares	Weighted- Average Grant Date fair value
Outstanding and unvested, as of December 31, 2018	703,188	\$ 1.22
Issued	—	\$ —
Vested	(335,610)	\$ 1.01
Exercised	363	\$ 2.15
Repurchases	(7,051)	\$ 2.01
Outstanding and unvested, as of September 30, 2019	360,890	\$ 1.43

Restricted stock awards of 4,195 shares with a weighted-average grant date fair value of \$0.08 per share, were not purchased by the award holders as of September 30, 2020. As these shares of the restricted common stock awards were not issued, they are not included in the table above.

The aggregate fair value of restricted stock awards vested during the nine months ended September 30, 2020 and 2019 was \$161,000 and \$336,000, respectively. Total intrinsic value of outstanding unvested restricted stock awards as of September 30, 2020 and December 31, 2019 was \$3.6 million and \$3.3 million, respectively.

Incentive Stock Options and Nonqualified Stock Options

Stock options issued under either the 2015 Plan or the 2020 Plan generally vest over a four-year period 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Expected volatility	72.39% - 74.79%	81.10%	72.10% - 77.50%	78.50% - 82.55%
Risk-free interest rate	0.27% - 0.38%	1.43%	0.27% - 0.82%	1.43% - 2.59%
Expected dividend	—	—	—	—
Expected term (in years)	5.26 - 6.08	5.83 - 6.06	5.26 - 6.75	5.00 - 6.08
Underlying common stock fair value	21.54 - 24.64	7.08	6.22 - 24.64	5.15 - 7.08

The Company granted 292,001 stock options under the 2020 Plan during the three months ended September 30, 2020.

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
Outstanding as of December 31, 2019	1,337,501	\$ 3.22	9.18	\$ 5,157
Granted	1,567,198	\$ 9.26		
Exercised	(82,454)	\$ 2.49		
Forfeited	(13,768)	\$ 5.67		
Outstanding as of September 30, 2020	2,808,477	\$ 6.60	9.05	\$ 45,033
Exercisable as of September 30, 2020	629,988	\$ 4.02	8.60	\$ 11,750
Vested and expected to vest as of September 30, 2020	2,808,477	\$ 6.60	9.05	\$ 45,033

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	113,174	\$ 2.08	9.77	\$ 348
Granted	1,220,104	\$ 3.08		
Exercised	(28,714)	\$ 5.08		
Forfeited	(4,458)	\$ 2.08		
Outstanding as of September 30, 2019	1,300,106	\$ 2.94	9.37	\$ 5,385
Exercisable as of September 30, 2019	118,835	\$ 2.15	9.30	\$ 585
Vested and expected to vest as of September 30, 2019	1,300,106	\$ 2.94	9.37	\$ 5,385

Aggregate intrinsic value represents the difference between the fair value of the underlying common stock and the exercise price as of September 30, 2020 and December 31, 2019. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2020 and 2019, was \$5.14 per share and \$4.37 per share, respectively.

In March 2020 the Company granted 26,573 stock options with a grant date fair value of \$0.1 million to a partner at Third Rock Ventures, who is also serving as a non-employee director on the Company's Board of Directors. The common shares subject to these options

vest 1/12th on the last day of each calendar quarter over a three-year period and commenced vesting upon the Company's IPO in June 2020. Lastly, in order to vest at each calendar quarter end date, the shareholder must be providing continuous service to the Company through such vesting date. The stock-based compensation expense related to these options was immaterial during the three and nine months ended September 30, 2020. See Note 14 for additional information.

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 nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Restricted stock awards and founders' common stock awards	\$ 51	\$ 118	\$ 160	\$ 262
Stock options and ESPP	1,118	362	2,220	1,036
Total stock-based compensation expense	\$ 1,169	\$ 480	\$ 2,380	\$ 1,298
Research and development expenses	\$ 564	\$ 198	\$ 1,015	\$ 423
General and administrative expenses	\$ 605	\$ 282	\$ 1,365	\$ 875

As of September 30, 2020, there was \$0.3 million of unrecognized compensation costs that is expected to be recognized over the weighted-average periods of 1.46 years related to restricted stock awards. As of September 30, 2020, there was \$11.4 million of unrecognized compensation costs that is expected to be recognized over the weighted-average periods of 2.68 years related to stock options.

2020 Employee Stock Purchase Plan

In June 2020, the Company adopted the 2020 ESPP. The Company reserved 700,000 shares of common stock for future issuance under the plan. 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.

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 \$0.2 million in stock-based compensation expense for the three and nine months ended September 30, 2020. There was no stock-based compensation expense attributed to the 2020 ESPP for the three and nine months ended September 30, 2019 as the 2020 ESPP was adopted in 2020. As of September 30, 2020, no shares of common stock were issued 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Risk-free interest rate	0.11%	—	0.11%	—
Expected term of options (in years)	0.58	—	0.58	—
Expected stock price volatility	83.72%	—	83.72%	—
Expected dividends	—	—	—	—

12. Income Taxes

For the three and nine months ended September 30, 2020 and 2019, 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 no items that are either estimated or discrete items would impact the tax provision.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was enacted and signed into law and GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. The CARES Act includes changes to the tax provisions that benefits business entities, and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act. The tax relief measures for businesses include a five-year net operating loss carryback, suspension of annual deduction limitation of 80% of taxable income from net operating losses generated in a tax year beginning after December 31, 2017 through December 31, 2020, changes the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. The CARES Act also provides other non-tax benefits to assist those impacted by the pandemic. The Company evaluated the impact of the CARES Act and determined that its adoption did not have a material impact to the income tax provision for the three and nine months ended September 30, 2020.

13. Commitments and Contingencies

Purchase Commitments

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

License and Collaboration Agreements

Potential payments related to the Company's license and research agreements, including milestone and royalty payments, are detailed in Notes 6 and 7.

Leases

In February 2018, the Company entered into a non-cancelable lease agreement (the "Lease") for premises consisting of approximately 32,974 square feet located in South San Francisco, California (the "Premises"). The Company moved into the Premises in July 2018. The Premises is being used for the Company's corporate headquarters and principal operating facility. The term of the Lease is eighty-four months, which commenced on July 1, 2018. Base rent was abated for the first two months of the lease term and thereafter is \$0.2 million per month during the first year of the lease term, with specified annual increases thereafter. The Company paid a refundable security deposit of approximately \$0.4 million, which is included in other non-current assets in the Balance Sheets at September 30, 2020 and December 31, 2019. The Company has the right to extend the lease term by seven years upon written notice not more than twelve months nor less than nine months prior to the expiration of the original lease term, with monthly payments equal to the "fair rental value" as defined in the Lease.

During the three months ended September 30, 2020 and 2019, rent expense, including common area maintenance expense, was \$0.6 million. For the nine months ended September 30, 2020 and 2019 rent expense was \$1.9 million.

Future minimum lease payments under the Lease as of September 30, 2020 were as follows (in thousands):

<u>Year ending December 31:</u>	<u>Operating Lease</u>
2020 (remainder of the year)	\$ 498
2021	2,027
2022	2,098
2023	2,171
2024 and beyond	3,390
Total	<u>\$ 10,184</u>

Legal Proceedings

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by us is required to determine both probability and the estimated amount. Management is currently not aware of any legal matters that could have a material adverse effect on our financial position, results of operations or cash flows.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

14. Related Party Transactions

In 2019, certain employees of Third Rock Ventures, a stockholder of the Company, provided consulting services to the Company. Commencing January 2020, Third Rock Ventures ceased providing management consulting services to the Company. The Company recorded no consulting expenses for consulting services provided by Third Rock Ventures during the three and nine months ended September 30, 2020. The Company recorded Third Rock Ventures consulting expenses to general and administrative expense of \$6,000 and \$32,000, respectively for the three and nine months ended September 30, 2019.

In March 2020, the Company granted 26,573 stock options with a grant date fair value of \$0.1 million to a partner at Third Rock Ventures, who is also serving as a non-employee director on the Company's Board of Directors. The common shares subject to these options vest 1/12th on the last day of each calendar quarter over a three-year period and commenced vesting upon our IPO. Lastly, in order to vest at each calendar quarter end date, the shareholder must be providing continuous service to the Company through such vesting date. See Note 11 for additional information.

From time to time, the Company makes charitable contributions to the University of California, San Francisco Foundation (the "UCSF Foundation"), which are directed to support research performed in the laboratories of two of the Company's scientific founders. The Company made no charitable contributions to the UCSF Foundation during the three months ended September 30, 2020 and 2019. The Company made charitable contributions to the UCSF Foundation in the amount of \$0.7 million and \$0.4 million during the nine months ended September 30, 2020 and 2019, respectively.

In October 2019, the Company entered into the Novartis Agreement with Novartis covering the development and commercialization of Pliant's preclinical product candidate, PLN-1474 and up to three additional targets. Upon execution of the Agreement, Pliant also entered into a financing side letter with Novartis, whereby Novartis committed to provide up to \$30.0 million in equity financing of which \$20.0 million was provided for preferred shares as a part of a Series C equity offering and the remaining \$10.0 million was completed in a private placement for common shares upon the Company's IPO. As of September 30, 2020 and December 31, 2019, Novartis owned approximately 6.1% and 7.4 %, respectively, of our outstanding shares of common stock on a fully diluted basis. See Notes 6 and Note 9 for additional information.

