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, 2021

OR

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

For the transition period from to

Commission File Number: 001-39386

ALX ONCOLOGY HOLDINGS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-0642577**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
323 Allerton Avenue, South San Francisco, **California**	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 650-466-7125

Former name, former address, and former fiscal year, if changed since last report:
866 Malcolm Road, Suite 100
Burlingame, California 94010

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ALXO	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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
Emerging growth company	☒		

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

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

As of November 8, 2021, the registrant had 40,499,538 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and our ability to grow a sales team;
- the implementation of our strategic plans for our business and product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates for various diseases;
- our reliance on third parties to conduct preclinical research activities, clinical trials, and for the manufacture of our product candidates;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials to demonstrate the safety and efficacy of our product candidates, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights, including our technology platform and product candidates;
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel;
- our expectations regarding the impact of the COVID-19 pandemic on our business;
- our plans for and prospects of our acquisitions and other business development activities, and our ability to successfully capitalize on these opportunities; and
- our anticipated use of our existing cash and cash equivalents.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Quarterly Report, whether as a result of any new information, future events or otherwise.

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, 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 that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

PART I—FINANCIAL INFORMATION

Item 1 – Financial Statements

ALX Oncology Holdings Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share data)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 385,149	$ 434,219
Prepaid expenses and other current assets	3,814	1,773
Total current assets	388,963	435,992
Property and equipment, net	562	52
Other assets	10,203	10
Total assets	$ 399,728	$ 436,054
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,683	$ 4
Payable and accrued liabilities due to related party	1,595	72
Accrued expenses and other current liabilities	7,210	6,128
Total current liabilities	12,488	6,204
Other non-current liabilities	2,068	5
Total liabilities	14,556	6,209
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, $0.001 par value; 1,000,000,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; 40,486,287 and 39,844,522 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	40	40
Additional paid-in capital	558,679	548,327
Accumulated deficit	(173,547)	(118,522)
Total stockholders' equity	385,172	429,845
Total liabilities and stockholders' equity	$ 399,728	$ 436,054

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Related-party revenue	$ —	$ —	$ —	$ 1,182
Operating expenses:				
Research and development	18,214	5,328	39,276	16,819
General and administrative	6,362	4,481	15,807	9,126
Cost of services for related-party revenue	—	—	—	1,075
Total operating expenses	24,576	9,809	55,083	27,020
Loss from operations	(24,576)	(9,809)	(55,083)	(25,838)
Interest expense	(4)	(226)	(10)	(660)
Other income (expense), net	14	(111)	68	(409)
Loss before income taxes	(24,566)	(10,146)	(55,025)	(26,907)
Income tax provision	—	(35)	—	(59)
Net loss and comprehensive loss	(24,566)	(10,181)	(55,025)	(26,966)
Cumulative dividends allocated to preferred stockholders	—	(578)	—	(5,202)
Net loss attributable to common stockholders	$ (24,566)	$ (10,759)	$ (55,025)	$ (32,168)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (0.36)	$ (1.37)	$ (2.67)
Weighted-average shares of common stock used to compute net loss per share attributable to common stockholders, basic and diluted	40,396,188	29,664,122	40,234,159	12,052,876

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)
(in thousands, except share amounts)

	Three Months Ended September 30, 2021						
	Convertible Preferred Stock		Stockholders' Equity				
			Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of June 30, 2021	—	$ —	40,325,270	$ 40	$ 553,955	$ (148,981)	$ 405,014
Issuance of common stock under equity incentive plan	—	—	161,017	—	533	—	533
Stock-based compensation	—	—	—	—	4,191	—	4,191
Net loss	—	—	—	—	—	(24,566)	(24,566)
Balance as of September 30, 2021	—	$ —	40,486,287	$ 40	$ 558,679	$ (173,547)	$ 385,172

	Three Months Ended September 30, 2020						
	Convertible Preferred Stock		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of June 30, 2020	21,369,774	$ 175,043	3,166,946	$ 3	$ 5,166	$ (89,567)	$ (84,398)
Vesting of early exercised stock options					4	—	4
Stock-based compensation	—	—	—	—	689	—	689
Reclassification of warrants from liability to equity	—	—	—	—	1,019	—	1,019
Conversion of convertible preferred stock into common stock	(21,369,774)	(175,043)	21,369,774	21	175,022	—	175,043
Cumulative dividends			2,564,759	3	(3)	—	—
Issuance of common stock in connection with initial public offering, net of underwriter discounts and issuance costs	—	—	9,775,000	10	169,531	—	169,541
Issuance of common stock under equity incentive plans	—	—	182,111		299		299
Issuance of common stock upon net exercise of warrants	—	—	48,932	—	—	—	—
Net loss	—	—	—	—	—	(10,181)	(10,181)
Balance as of September 30, 2020	—	$ —	37,107,522	$ 37	$ 351,727	$ (99,748)	$ 252,016

See accompanying notes to these condensed consolidated financial statements (unaudited).