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 \$0.1 million for the three months ended September 30, 2020 and 2019, and \$0.3 million and \$0.2 million for the nine months ended September 30, 2020 and 2019, 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:

	Nine Months Ended September 30,	
	2020	2019
Redeemable convertible preferred stock (on an as-converted basis)	—	14,755,415
Options to purchase common stock	2,808,477	1,304,302
Restricted stock awards granted and not purchased	4,195	4,195
Unvested restricted shares	159,833	360,890
Total	2,972,505	16,424,802

A reconciliation of the numerator and denominator used in the calculation of the basic and diluted net loss per share attributable to common stockholders is as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss per share:				
Numerator				
Net loss	\$ (16,534)	\$ (13,255)	\$ (22,506)	\$ (42,800)
Add: accretion to redemption value and cumulative dividends on redeemable convertible preferred shares	—	(1,375)	—	(4,078)
Net loss attributable to common stockholders	<u>\$ (16,534)</u>	<u>\$ (14,630)</u>	<u>\$ (22,506)</u>	<u>\$ (46,878)</u>
Denominator				
Weighted-average common shares outstanding used to calculate net loss per share attributable to common stockholders:				
Basic	35,445,504	1,714,285	16,592,746	1,561,242
Diluted	<u>35,445,504</u>	<u>1,714,285</u>	<u>16,592,746</u>	<u>1,561,242</u>
Net loss per share attributable to common stockholders:				
Basic	<u>\$ (0.47)</u>	<u>\$ (8.53)</u>	<u>\$ (1.36)</u>	<u>\$ (30.03)</u>
Diluted	<u>\$ (0.47)</u>	<u>\$ (8.53)</u>	<u>\$ (1.36)</u>	<u>\$ (30.03)</u>

17. Subsequent Events

The Company has evaluated subsequent events for financial statement purposes occurring through November 10, 2020, the date these financial statements were issued.

The following discussion and analysis should be read in conjunction with the audited consolidated financial statements and notes for the year ended December 31, 2019, included in the Company's final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on June 3, 2020 (the "Prospectus"), the Quarterly Report for the second quarter of 2020 filed with the SEC on Form 10-Q on August 11, 2020 and other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. 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 below. 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 Quarterly Report on Form 10-Q, 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 clinical stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis. 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, PLN-74809, is an oral small-molecule dual selective inhibitor of $\alpha_v\beta_6$ and $\alpha_v\beta_1$ integrins that we are developing for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. We have completed a Phase 1a SAD/MAD trial and a Phase 1b proof-of-mechanism trial of PLN-74809 in IPF. We are currently recruiting patients for two Phase 2a trials of PLN-74809 in IPF and one Phase 2a trial in PSC. We opened an additional IND for PLN-74809 for the treatment of COVID-19 related acute respiratory distress syndrome, or ARDS, in July of 2020, and have initiated a Phase 2a trial in that indication. Our second product candidate, PLN-1474, is a small-molecule selective inhibitor of $\alpha_v\beta_1$ for the treatment of liver fibrosis associated with NASH, which we have partnered with Novartis. PLN-1474 is currently undergoing Phase 1 testing. In addition to our clinical programs, we currently have preclinical integrin-based programs targeting oncology and muscular dystrophies.

Recent Highlights

- **Enrollment of Phase 2a 12-week trials of PLN-74809 in idiopathic pulmonary fibrosis (IPF) and primary sclerosing cholangitis (PSC) progressing.** After resuming enrollment earlier in the year, Pliant has remained in close coordination with its global trial sites in order to facilitate enrollment in both Phase 2a trials. The Company also continues to open additional trial sites as COVID-19 related restrictions are eased. The hybrid approach to clinical trial participation utilizing home-health solutions to maximize patient safety is expected to aid in trial recruitment.
- **Phase 2a PET imaging trial of PLN-74809 in IPF is enrolling.** The Phase 2a PET trial will evaluate safety, tolerability, and target engagement of PLN-74809 in IPF patients. We expect to report preliminary data by the first half of 2021.
- **Completed dosing of an extended Phase 1 dose escalation trial of PLN-74809 in healthy volunteers.** PLN-74809 has completed dosing multiple ascending dose cohorts of 120mg and 160mg once daily in an extended dose escalation trial. The pharmacokinetic profile remains in line with previous cohorts, and PLN-74809 remains generally well tolerated with no drug related severe adverse events or serious adverse events reported in either cohort.
- **Phase 2a trial of PLN-74809 treatment of COVID-19 related acute respiratory distress syndrome (ARDS) has been initiated.** The Company initiated a Phase 2a trial evaluating safety, tolerability and pharmacokinetics (PK) of PLN-74809, as well as exploratory clinical outcome measures in patients hospitalized with severe and critical COVID-19.
- **Phase 1 trial of PLN-1474 in healthy volunteers is nearing completion.** The Phase 1 trial is designed to evaluate safety and tolerability, as well as PK of PLN-1474 in approximately 100 healthy volunteers across a dose range compared to placebo. After resuming enrollment following delays related to COVID-19, the trial remains on track to deliver topline data by the first quarter of 2021. PLN-1474 is partnered with Novartis.

In October 2019, we entered into a Collaboration and License Agreement with Novartis, or the Novartis Agreement, for the development and commercialization of our then preclinical product candidate, PLN-1474 and up to three integrin research targets. PLN-1474 is an internally discovered small molecule selective inhibitor of integrin $\alpha_v\beta_1$, currently being developed for the treatment of liver fibrosis associated with nonalcoholic steatohepatitis, or NASH. In December 2019, we received an upfront license payment of \$50.0 million for the worldwide exclusive license to PLN-1474. Pursuant to the Novartis Agreement, we expect to receive research and development funding totaling \$19.6 million for PLN-1474 development services and funding of up to \$13.4 million for optional research and development services on the integrin research targets. Additionally, we are eligible to receive developmental, regulatory and commercial milestone payments of up to \$416.0 million in total, if defined development, regulatory and commercialization milestones are achieved and tiered royalties, on a product-by-product basis based on annual net sales of products, at percentages ranging from high-single digits to low teens of the applicable licensed products and mid-single digits to high-single digits for any products resulting from the research programs.

On December 19, 2019, we issued 26.4 million shares of Series C redeemable convertible preferred stock, or the Series C Funding, for aggregate cash proceeds of \$48.2 million. Novartis purchased 10.9 million shares of the December 19, 2019 Series C redeemable convertible preferred stock offering at \$1.83 per share, which as at fair value as the Company sold Series C redeemable convertible preferred stock investor which is at arms-length transaction as \$1.83 per share was the purchase price paid for shares by other unrelated investors who participated in the funding round. In February 2020, we issued an additional 28.5 million shares of Series C redeemable convertible preferred stock for aggregate cash proceeds of \$52.2 million.

In June 2020, we completed an IPO issuing an aggregate of 10,350,000 shares of common stock, which included 1,350,000 shares of common stock issued pursuant to the over-allotment option granted to the underwriters at a price of \$16.00 per share generating gross proceeds of \$165.6 million, before underwriting discounts and commissions and offering expenses payable by the Company. As a result of the IPO, we received approximately \$148.3 million in net proceeds, after deducting underwriting discounts, commissions and offering expenses of \$5.7 million, of which \$2.6 million was paid in 2019. We offset the deferred offering costs against the net proceeds received from the sale of common stock. At the closing of the IPO, 160,389,279 shares of outstanding convertible preferred stock were automatically converted to 22,423,029 shares common stock on a 7.15:1 basis. Following the IPO, there were no shares of preferred stock outstanding.

Concurrent with the completion of the IPO, we also issued 625,000 shares to Novartis in a private placement at a price of \$16.00 per share for proceeds of \$10.0 million, which resulted in Novartis owning approximately 6.1% of our outstanding shares of common stock.

Company background

Since our inception in 2015, our operations have included organizing and hiring personnel for our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of TGF- β signaling and integrin biology, medicinal chemistry, translational screening technologies, and clinical insights to create tissue-specific inhibitors of fibrotic diseases.

We have incurred net losses since inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through private placements of our redeemable convertible preferred stock and from revenue generated from the Novartis Agreement.

To date, all our revenue has solely been generated from the Novartis Agreement. We expect revenue will continue to fluctuate from period to period and there can be no assurance that we will generate other revenue, that we will enter into new collaborations, or that new or existing collaborations will continue beyond their initial terms or that we will be able to meet the milestones specified in these agreements.

Since our inception, we have incurred significant operating losses. Our net losses were \$16.5 million and \$22.5 million for the three and nine months ended September 30, 2020, respectively, compared to losses of \$13.3 million and \$42.8 million for the three and nine months ended September 30, 2019, respectively. Our net loss was \$0.6 million and \$30.3 million for the years ended December 31, 2019 and December 31, 2018. As of September 30, 2020 and December 31, 2019, we had an accumulated deficit of \$98.8 million and \$76.3 million, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- advance our lead product candidate, PLN-74809, through clinical development, and, if approved by the FDA, commercialization;
- advance our other clinical programs through clinical development and our preclinical development programs into clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- increase the amount of research and development activities to identify and develop product candidates;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including 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;

- 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; and
- invest in or in-license other technologies or product candidates.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for PLN-74809 or any of our other product candidates. In addition, if we obtain regulatory approval for PLN-74809 or any of our other product candidates and do not enter into one or more collaborations with third-parties for commercialization, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution activities.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and the economic and developmental uncertainty arising from the COVID-19 pandemic, we may be unable to accurately predict the timing or magnitude of all expenses. Even if we can generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2020, we had cash, cash equivalents and short-term investments of \$294.0 million. We expect to continue to incur losses for the foreseeable future and will require additional financial resources to continue to advance our products and intellectual property. We believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into 2023. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, government funding arrangements, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic, which continues to spread throughout the United States and worldwide. We could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the recent outbreak of COVID-19. Among other things, our clinical trials have experienced delays, and may experience additional delays in the future, extending the timelines and increasing the overall costs to finish the clinical trials, as our fixed costs are not substantially reduced while the clinical trials are delayed. For example, the clinical site conducting our Phase 2a PET trial of PLN-74809 in IPF was closed to clinical research in March 2020, but resumed enrollment and trial activities in the third quarter of 2020. The ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, among others. Accordingly, we cannot predict the extent to which our business, financial condition and results of operations will be affected. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from a business and financial perspective relating to COVID-19.

Financial Operations Overview

Revenue—Related Party

In October 2019, we entered into the Novartis Agreement for the development and commercialization of our then preclinical product candidate, PLN-1474 and up to three additional integrin research targets. Under the terms of the Novartis Agreement, in December 2019, Novartis paid Pliant an upfront license fee payment of \$50.0 million for the worldwide exclusive license to PLN-1474. Novartis will fund our research and development activities for PLN-1474 through Phase 1 after which Novartis will assume responsibility for all future development, manufacturing and commercialization of PLN-1474. Novartis will also fund the research and development activities associated with the integrin research targets as outlined in the Novartis Agreement. We are scheduled to receive up to \$19.6 million in funding for PLN -1474 development services through Phase 1 and are expected to receive up to \$13.4 million in funding for optional development and research services on the integrin research targets. The research and development funding payments are expected to be paid periodically throughout

2020, 2021 and 2022. We are eligible for milestone payments of up to \$416.0 million in total, if defined developmental, regulatory and commercialization milestones are achieved, and tiered royalties on a product-by-product basis based on annual nets sales of products, at percentages ranging from high-single digits to low teens of the applicable licensed products and mid-single digits to high-single digits for any products resulting from the research programs.

Revenue-related party was \$4.8 million and \$37.4 million for the three and nine months ended September 30, 2020, respectively, compared to no revenue for the three and nine months ended September 30, 2019, respectively. Novartis became a related party to us following its purchase of 10.9 million shares of our Series C redeemable convertible preferred stock on December 19, 2019 which were subsequently converted to common stock upon our IPO, along with the concurrent private placement of 625,000 shares upon our IPO, representing aggregate holdings of 6.1% and 7.4% of our outstanding shares of common stock on a fully diluted basis as of September 30, 2020 and December 31, 2019, 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, investigative clinical trial sites and consultants that conduct research and development activities on our behalf;
- costs associated with 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.

The following table summarizes our research and development expenses for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Employee-related expenses	\$ 4,028	\$ 2,611	\$ 10,697	\$ 7,166
Outside and consulting services for preclinical studies and research and development activities by third party contract organizations	3,607	4,978	10,692	17,151
Clinical trials expenses	6,505	1,167	17,440	4,957
Depreciation of lab equipment and costs of equipment and supplies	1,183	1,279	3,380	3,725
Technology and intellectual property licenses	29	40	2,465	277
Facilities and other allocated expenses	1,532	704	3,665	2,350
Total research and development expenses	<u>\$ 16,884</u>	<u>\$ 10,779</u>	<u>\$ 48,339</u>	<u>\$ 35,626</u>

We expense all research and development costs in the periods in which they are incurred. 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 substantially 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. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, marketing, investor relations, human resource and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation for our general and administrative personnel. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, The Nasdaq Global Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Interest Income

Our interest income consists of interest income earned on cash and cash equivalents, money market funds and short-term investments.

Results of Operations

As described above in “COVID 19 Pandemic”, the ultimate extent of the impact of any epidemic, pandemic, outbreak or other public health crisis on our results of operations will depend on future developments, which are highly uncertain, including new information that may emerge concerning the severity of the COVID-19 pandemic or other public health crisis and actions taken to contain or prevent the further spread, among others. Accordingly, we cannot fully predict the extent to which our business and results of operations will be affected; however, we expect the COVID-19 pandemic to impact our operations in several ways. Many clinical trial sites have been impacted by the pandemic, forcing them to delay enrollment in research trials, including ours. This will likely impact the speed of enrollment in our current trials. Additionally, the pandemic has limited our ability to perform basic science R&D in our facilities due to government shelter-in-place orders, ultimately slowing, but not stopping, progress of several early stage projects.

Comparison of the Three Months Ended September 30, 2020 and 2019

(In thousands, except percentages)	Three Months Ended September 30,		\$ Change	% Change
	2020	2019		
Revenue—related party	\$ 4,814	\$ -	\$ 4,814	NM
Operating expenses:				
Research and development	(16,884)	(10,779)	(6,105)	56.6%
General and administrative	(4,591)	(2,583)	(2,008)	77.7%
Total operating expenses	(21,475)	(13,362)	(8,113)	60.7%
Loss from operations	(16,661)	(13,362)	(3,299)	24.7%
Interest income	72	148	(76)	(51.4%)
Other income (expense), net	55	(41)	96	(234.1)%
Net loss	<u>\$ (16,534)</u>	<u>\$ (13,255)</u>	<u>\$ (3,279)</u>	24.7%

NM: Results not meaningful

Revenue - Related Party

Revenue-related party consisted exclusively of revenue generated from the Novartis Agreement. Related party revenue was \$4.8 million and none the three months ended September 30, 2020 and 2019, respectively. The increase of \$4.8 million in revenue-related party for the three months ended September 30, 2020 compared to the same period in 2019 was due to \$4.8 million in revenue generated from research and development services performed during the period. We anticipate revenue over the next several quarters will be derived primarily from the Novartis Agreement as we continue to recognize revenue-related party from research and development services and from the potential achievement of the Novartis Agreement’s developmental, regulatory and commercial milestones.

Research and Development Expenses

Research and development expenses were \$16.9 million and \$10.8 million for the three months ended September 30, 2020 and 2019, respectively. Research and development expenses increased by \$6.1 million, or 56.6%, which was primarily due to \$4.0 million of increased consulting and outside services costs, \$1.0 million of increased compensation costs, \$0.4 million of increased stock-based compensation costs and \$0.7 million of increase for insurance expenses. Consulting and outside services costs increased due to increased PLN-74809 and PLN-1474 development activities. Compensation costs and stock-based compensation costs increased as a result of increased headcount. Insurance expenses increased due to additional costs for insurance as a public company.

General and Administrative Expenses

General and administrative expenses were \$4.6 million and \$2.6 million for the three months ended September 30, 2020 and 2019, respectively. The increase of \$2.0 million, or 77.7%, was primarily due to \$0.9 million of increased professional and consulting costs, \$0.4 million of increased compensation costs, \$0.3 million of increased stock-based compensation costs, \$0.2 million of increased insurance expenses, \$0.2 million of increased recruiting expenses, and \$0.1 million of increased charitable contributions, partially offset by a decrease of \$0.1 million in travel expense. Compensation costs and stock-based compensation costs increased as a result of increased headcount. Professional and consulting costs increased primarily as a result of increased legal, marketing, investor relations and accounting fees. Insurance expenses increased due to additional costs for insurance as a public company. Travel expenses decreased primarily due to decreased executive travel as a result of the COVID-19 pandemic.

Interest Income

Interest income decreased by \$0.1 million for the three months ended September 30, 2020, when compared to the three months ended September 30, 2019. The decrease was primarily attributable lower interest rates in the three months ended September 30, 2020 when compared to the corresponding period in 2019.

Comparison of the Nine Months Ended September 30, 2020 and 2019

(In thousands, except percentages)	Nine Months Ended September 30,		\$ Change	% Change
	2020	2019		
Revenue—related party	\$ 37,352	\$ -	\$ 37,352	NM
Operating expenses:				
Research and development	(48,339)	(35,626)	(12,713)	35.7%
General and administrative	(11,642)	(7,827)	(3,815)	48.7%
Total operating expenses	(59,981)	(43,453)	(16,528)	38.0%
Loss from operations	(22,629)	(43,453)	20,824	(47.9)%
Interest income	392	701	(309)	(44.1)%
Other expense, net	(269)	(48)	(221)	460.4%
Net loss	\$ (22,506)	\$ (42,800)	\$ 20,294	(47.4)%

NM: Results not meaningful

Revenue - Related Party

Revenue-related party of \$37.4 million consisted exclusively of revenue generated from the Novartis Agreement. The increase of \$37.4 million in revenue-related party for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was due to the recognition of related party revenue of \$25.0 million for the milestone payment that was achieved with the first patient dosing under the Novartis agreement in the first quarter of 2020. In addition, we recognized revenue—related party of \$12.4 million generated from research and development services performed during the period. Over the next several years, we expect our revenue will be derived primarily from the Novartis Agreement as we continue to recognize related party revenue from research and development services funding and from the potential achievement of the Novartis Agreement's developmental, regulatory and commercial milestones.