	Nine Months Ended September 30, 2021						
	Convertible Preferred Stock		Stockholders' Equity				
			Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2020	—	$ —	39,844,522	$ 40	$ 548,327	$ (118,522)	$ 429,845
Issuance of common stock under equity incentive plan	—	—	639,552	—	2,021	—	2,021
Issuance of common stock under employee stock purchase plan	—	—	2,213	—	103	—	103
Stock-based compensation	—	—	—	—	8,228	—	8,228
Net loss	—	—	—	—	—	(55,025)	(55,025)
Balance as of September 30, 2021	—	$ —	40,486,287	$ 40	$ 558,679	$ (173,547)	$ 385,172

	Nine Months Ended September 30, 2020						
	Convertible Preferred Stock		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of December 31, 2019	10,313,808	$ 70,363	3,166,946	$ 3	$ 2,140	$ (72,782)	$ (70,639)
Issuance of convertible preferred stock, net of issuance costs	11,055,966	$ 104,680	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	26	—	26
Stock-based compensation	—	—	—	—	3,693	—	3,693
Reclassification of warrants from liability to equity	—	—	—	—	1,019	—	1,019
Conversion of convertible preferred stock into common stock	(21,369,774)	(175,043)	21,369,774	21	175,022	—	175,043
Cumulative dividends			2,564,759	3	(3)	—	—
Issuance of common stock in connection with initial public offering, net of underwriter discounts and issuance costs	—	—	9,775,000	10	169,531	—	169,541
Issuance of common stock under equity incentive plans	—	—	182,111	—	299	—	299
Issuance of common stock upon net exercise of warrants	—	—	48,932	—	—	—	—
Net loss	—	—	—	—	—	(26,966)	(26,966)
Balance as of September 30, 2020	—	$ —	$ 37,107,522	$ 37	$ 351,727	$ (99,748)	$ 252,016

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Operating activities		
Net loss	$ (55,025)	$ (26,966)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	17	197
Non-cash lease costs	460	—
Stock-based compensation	8,228	3,693
Amortization of term loan discount and issuance costs	—	339
Changes in fair value of compound derivative liability and warrants	—	650
Gain on assignment of lease	—	(126)
Changes in operating assets and liabilities		
Receivables due from related-party	—	9
Prepaid expenses and other current assets	(2,042)	(2,137)
Other assets	(10,653)	—
Accounts payable	3,620	(2,323)
Payable and accrued liabilities due to related party	386	—
Accrued expenses and other current liabilities	2,333	1,995
Other non-current liabilities	2,063	(5)
Net cash used in operating activities	(50,613)	(24,674)
Investing activities		
Purchase of property and equipment	(405)	(20)
Proceeds from assets held for sale	—	641
Net cash (used in)/provided by investing activities	(405)	621
Financing activities		
Proceeds from equity offerings, net	—	172,724
Payments of offering costs	—	(3,183)
Proceeds from exercise of stock options under equity incentive plan	2,022	299
Proceeds from issuance of common stock pursuant to employee stock purchase plan	103	—
Proceeds from issuance of convertible preferred stock, net	—	104,680
Principal payments on finance lease obligations	(177)	—
Net cash provided by financing activities	1,948	274,520
Net (decrease)/increase in cash and cash equivalents	(49,070)	250,467
Cash and cash equivalents at beginning of period	434,219	9,017
Cash and cash equivalents at end of period	$ 385,149	$ 259,484
Supplemental disclosure		
Cash paid for interest	$ 7	$ 295
Cash paid for taxes	$ 274	$ 47
Supplemental disclosure of non-cash investing and financing activities		
Vesting of early exercised stock options	$ —	$ 26
Right-of-use asset acquired under operating leases	$ 1,812	$ —
Right-of-use asset acquired under finance leases	$ 834	$ —
Acquisition of property and equipment in accounts payable and other current liabilities	$ 129	$ 3
Conversion of convertible preferred stock into common stock upon closing of initial public offering	$ —	$ 175,043
Accumulated dividend on convertible preferred stock	$ —	$ 3

See accompanying notes to these condensed consolidated financial statements (unaudited).