Research and Development Expenses

Research and development expenses were \$48.3 million and \$35.6 million for the nine months ended September 30, 2020 and 2019, respectively. Research and development expenses increased by \$12.7 million, or 35.7%, which was primarily due to \$6.3 million of increased consulting and outside services costs, \$2.9 million of increased compensation costs, \$0.6 million of increased stock-based compensation costs, \$2.2 million in increased license fees, \$0.9 million of increased insurance expense, and \$0.1 million of increased depreciation expense, partially offset by a \$0.3 million in decreased research studies expense and a decrease of \$0.2 million in equipment and supplies expense. Consulting and outside services costs increased due to increased PLN-74809 and PLN-1474 development activities with external vendors. Compensation costs and stock-based compensation costs increased as a result of increased headcount. License fees increased due to the \$2.4 milestone payment to the UC Regents in connection with our IPO in the second quarter of 2020. Insurance expenses increased due to additional costs for insurance as a public company. The decreases in equipment and supplies expense and research expenses is primarily due to delayed research related activities stemming from the Covid-19 pandemic.

General and Administrative Expenses

General and administrative expenses were \$11.6 million and \$7.8 million for the nine months ended September 30, 2020 and 2019, respectively. The increase of \$3.8 million, or 48.7%, was primarily due to \$1.8 million of increased consulting and outside services costs, \$1.0 million of increased compensation costs, \$0.5 million of increased stock-based compensation expense, \$0.5 million of increased charitable contributions and \$0.2 million of increased insurance expenses, partially offset by \$0.3 million decrease in travel expenses. Professional and consulting costs increased primarily as a result of increased legal, marketing, investor relations and accounting fees. Compensation costs and stock-based compensation costs increased as a result of increased headcount. Insurance expenses increased due to additional cost for insurance as a public company. Travel expenses decreased primarily due to decreased executive travel as a result of the COVID-19 pandemic.

Interest Income

Interest income was \$0.4 million and \$0.7 million for the nine months ended September 30, 2020 and 2019, respectively. The decrease of \$0.3 million was primarily attributable to lower interest rates in the nine months ended September 30, 2020 when compared to the corresponding period in 2019.

Liquidity and Capital Resources

Overview

As of September 30, 2020, we had cash, cash equivalents and short-term investments of \$294.0 million. This amount includes the net proceeds from our IPO in June 2020, in which we issued an aggregate of 10,350,000 shares of common stock, which included 9,000,000 shares of common shares and 1,350,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares, at an offering price of \$16.00 per share. We received \$148.3 million, net of underwriting discounts, commissions and offering expenses payable by us. We concurrently completed a private placement of 625,000 common shares to Novartis at a price of \$16.00 per share for proceeds of \$10.0 million. Our cash position as of September 30, 2020 also includes an additional \$52.2 million from the issuance of an additional 28.5 million shares of our Series C redeemable convertible preferred stock in February of 2020, and reflects the achievement of the first patient dosing milestone of the Novartis Agreement that triggered the receipt of a \$25.0 million payment which was received from Novartis in the second quarter of 2020.

Due to the COVID-19 pandemic, our clinical trials with universities were temporarily delayed and our ability to identify and enroll patients in future clinical trials may become more difficult and costly. Our liquidity and capital resource evaluation includes an estimate of the financial impact of the delay in clinical trials and increased patient enrollment costs.

Based on our current cash balance and our ability to control discretionary spending, such as research and development expenditures with outside service providers, we have evaluated and concluded our financial condition is sufficient to fund our planned operations, commitments and contractual obligations for a period of at least one year following the date that these financial statements are issued.

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 the COVID-19 pandemic;
- 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;
- 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 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 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.

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 arrangements. If we raise additional capital through 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 or licensing 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 Nine Months Ended September 30, 2020 and 2019

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

	<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Net cash used in operating activities	\$ (20,786)	\$ (39,494)
Net cash used in investing activities	(222,772)	(8,750)
Net cash provided by/(used) in financing activities	212,975	(1,292)
Net decrease in cash and cash equivalents	<u>\$ (30,583)</u>	<u>\$ (49,536)</u>

Cash Used in Operating Activities

Net cash used in operating activities was \$20.8 million for the nine months ended September 30, 2020 and \$39.5 million for the nine months ended September 30, 2019.

Cash used in operating activities in the nine months ended September 30, 2020 was primarily due to our net loss for the period of \$22.5 million adjusted by non-cash charges of \$3.3 million and net change of \$1.6 million in our net operating assets and liabilities. The non-cash charges consisted of \$0.9 million of depreciation expense and \$2.4 million of stock-based compensation expense. The changes in our net operating assets and liabilities were primarily due to an increase of \$4.8 million in prepaid expense and other current assets, partially offset by an increase of \$1.8 million in accounts payable, an increase of \$1.2 million in accrued expenses, and a decrease of \$0.3 million in tax credit receivables.

Cash used in operating activities in the nine months ended September 30, 2019, was primarily due to our net loss for the year of \$42.8 million adjusted by non-cash charges of \$2.1 million and a net change of \$1.2 million in our net operating assets and liabilities. The non-cash charges consisted of \$0.8 million of depreciation expense and \$1.3 million of stock-based compensation expense. The changes in our net operating assets and liabilities were primarily due to an increase of \$2.6 million in accounts payable and accrued expenses, partially offset by an increase of \$1.4 million in prepaid expenses and other non-current assets.

Cash Used in Investing Activities

During the nine months ended September 30, 2020 and 2019, cash used in investing activities was \$222.8 million and \$8.8 million, respectively. Cash used in investing activities for the nine months ended September 30, 2020 was primarily due to the purchase of short-term investments of \$267.8 million and purchases of property, plant and equipment of \$1.0 million, partially offset by \$46.0 million in maturities of short-term investments.

Cash used in investing activities for the nine months ended September 30, 2019 was primarily due to the purchase of short-term investments of \$34.8 million, purchases of property, plant and equipment of \$0.8 million and accretion on short-term investments of \$0.2 million, partially offset by \$27.0 million in maturities on short-term investments.

Cash Provided by Financing Activities

During the nine months ended September 30, 2020, cash provided by financing activities was \$213.0 million. Cash provided by financing activities for the nine months ended September 30, 2020 was primarily due to the net proceeds from issuance of common stock upon completion of our IPO of \$150.8 million, issuance of common stock upon completion of the private placement with Novartis of \$10.0 million, issuance our Series C convertible preferred stock net of issuance costs of \$52.0 million, and the issuance of common stock upon the exercise of previously granted stock options of \$0.2 million. The net proceeds from the completion of the IPO of \$150.8 million were comprised of our proceeds of \$154.0 million, after deducting underwriting discounts and commissions, less offering expenses of \$5.7 million, of which \$3.1 million was paid in 2020.

Cash used by financing activities for the nine months ended September 30, 2019 was \$1.3 million which was primarily due to payment of deferred offering costs of \$1.4 million, partially offset by \$0.1 million of proceeds from the issuance of restricted common stock.

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 United States generally accepted accounting principles. 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.

While our significant accounting policies are described in more detail in Note 2 to our financial statements appearing elsewhere in this Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

As of September 30, 2020, all of our revenue to date has been generated from the Novartis Agreement. Effective January 1, 2018, we adopted the provisions of ASC Topic 606, Revenue from Contracts with Customers ("Topic 606") using the full retrospective transition method. We did not have any prior collaboration agreements and did not recognize revenue during the year ended December 31, 2018.

Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of Topic 606, we perform the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer.

Identification of the Contracts with the Customers

We evaluate every contract to determine whether it in its entirety or in part represent a contract with a customer, or a collaboration agreement and, based on this determination, apply appropriate accounting guidance.

We account for a contract with a customer that is within the scope of Topic 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

Identification of the Performance Obligations

The promised goods or services in our collaboration and option arrangements consist of research and development services. The arrangements also have options for additional items (i.e., license rights). Options are considered to be marketing offers and are to be accounted for as separate contracts when the customer elects such options, unless we determine the option provides a material right which would not be provided without entering into the contract. The determination as to whether such options are material rights requires significant management judgment, and management considers factors such as other similar arrangements, market data and the terms of the contractual arrangement to make such conclusion. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of our customer to develop the intellectual property on their own and whether the required expertise is readily available.

Determination of the Transaction Price

We estimate the transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

All contingent future payments, which include research, development, regulatory, and sales-based royalty payments, have not been considered in the initial analysis, as they are contingent upon option(s) being exercised or are subject to significant risk of achievement.

Allocation of Transaction Price

We allocate the transaction price based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for satisfying each performance obligation.

Recognition of Revenue

We considered the license to PLN-1474 as functional intellectual property, as when control of the license was transferred to Novartis at the inception of the Novartis Agreement, Novartis had the right to access its technology and it was functional. The license was distinct from the research and development services as the services are not transformative in nature. As such, under Topic 606, the Company determined the \$50.0 million was standalone selling price PLN-1474 license and was recorded to revenue at the inception of the Novartis Agreement.

We recognize revenue as we perform the research and development services based on an input method, as such costs have direct relationship between our effort and the progress made towards satisfying its performance obligations to Novartis.

Accrued Research and Development Costs

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conduct of clinical studies and preclinical studies. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations and comprehensive loss. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on factors such as estimates of the work completed and in accordance with agreements established with these third-party service providers. Any payments made in advance of services provided are recorded as prepaid assets, which are expensed as the contracted services are performed.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. If we underestimate or overestimate the level of services performed or the costs of these services, our accrued expenses could differ from our estimates. For the periods presented, we have experienced no material differences between our accrued expenses and actual expenses.

Stock-Based Compensation

We recognize compensation costs related to stock awards, stock options and ESPP awards granted to employees, nonemployees and directors based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized over the requisite service periods, which is generally on a straight-line of the awards. Forfeitures are accounted for as they occur.

The Black-Scholes option-pricing model requires the use of subjective assumptions which determine the fair value of stock-based awards, including the expected term and the price volatility of the underlying stock. These assumptions include:

- *Fair value of common stock*—See “Determination of the Fair Value of Our Common Stock” below.
- *Expected term*—The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or simplified method, as allowed by the SEC. The expected term for the ESPP is the offering period.
- *Expected volatility*—Prior to the company being public, the Company did not have any trading history for our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their size, stage in the life cycle or area of specialty. As the Company went public in June 2020, we will continue to apply this process for stock options and ESPP awards until enough historical information regarding the volatility of its stock price becomes available.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

Determination of the Fair Value of Our Common Stock

Given the absence of a public trading market for our common stock historically prior to our IPO, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Following our IPO, we use our stock price traded on NASDAQ to determine its fair value.

For stock awards and options granted in 2018 and 2019, we considered the use of the Income and Market approaches. Under the income approach, the cash generating ability of the company is valued. This approach focuses on determining a forecast benefit stream that is reflective of the subject company’s most likely future performance. The forecast benefit stream is then discounted to present value based on the appropriate risk-adjusted discount rate or capitalization rate.

Under the Market approach, we referenced actual transactions involving our company or similar assets and/or enterprises. The Market approach generally consists of two primary methodologies: The Guideline Comparables Method, or GCM and the Guideline Transaction Method, or GTM. The GCM involves identifying and selecting publicly traded companies or guideline public companies, or Guideline Public Companies, with financial and operating characteristics like the subject being valued, and subsequently deriving multiples and other metrics from such Guideline Public Companies to apply to the subject being valued.

Taking the stage of our development into consideration and expected liquidity events into account, we elected not to rely upon a pure application of the Income or Market valuation approaches. We determined that the PWERM was more appropriate to value our equity classes as the approach is based upon an analysis of future values for the entire enterprise assuming various future outcomes. We did consider elements of the Income and Market approaches for gauging the appropriateness of certain PWERM inputs and assumptions.

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be as a date later than the most recent third-party valuation date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of pre-clinical and planned clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;

- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or a sale of our company considering prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

For financial reporting purposes, we considered the amount of time between the valuation date and the grant date of our stock awards and options to determine whether to use the latest common stock valuation or an interpolated fair value between the two valuation dates. This determination included an evaluation of whether the subsequent valuation indicated that any significant change in valuation had occurred between the previous valuation and the grant date.

The assumptions underlying these valuations represent management’s best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different. Following the closing of our IPO, the fair value of our common stock was determined based on the quoted market price of our common stock.

Recent Accounting Pronouncements

See Note 2 to our condensed financial statements appearing elsewhere in this Report for more information.

Emerging Growth Company Status and JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and adopt ASU No. 2016-02 (*Topic 842*), Leases when the standard is effective for private companies which is for fiscal years beginning after December 15, 2021. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an “emerging growth company” we intend to rely on such exemptions, we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of this offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

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, cash equivalents and short-term investments of \$294.0 million as of September 30, 2020 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. Historical fluctuations in interest rates have not been significant for us. We had no outstanding debt as of September 30, 2020. 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 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

Item 4. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

As of September 30, 2020, 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) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed 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 the 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 September 30, 2020, 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) of the Exchange Act that occurred during the quarter ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We considered our internal controls over financial reporting in regards to the impact of COVID-19 and concluded that our controls continue to operate in a remote environment without material effect on our internal controls 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.

RISK FACTORS

Summary of the Material Risks Associated with Our Business

Our business involves significant risks, some of which are described below. The summary risk factors listed below should be read together with the text of the full risk factors that follow this summary. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as in other documents that we file with 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, and you may lose all or part of your investment. 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.

- 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, PLN-74809, as well as PLN-1474 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.
- Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of PLN-74809 or any other 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 have entered into a collaboration agreement with Novartis for the development of PLN-1474, and may in the future seek to enter into collaborations with third parties for the development and commercialization of other product candidates. If we fail to enter into such collaborations, or our collaborations are not successful, we may be unable to continue development of such product candidates, we would not receive any contemplated milestone payments or royalties, and we could fail to capitalize on the market potential of such product candidates.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.
- 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.
- 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 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.

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 financing. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, 2019 and 2018, we reported a net loss of \$0.6 million and \$30.3 million, respectively, and for the nine months ended September 30, 2020 and 2019, we reported a net loss of \$22.5 million and \$42.8 million, respectively. As of September 30, 2020 and December 31, 2019, we had an accumulated deficit of \$98.8 million and \$76.3 million, respectively. We have devoted substantially all of our resources and efforts to research and development and we expect that it will be 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 develop and 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, PLN-74809, and our second product candidate, PLN 1474, 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;
- 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 COVID-19 pandemic;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize PLN-74809, 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 and our operations as a public company;
- 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; and
- invest in or in-license other technologies or product candidates.

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 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.

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 PLN-74809 and PLN-1474 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. We also expect to incur additional costs associated with operating as a public company. 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 September 30, 2020, we had approximately \$294.0 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that the existing cash, cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into 2023. 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 due to the COVID-19 pandemic;
- 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;
- whether we are able to maintain our existing collaboration with Novartis and enter into additional 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 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 do not have any committed external source of funds or other support for our development efforts and 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 the COVID-19 pandemic or other factors 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.

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 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 COVID-19 pandemic;
- the changing and volatile U.S. and global economic 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 are a clinical-stage biopharmaceutical company with a limited operating history. We were incorporated in 2015, have no products approved for commercial sale and have not generated any revenue. 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. In addition, our lead product candidate, PLN-74809, is in early clinical development for the treatment of IPF and preclinical development for the treatment of PSC, and our second product candidate, PLN-1474, is in early clinical development. Both programs will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have not yet demonstrated the ability to progress any product candidate through clinical trials. We are still in preclinical and early clinical development and may be unable to 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. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. 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 have no meaningful history of operations upon which to evaluate our business, 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, PLN-74809, as well as PLN-1474 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.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are very early in our development efforts and have only one product candidate, PLN-74809, in early clinical development. Because PLN-74809 is our lead product candidate, if PLN-74809 encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. We have completed a Phase 1a SAD/MAD trial and a Phase 1b proof-of-mechanism trial of PLN-74809 in IPF and are recruiting two Phase 2a trials and a Phase 2a PET imaging trial in IPF. We are also conducting a Phase 2a PSC trial for which we are currently enrolling patients. PLN-74809 is also being evaluated in an ongoing Phase 2a trial to evaluate its potential to address COVID-19 related ARDS. We are also collaborating with Novartis to develop PLN-1474 for liver fibrosis associated with nonalcoholic steatohepatitis, or NASH, and are currently evaluating PLN-1474 in Phase 1a SAD/MAD testing.

Before we can generate any revenue from sales of our lead product candidate, PLN-74809, 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 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 INDs 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 the COVID-19 pandemic;
- high drop-out rates of subjects from clinical trials; inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- 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 related to the impact of the spread of the COVID-19 pandemic, including the impact of COVID-19 on the FDA's ability to continue its normal operations;
- 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, although multiple studies are currently underway, to date, 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. We have only tested our lead product candidate, PLN-74809, in healthy volunteers. Therefore, we may ultimately discover that our approach and any product candidates resulting therefrom do not possess properties required for therapeutic effectiveness. As a result, we may never succeed in developing a marketable product.

In addition, while we have developed an extensive panel of cell assays and precision cut tissue assays and have utilized animal models to uncover biological pathways, understood gene expression changes and optimized the potency and selectivity of our potential product candidates, there can be no assurance that our technology will yield their intended benefits. While we believe our assays represent a differentiator in our approach to drug development, our approach has not yet been clinically proven to yield results. Our practice of evaluating our product candidates in live human fibrotic tissue samples before advancing them into the clinic is intended to serve as a bridge between animal models and clinical proof-of-concept. However, there can be no assurance that positive results observed from preclinical animal testing and human fibrotic tissue models will be replicated when a program is advanced into clinical development. In addition, our practice of utilizing live human fibrotic tissue as part of our development efforts may become more widespread in the future, and this approach may be adopted and replicated by others, including our competitors.