(1) ORGANIZATION

Organization

ALX Oncology Holdings Inc., or the Company, is a clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 checkpoint pathway and bridge the innate and adaptive immune system. The Company was formed as a Delaware corporation on April 1, 2020, or Inception, for the purpose of completing the Company's initial public offering of its common stock and related transactions in order to carry on the business of ALX Oncology Limited. After Inception, ALX Oncology Limited became a wholly-owned subsidiary of the Company as a result of the internal reorganization. As part of the internal reorganization, all of the equity, option and warrant holders of ALX Oncology Limited became equity, option and warrant holders of the Company, holding the same number of corresponding shares, options and/or warrants in the Company as they did in ALX Oncology Limited immediately prior to the internal reorganization. The information included herein is presented as that of ALX Oncology Holdings Inc. unless such information refers to a date prior to April 1, 2020, in which case it will reflect that of ALX Oncology Limited, the predecessor company.

The Company owns subsidiaries, consisting of ALX Oncology Limited, incorporated in Ireland; ALX Oncology Inc., incorporated in the United States, and Alexo International Holdings Ltd, incorporated in Malta; Alexo Therapeutics International, incorporated in the Cayman Islands, which is a wholly-owned subsidiary of Alexo International Holdings Ltd. and Sirpant Therapeutics, incorporated in the Cayman Islands, which is a wholly-owned subsidiary of Alexo Therapeutics International, or collectively, the Subsidiaries.

As of September 30, 2021, the Company has devoted substantially all of its efforts to the product development as well as formation and financing of the Company, and has not realized product revenues from its planned principal operations. The Company has no manufacturing facilities and all manufacturing related activities are contracted out to third-party service providers.

Management expects to incur additional losses in the future to conduct product candidate research and development and to conduct pre-commercialization activities and recognizes that the Company will likely raise additional capital to fully implement its business plan. The Company intends to raise such capital through the sale of additional equity, debt financings or strategic alliances with third parties. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms acceptable to the Company. If the Company is unsuccessful in its efforts to raise additional financing, the Company could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate some of its development programs or its future commercialization efforts, out-license intellectual property rights to its product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all. The Company believes that the existing capital resources will be sufficient to fund the projected operating requirements for at least the next twelve months.

(2) SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP and applicable rules and regulations of the Securities and Exchange Commission, or SEC regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this quarterly report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 18, 2021.

The condensed consolidated balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date, but does not include all disclosures including notes required by GAAP.

The accompanying condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year ending December 31, 2021.

All intercompany balances and transactions have been eliminated in consolidation.

Reclassifications

Certain reclassifications have also been made within the condensed consolidated balance sheet as of December 31, 2020 to conform to the current year presentation. The Company reclassified approximately $0.1 million out of accrued expenses and other current liabilities into payable and accrued liabilities due to related-party. Total current liabilities as of December 31, 2020 did not change as a result of these reclassifications.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates, including those related to the estimated useful lives of long-lived assets, clinical trial accruals, fair value of assets and liabilities, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could materially differ from those estimates.

Significant Accounting Policies

With the exception of the change in the accounting for leases as a result of the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases, Topic 842, or Accounting Standards Codification (ASC) 842, on January 1, 2021, there have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, leases are included in operating or finance lease right-of-use, or ROU, assets; current operating or finance lease liabilities; and non-current operating or finance lease liabilities.

Lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The incremental borrowing rate is reevaluated upon a lease modification. The Company considered information available at the adoption date of ASC 842 to determine the incremental borrowing rate for leases in existence as of this date. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Lease expense for operating leases is recognized on a straight-line basis over the lease term. For finance leases, ROU assets are amortized on a straight-line basis over the shorter of the expected useful life or the lease term, and the carrying amount of the lease liability is adjusted to reflect interest, which is recorded in interest expense.

The Company elected to apply each of the practical expedients described in Topic 842 which allow companies (i) not to reassess prior conclusions on whether any expired or existing contracts are or contain a lease, lease classification, and initial direct costs, (ii) combine lease and non-lease components for all underlying assets groups, and (iii) not recognize ROU assets or lease liabilities for short term leases. A short-term lease is a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02, Topic 842, Leases (ASU 2016-02). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both operating and finance leases. ASU No. 2016-02 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. In June 2020, the FASB issued ASU No. 2020-05, which extended the effective date of ASU No. 2016-02 for non-public business entities, including smaller reporting companies, to fiscal years beginning after December 15, 2021, with early adoption permitted. The Company adopted ASC 842 on January 1, 2021 using the alternative modified transition method, which applies the standard as of the adoption date and therefore, the Company has not applied the standard to the comparative periods presented in the Company's financial statements. The Company elected the following practical expedients:

(i) not to reassess prior conclusions on whether any expired or existing contracts are or contain a lease, lease classification, and initial direct costs;

(ii) combine lease and non-lease components

(iii) not to recognize ROU assets or lease liabilities for short term leases

As a lessee, the primary impact of the adoption of ASC 842 was the recognition of operating and finance lease ROU assets of $0.3 million and $0.2 million, respectively, and operating and finance lease liabilities of $0.3 million and $0.2 million, respectively, as of January 1, 2021. ROU assets are presented within other assets, current lease liabilities are presented within accrued expenses and other current liabilities, and non-current lease liabilities are presented within other non-current liabilities on the condensed consolidated balance sheet. See Note 5 "Leases" for additional details.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes, Topic 740: Simplifying the Accounting for Income Taxes, which is intended to simplify various aspects related to accounting for income taxes. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2021. ASU 2019-12 is effective for the Company beginning January 1, 2022. Early adoption is permitted. The Company adopted this standard as of January 1, 2021 on a prospective basis and there was no material impact on its condensed consolidated financial statements and disclosures as a result of the adoption.