Studies involving human tissue samples may also be subject to institutional and government human subject privacy policies that may vary by territory. We or our partners who provide us with human tissue samples, or conduct tissue and/or animal studies on our behalf, may be found to be in violation of one or more of these regulations or policies and may be subject to closure, censure or other penalties. In some cases, these penalties could materially impact the performance, availability, or validity of studies conducted by us on our behalf. Even in the absence of violations resulting in penalties, regulatory and other authorities may refuse to authorize the conduct or to accept the results of studies for regulatory or ethical reasons.

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 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 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 PLN-74809 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;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; 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. 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 may be 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 may in the future pursue 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. Examples of such regulations 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.

If we seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, 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.

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 PLN-74809 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 PLN-74809 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;
- due to the impact of the COVID-19 pandemic, we have experienced, and may continue to experience, delays and interruptions to our preclinical studies and clinical trials, 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;
- 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 time frames 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.

We completed our Phase 1a clinical trial of our lead product candidate PLN-74809 in healthy volunteers, and, with the exception of a number of reported minor adverse events, the product candidate was observed to be generally well-tolerated across all doses in 71 trial participants. 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 PLN-74809 administered with approved IPF agents. As a result, we may encounter unexpected drug-drug interactions in our planned trials, and may be required to further test these candidates, including in drug-drug interaction studies, which may be expensive, time-consuming and result in delays to our programs. In addition, the FDA recently issued a “safe to proceed” letter in relation to our plans to evaluate PLN-74809 in COVID-19-related acute respiratory distress syndrome, for which we recently initiated a Phase 2a trial. We thus far have not conducted any clinical development of this product candidate for such indication or in an acute setting. As a result, we may observe the incidence of adverse events or serious adverse events upon further development of PLN-74809 in this patient population, and such incidence may be magnified in patients with COVID-19 due to the critical and often life-threatening nature of the underlying disease. If we encounter adverse safety issues with PLN-74809 during its development for COVID-19-related acute respiratory distress syndrome, such an outcome may adversely color the perceptions of clinicians, regulatory agencies, patients and others with respect to the safety profile of PLN-74809 in other indications.

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 (including legality under applicable COVID-19 shelter-in-place regulations) of patients to participate in our trials (including due to fears of contracting COVID-19);
- 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;
- 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 PLN-74809 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 PLN-74809 due, in part, to the small size of these patient populations. In addition, our clinical trials will 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. Certain of our planned clinical trials may also involve invasive procedures such as bronchoscopy and broncho-alveolar lavage, or BAL, procedure, which may lead some patients to drop out of trials to avoid these follow-up procedures.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. For example, our clinical trial sites have been affected by the COVID-19 pandemic. Commencement of enrollment of our clinical trials of PLN-74809 in IPF and PSC was delayed. While these trials have resumed patient enrollment, we could experience slower than expected enrollment. With respect to our PLN-74809 program for COVID-19 ARDS, we have initiated a Phase 2a trial evaluating the potential of this candidate, but there can be no assurance that we will not encounter challenges in patient enrollment or the conduct of the trial generally. With respect to the ongoing Phase 1 trial of PLN-1474, the trial site has experienced delays due to its location in an area currently impacted by COVID-19; however, it is now open and expected to continue dosing the remaining cohorts of the Phase 1 trial with topline data expected in the first quarter of 2021, subject to further impact of the COVID-19 pandemic. In addition, after enrollment in these trials, if patients contract COVID-19 during participation in our trials or are subject to isolation or shelter-in-place restrictions, this may cause them to drop out of our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols. If patients are unable to follow the trial protocols or if our trial results are otherwise disputed due to the effects of the COVID-19 pandemic or actions taken to mitigate its spread, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Some factors from the COVID-19 pandemic that we believe may adversely affect enrollment in our trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- given that our clinical trials target respiratory indications, patients who would otherwise be candidates for enrollment in our clinical trials, may become infected with coronavirus, which may kill some patients and render others too ill to participate, limiting the available pool of participants for our trials;
- the inability of patients to come to hospitals and universities to participate in our trial, which may force us to conduct our trials in patients' homes, rendering the trials more difficult and costly to conduct;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our clinical trials. The global outbreak of the COVID-19 pandemic continues to evolve and the conduct of our trials may continue to be adversely affected, despite efforts to mitigate this impact.

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. We are currently recruiting two Phase 2a trials of PLN-74809 in IPF, subject to the impact of the COVID-19 pandemic. In the first of these trials, the study is designed to enroll IPF patients and utilize a positron emission tomography, or PET, ligand to measure $\alpha\beta6$ target engagement by PLN-74809 in the lungs post-treatment. The second trial is a 12-week double blind placebo-controlled trial recruiting IPF patients across up to four cohorts consisting of up to three doses of PLN-74809 and one placebo and will evaluate safety, tolerability and pharmacokinetics, or PK. It is possible that we may need to amend our clinical trial, which would require us to resubmit our clinical trial protocols to IRBs for reexamination, and may impact the costs, timing or successful completion of such clinical trial. In addition, we may desire to test PLN-74809 at doses exceeding those evaluated in the Phase 1a trial, and may not be able to do so.

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. 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 PLN-74809 for IPF and PSC indications, 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.

Although we have received U.S. orphan drug designation for PLN-74809 for IPF and PSC indications, 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 the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States. 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.

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 can be approved for the same condition in the United States. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

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 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 PLN-74809 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 PLN-74809 and PLN-1474 continue 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 large 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 large companies with significant financial resources such as Biogen, Inc., AbbVie Inc., Gilead Sciences, Inc., Indalo Therapeutics, Inc., FibroGen, Inc., Galapagos NV, Bristol Myers Squibb Co., and Novartis AG. However, we know of no other companies currently in clinical development with an orally bioavailable small-molecule, selective integrin inhibitor. In addition, the FDA recently issued a “safe to proceed” letter in relation to our plans to evaluate PLN-74809 in COVID-19-related acute respiratory distress syndrome, for which we recently initiated a Phase 2a trial. We are aware of numerous companies in the U.S. and globally that are developing or have announced plans to develop therapies intended to address COVID-19, including in the form of vaccines, antiviral agents and treatments to manage the symptoms of COVID-19, including acute respiratory distress syndrome.

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 PLN-74809 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 and may do, 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.

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 PLN-74809 or any other product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future health care 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;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; 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 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 U.S., sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and 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 is 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 reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

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, no uniform policy of coverage and reimbursement for products exists among third-party payors. 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.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug and biologic benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs and biologics. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs and biologics, and each drug plan can develop its own formulary that identifies which drugs and biologics it will cover, and at what tier or level. However, Part D prescription drug formularies must include products within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs and biologics in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs and biologics may increase demand for products for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug or biologic product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Further, on December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change instituted by the Centers for Medicare & Medicaid Services, or CMS, under the 340B program. For the 2019 and 2018 fiscal years, CMS altered the reimbursement formula. The court ruled this change was not an "adjustment" that was within the Secretary's discretion to make but was instead a fundamental change in the

reimbursement calculation, and such a dramatic change was beyond the scope of the Secretary's authority. On May 6, 2019, the district court reiterated that the rate reduction exceeded the Secretary's authority and declared that the rate reduction for 2019 also exceeded the Secretary's authority and remanded the issue to HHS to devise an appropriate remedy. On July 10, 2019, the district court entered its final judgment and CMS has filed an appeal and a decision by the Court of Appeals for the D.C. Circuit is pending. However, subsequently, hospitals have filed a complaint in the U.S. District Court for D.C. to enjoin the reimbursement cuts for 2020. It is unclear how such litigation could affect covered hospitals who might purchase our products in the future, and affect the rates we may charge such facilities for our approved products.

Changes to these current laws and state and federal healthcare reform measures that may be adopted in the future may result in additional 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.

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 and physicians and third-party payors 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 and third-party payors in the United States and elsewhere play a primary role in the 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, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as 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 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 applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim submitted for payment to any federal health care program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring *qui tam* actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective “business associates,” those independent contractors or agents of covered entities that perform services for covered entities that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of biopharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

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 obligations 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 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 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 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;
- 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.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) 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. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2030, unless additional congressional action is taken. However, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The BBA also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the federal level, the Trump administration's budget for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

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. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which has since been further updated. As of June 23, 2020, the FDA noted it was conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections during the week of July 20, 2020, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. In April 2020, the FDA stated that its New Drug Program was continuing to meet program user fee performance goals, but due to many agency staff working on COVID-19 activities, it was possible that the FDA would not be able to sustain that level of performance indefinitely. Additionally, as of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time.

Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

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. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. 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 physicians 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 physicians is governed by the national anti-bribery laws of EU Member States, and in respect of the U.K. (which is longer a member of the EU), the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. 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 the European Economic Area, or EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement 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 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 Securities and Exchange Commission, or 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, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase 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, 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 are 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 achieve 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 enacted 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 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;
- 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;

- 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 in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future 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 in the future 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. 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 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 claim 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, if issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

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.

Likewise, our current licensed patents covering our companion technologies, licensed from UCSF are expected to expire in 2036, without taking into account any possible patent term adjustments or extensions. 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 2040, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or 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 Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. 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, and the USPTO, 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.

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

Depending upon the timing, duration and specifics of any FDA 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 Action 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. If we are unable to obtain patent term extension or the term of any such extension is less than we request, 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.

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.

Risks Related to Our Reliance on Third Parties

We have entered into a collaboration agreement with Novartis for the development of PLN-1474, and may in the future seek to enter into collaborations with third parties for the development and commercialization of other product candidates. If we fail to enter into such collaborations, or our collaborations are not successful, we may be unable to continue development of such product candidates, we would not receive any contemplated milestone payments or royalties, and we could fail to capitalize on the market potential of such product candidates.

In October 2019, we entered into a license and collaboration agreement with Novartis for the development and commercialization of our then preclinical product candidate, PLN-1474 and up to three integrin research targets. In December 2019, we received an upfront license payment of \$50.0 million for the worldwide exclusive license to PLN-1474. Pursuant to the Novartis Agreement, we expect to receive research and development funding totaling \$19.6 million for PLN-1474 development services and funding of up to \$13.4 million for option research and development services on the integrin research targets. Additionally, we are eligible to receive developmental, regulatory and commercial milestone payments of up to \$416.0 million if defined development, regulatory and commercialization milestones are achieved and tiered royalties, on a product-by-product basis based on annual nets sales of products, at percentages ranging from high-single digits to low teens of the applicable licensed products and mid-single digits to high-single digits for any products resulting from the research programs. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected.

In addition, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and a material and adverse effect on our business, financial condition, results of operations and prospects.

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 the COVID-19 pandemic 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 our ability to implement a key part of our development strategy will be compromised.

Because we rely on third-party manufacturing and supply vendors, 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. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

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 PLN-74809 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 PLN-74809. 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.

Our existing collaborations and future collaborations are and will be important to our business. 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 and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology.

Our existing collaborations and any future collaborations we enter into may pose a number of risks, including the following:

- collaborators 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 our existing collaborations and any future collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under 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.

Additionally, if one of our existing or future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

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.

Risks Related to Managing Our Business and Operations

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and has spread to a number of countries globally, including the United States. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we significantly limited access to our executive offices with the majority of our administrative employees continuing their work outside of our offices and limited the presence of our staff in the laboratory and in the administrative spaces to levels that adhere to social distancing protocols. As a result of the COVID-19 pandemic, we have experienced disruptions and may continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in commencing enrollment of patients in our clinical trials, including our Phase 2a clinical trials of PLN-74809 in IPF and PSC and our Phase 1 clinical trial of PLN-1474. With respect to the ongoing Phase 2a trials of PLN-74809 in IPF and PSC, following delays in site initiation due to the impacts of COVID-19, both trials have resumed active enrollment of patients. With respect to the ongoing Phase 1 trial of PLN-1474, due to the location of the Phase 1 trial site has experienced delays due to its location in an area currently impacted by COVID-19; however, it is now open and expected to continue dosing the remaining cohorts with topline data expected in the first quarter of 2021, subject to further impact of the COVID-19 pandemic;
- the impact from potential delays, including potential difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures that are deemed non-essential, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;

- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

As of September 30, 2020, we had 70 full-time employees. As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, 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, maintaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for PLN-74809 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.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including contract manufacturers and companies focused on research and development and discovery activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

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 PLN-74809 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 Bernard Coulie, M.D., Ph.D., our Chief Executive Officer and President, Keith Cummings, M.D., our Chief Financial Officer, Barbara Howes, our Chief Human Resources Officer, Johannes (Hans) Hull, J.D., our Chief Business Officer and Éric Lefebvre, M.D., our Chief Medical Officer. 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 restricted stock awards and stock options that vest over time. The value to employees of restricted stock awards and stock options 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 current 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 manmade 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, particularly on a daily basis, 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.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. 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 currently only 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, 2019, we had net operating loss carryforwards for U.S. federal and state income tax purposes of \$58.7 million and \$60.7 million, respectively, some of which will begin to expire in 2035. As of December 31, 2019, we also had available tax credit carryforwards for U.S. federal income tax purposes of \$4.7 million, which begin to expire in 2036, and state income tax purposes of \$2.1 million. Under Section 382 of the Internal Revenue Code of 1986, 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. Private placements and other transactions that have occurred since our inception, as well as our IPO and the Concurrent Private Placement that we completed in June 2020, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of the IPO, the Concurrent Private Placement, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, 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 stock price of our common stock may be volatile or may decline regardless of our operating performance.

Prior to our initial public offering in June 2020, there was no public market for shares of our common stock. In connection with our initial public offering, our common stock was listed for trading on the Nasdaq Global Select Market. However, an active or liquid market in our common stock may not develop, and if it does develop, it may not be sustainable.

Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

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 clinical trials of PLN-74809 and our ongoing Phase 1 clinical trial of PLN-1474;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings for PLN-74809 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 PLN-74809 or any other product candidate;
- changes in laws or regulations applicable to PLN-74809 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;
- 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 PLN-74809 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 the COVID-19 pandemic. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. 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 currently anticipate that we will retain future earnings for the development, operation and expansion 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.

Based on shares outstanding as of September 30, 2020, our executive officers, directors and their affiliates and our principal stockholders beneficially held, in the aggregate, approximately 25.6% of our outstanding voting stock. These stockholders, acting together, would be able to significantly influence all 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.

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

We are an emerging growth company, or EGC, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we complete the IPO, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which will require, 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 Global Market 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, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. 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. Recent legislation permits EGCs to implement many of these requirements over a longer period and up to five years from the pricing of the IPO. 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.

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 will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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.

Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

In connection with our IPO, our directors, officers and holders of substantially all of our common stock prior to the IPO entered into lock-up agreements that restrict the sale or disposition of their shares for a period of time following our IPO. These lock-up agreements pertaining to the IPO will expire 180 days from the date of the prospectus used for our initial public offering in June 2020, subject to earlier release of all or a portion of the shares subject to such agreements by the representatives of the underwriters in the IPO in their sole discretion. After the lock-up agreements expire up to an additional approximately 24.6 million shares of common stock will be eligible for sale in the public market. Approximately 36.8% of these additional shares are beneficially held by directors, executive officers and their affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline.

In addition, 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 to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. 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, beginning on January 1, 2021, 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 will automatically increase on January 1 of each year, beginning on January 1, 2021, 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.

The holders of approximately 23.1 million shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act as provided under the terms of an investors' rights agreement between us and the holders of our redeemable convertible preferred stock, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have broad discretion in the use of our existing cash, cash equivalents and short-term investments and may not use them effectively.

Our management will have broad discretion in the application of our existing cash, cash equivalents and short-term investments. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and short-term investments, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and short-term investments in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our existing cash, cash equivalents and short-term investments in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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 amended and restated certificate of incorporation and amended and restated bylaws, which became effective upon the completion of our IPO, 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 convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible 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, 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 amended and restated certificate of incorporation and amended and restated 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 you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you 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.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If 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.

Our amended and restated by-laws 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 amended and restated by-laws, that became effective upon the completion of our IPO, 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 General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our amended and restated by-laws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by-laws; 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 United States District Court for the Northern District of California 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, as our principal office is located in South San Francisco, California. In addition, our amended and restated 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 United States District Court for the Northern District of California 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

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 grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. 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.

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. Recently, California passed the California Data Privacy Protection Act of 2018, or the CCPA, which went into effect in January 2020 and provides new 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. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. 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. The new California law may lead to similar laws in other U.S. states or at a national level, which could increase our potential liability and adversely affect our business.

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 information, may seek to conduct clinical trials in EEA and may become subject to additional European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover, whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

Further, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. The United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

In the event we commence clinical trials in the EEA, the GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be 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. 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, including the GDPR. 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 forgoing could materially harm our business, prospects, financial condition and results of operations.

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 June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted to leave the EU, commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on EU, the U.K. ceased being a Member State of the EU on January 31, 2020. However, the terms of the withdrawal have yet to be fully negotiated. The implementation period began February 1, 2020 and will continue until December 31, 2020. During this 11-month period, the U.K. will continue to follow all of the EU's rules, the EU's pharmaceutical law remains applicable to the U.K. and the U.K.'s trading relationship will remain the same. However, regulations (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations medicine licensing and regulations, immigration laws and employment laws), have yet to be addressed. This lack of clarity on future U.K. laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the U.K., increase costs, depress economic activity and restrict access to capital.

The uncertainty concerning the U.K.'s legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit.

These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the EU are unable to negotiate acceptable agreements or if other EU member states pursue withdrawal, barrier-free access between the U.K. and other EU member states or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets either during a transitional period from January 1, 2021 or more permanently.

Such a withdrawal from the EU is unprecedented, and it is unclear how 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. In addition to the foregoing, our U.K. operations support our current and future operations and clinical activities in the EU and European Economic Area, or EEA, and these operations and clinical activities could be disrupted by Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Depending on the terms of the U.K.'s withdrawal from the EU, the U.K. could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. 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. For instance, in November 2017, EU member states voted to move the EMA, the EU's regulatory body, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K. 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. Even prior to any change to the U.K.'s relationship with the EU, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our product candidates, if approved, which could adversely affect our business, financial condition, results of operations and could adversely affect the market price of our common stock.

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 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 internal computer 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 internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. 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 operations, 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. 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 could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release 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 codes and viruses, phishing and other cyberattack. The number and complexity of these threats continue to increase over time. 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. 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.

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, including due to the impact of the COVID-19 pandemic, 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, we 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.

Use of Proceeds from our Initial Public Offering of Common Stock

In June 2020, our Registration Statement on Form S-1 (No. 333-2381146) was declared effective by the SEC pursuant to which we issued and sold an aggregate of 10,350,000 shares of common stock (inclusive of 9,000,000 shares of common stock and 1,350,000 shares of common stock pursuant to the underwriters' exercise of their over-allotment option) at a public offering price of \$16.00 per share for aggregate net cash proceeds of \$148.3 million, after deducting underwriting discounts, commissions and offering costs. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The sale and issuance of 10,350,000 shares closed on June 5, 2020. Citigroup Global Markets Inc., Cowen and Company, LLC and Piper Sandler & Co. acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the Prospectus.

Repurchase of Shares of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

See Exhibit Index

Exhibit Index.

Exhibit No.	Description
3.1	<u>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).</u>
3.2	<u>Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrant's quarterly report on Form 10-Q (File No. 001-39303) filed on August 11, 2020).</u>
4.1	<u>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).</u>
10.1#*	<u>Offer Letter, by and between the Registrant and Mike Ouimette, dated August 17, 2020.</u>
31.1*	<u>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.</u>
31.2*	<u>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.</u>
32.1**	<u>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.</u>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Document
101.LAB*	XBRL Taxonomy Label Linkbase Document
101.PRE*	XBRL Taxonomy Presentation Linkbase Document

* Filed herewith

** 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

Represents management compensation plan, contract or arrangement.

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: November 10, 2020

PLIANT THERAPEUTICS, INC.

By: /s/ Bernard Coulie
Bernard Coulie, M.D., Ph.D.
President and Chief Executive Officer

By: /s/ Keith Cummings
Keith Cummings, M.D., M.B.A.
Chief Financial Officer



August 12, 2020

Dear Mike:

We are very pleased to offer you the position of General Counsel & Corporate Secretary, at Pliant Therapeutics, Inc., a Delaware corporation (the "**Company**"), with an employment commencement date by October 1, 2020. This letter outlines certain terms and conditions of your employment with the Company. We would be delighted to answer any questions you may have.

You will report to the Bernard Coulie, President & CEO at Pliant. You agree that you will devote your best efforts and your full business time to the business and affairs of the Company and its subsidiaries, and you will be expected to be present during regular business hours. Your work location will be at the Company's offices at 260 Littlefield Avenue, South San Francisco, CA 94080. This is a full-time exempt position.

Base Salary. We are offering you starting compensation at the annual salary of \$360,000, less applicable withholdings and deductions. Wages are paid semi-monthly in accordance with the Company's normal payroll procedures.

Annual Cash Incentive Bonus. Beginning with calendar year 2020, you will be eligible to receive an annual cash incentive bonus based upon the achievement of annual performance goals or objectives established and measured by the Compensation Committee (the "**Committee**") of the Company's Board of Directors (the "**Board**") in its sole discretion. You will have a target annual incentive bonus opportunity equal to 35% of your annual base salary, payable in accordance with the Company's annual cash incentive bonus program, as may be amended from time to time. Actual bonus awards may pay below or above your target opportunity, including a zero payout, based on your and the Company's achievement of the applicable performance goals or objectives. In order to earn a bonus for any particular calendar year of employment, you must remain employed by the Company through the date the bonus is paid.

Incentive Compensation. In addition, if you decide to join the Company, subject to approval by the Board or the Committee, following the commencement of your employment, you will be granted an option to purchase 108,240 shares of the Company's Common Stock at an exercise price per share equal to the fair market value per share of such Common Stock on the date of grant (the "**Option**"). Twenty-five percent (25%) of the shares subject to the Option shall vest on the one-year anniversary of the commencement date of your employment (the "**Vesting Commencement Date**"), and 1/48th of the shares subject to the Option shall vest each month thereafter on the same day of the month as the Vesting Commencement Date (or if there is no corresponding day, on the last day of such month), subject to your continued service relationship

with the Company through each such date. Your Option shall be subject to the terms and conditions of the Company's 2020 Stock Option and Incentive Plan, as amended from time to time, and form of stock option agreement thereunder, which you will be required to sign as a condition to receiving the Option. No right to any stock is earned or accrued until such time that Company Common Stock is delivered to you upon the exercise of the Option, nor does the Option confer any right to continue vesting, employment or other service relationship with the Company.

Employee Benefits. You will be eligible to participate in the Company's standard employee benefits including vacation, sick leave, medical, dental, life, 401(k), accidental life and dismemberment, and disability benefits, as in effect at the time of hire. Certain participation costs for our employee benefit programs are borne by our employees. Participation in our employee benefit programs is subject to the terms of the underlying plans and requirements established by the group insurance carriers. The Company reserves the right to discontinue or amend its employee benefits, including group insurance programs, from time to time in its sole discretion. Participation in any benefit program is not to be regarded as assurance of continued employment or other service relationship with the Company for any particular period of time.

No conflicts. By signing below, you agree that there is no lawful reason to prevent you from accepting a position with the Company. We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed by the Company. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position with the Company, and you represent that such is the case.

Company Policies. As a Company employee, you will be expected to abide by the Company's rules and policies which may change from time to time in accordance with applicable laws. Such policies may include, without limitation, stock ownership guidelines, clawback policies, insider trading policies and policies regarding hedging or pledging of Company Common Stock.

Confidential Information/Nondisclosure/Nonsolicitation of Employees. As a condition of your employment with the Company, you will be required to sign the Company's Confidential Information and Invention Assignment Agreement, a copy of which is enclosed (the "**Confidentiality Agreement**"). For the avoidance of doubt, nothing contained in this letter or the Confidentiality Agreement limits your ability to report possible violations of law or regulation to, or file a charge or complaint with any federal, state or local governmental agency or commission ("**Government Agencies**"). Further, nothing in this letter or the Confidentiality Agreement shall limit your ability under applicable law to (i) disclose in confidence trade secrets to federal, state, and local government officials, or to an attorney, for the sole purpose of reporting or investigating a suspected violation of law, (ii) disclose trade secrets in a document filed in a lawsuit or other proceeding, but only if the filing is made under seal and protected from public disclosure or (iii) communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company.

Dispute Resolution Arbitration. As a condition of your employment, you must sign the enclosed Mutual Arbitration Agreement which you should carefully review. Also enclosed are the related JAMS Rules.

At-Will Employment. Your employment is at will, which means that either you or the Company can terminate your employment with the Company at any time with or without notice and with or without cause. Nothing in this letter or the Offer Package Documents (as defined below) shall be construed to alter the at-will nature of your employment relationship with the Company. In addition, nothing in this letter prohibits the Company from terminating or modifying any of its compensation or benefits programs at any time.

Conditions to Employment. The Company reserves the right to conduct background investigations and reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such background investigations and reference checks. For purposes of federal immigration law, you are required, as a condition of employment, to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire or our employment relationship with you may be terminated.

Severability. Should any provision contained in this letter be held as invalid, illegal or unenforceable, such holding shall not affect the validity of the remainder of this letter, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth herein.

Enclosures. The Confidentiality Agreement and the Mutual Arbitration Agreement are collectively referred to as the “*Offer Package Documents*.”

Acceptance of Offer. To accept the Company’s offer of employment, please sign and date this letter in the space provided below and return it to me no later than seven (7) days after the date of this letter (the “**Offer Deadline**”) along with the Offer Package Documents. A duplicate original of this letter is enclosed for your records.

Entire Agreement. This letter, along with the Offer Package Documents, sets forth the terms of your employment with the Company and supersedes any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by you and the Company’s Chief Executive Officer. This offer of employment will terminate if it is not accepted, signed and returned by the Offer Deadline.

We are excited by the prospect of your joining our team and our working together to promote you and the Company’s success.

Sincerely,

/s/Bernard Coulie
Bernard Coulie, M.D., Ph.D.
President and Chief Executive Officer

Agreed to and accepted:

Signature: /s/ Mike Ouimette

Printed Name: Mike Ouimette

Date: 8/17/2020

Enclosures: Confidential Information and Invention Assignment Agreement; Mutual Arbitration Agreement; JAMS Rules; Executive Severance Document, Executive Severance Letter

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

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

Date: November 10, 2020

/s/ Bernard Coulie

Bernard Coulie, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

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

Date: November 10, 2020

/s/ Keith Cummings

Keith Cummings, M.D., MBA
Chief Financial Officer
(Principal Financial Officer)

**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 September 30, 2020, 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: November 10, 2020

/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.