(3) FAIR VALUE OF FINANCIAL INSTRUMENTS

The fair value of the Company's financial assets and liabilities are determined in accordance with the fair value hierarchy established in ASC 820, Fair Value Measurements and Disclosures. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy of ASC 820 requires an entity to maximize the use of observable inputs when measuring fair value and classifies those inputs into three levels:

Level 1—Observable inputs, such as quoted prices in active markets

Level 2—Inputs, other than the quoted prices in active markets, which are observable either directly or indirectly such as quoted prices for similar assets or liabilities; quoted prices 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 instrument's anticipated life

Level 3—Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions

Cash and cash equivalents are reported at their respective fair values on the Company's condensed consolidated balance sheets. Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. If quoted market prices are not available for the specific security, then the Company would estimate fair value by using quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, reported trades and broker/dealer quotes. Where applicable the market approach utilizes prices and information from market transactions for similar or identical assets.

The following table sets forth the Company's financial assets that are measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	As of September 30, 2021			
	Level 1	Level 2	Level 3	Fair Value
Financial assets				
Cash equivalents				
Money market funds	$ 375,667	$ —	$ —	$ 375,667

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Fair Value
Financial assets				
Cash equivalents				
Money market funds	$ 424,115	$ —	$ —	$ 424,115

The Company did not have any outstanding financial liabilities to be re-measured on a recurring basis as of September 30, 2021 and December 31, 2020.

There were no transfers of assets or liabilities between the fair value measurement levels during the three and nine months ended September 30, 2021 and 2020.

The carrying values of the Company's financial instruments, such as accounts payable and accrued expenses and other current liabilities, approximated fair value due to the short-term nature of these items.

(4) BALANCE SHEET COMPONENTS

Property and Equipment, Net

The following table presents the components of property and equipment, net as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Computer hardware and software	$ 195	$ 63
Furniture and fixtures	167	9
Leasehold improvements	229	5
Laboratory Equipment	10	—
Property and equipment, gross	601	77
Less: accumulated depreciation and amortization	(39)	(25)
Total property and equipment, net	$ 562	$ 52

Depreciation and amortization expense was insignificant during the three and nine months ended September 30, 2021. Depreciation and amortization expense was $0.1 million and $0.2 million during the three and nine months ended September 30, 2020, respectively.

Other Assets

As of September 30, 2021, other assets consist of $6.6 million of prepaid clinical expenses, $1.9 million of operating lease ROU assets, $0.9 million of finance lease ROU assets, $0.6 million of prepaid contract manufacturing costs, and $0.2 million of other deposits. As of December 31, 2020, the amount of other assets was considered insignificant.

Accrued Expenses and Other Current Liabilities

The following table presents the components of accrued expenses and other current liabilities as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Accrued clinical and nonclinical study costs	3,299	1,401
Accrued compensation	2,173	1,974
Accrued contract manufacturing	654	2,123
Finance lease liabilities, current	429	—
Accrued professional fees	279	300
Operating lease liabilities, current	274	—
Other	102	151
Accrued federal income tax	—	179
Total accrued expenses and other current liabilities	7,210	6,128

(5) LEASES

In 2017, the Company entered into a lease agreement for office space for a period of five years and four months, commencing February 1, 2018 and ending May 31, 2023. In July 2020, the Company (i) assigned to Tallac Therapeutics, Inc., or Tallac Therapeutics, a related party, the Company's lease with respect to the premises located at 866 Malcolm Road, Burlingame, California, and (ii) entered a sub-lease agreement for the same premise from Tallac Therapeutics. The sub-lease is an operating lease. As of September 30, 2021, the Company had approximately $0.2 million right-of-use asset and lease liability related to this lease.

The Company evaluated its vendor contracts to identify embedded leases, if any, and noted that a pharmaceutical support services agreement entered into in May 2016, included leases under ASC 842 because the Company has the right to direct the use of certain equipment. The embedded leases commenced in September 2020 and expire in August 2023 with no stated option to extend the term. The Company classified the leases as finance leases.

In May 2021, the Company entered into a lease agreement for office space totaling approximately 10,000 square feet at 323 Allerton Avenue, South San Francisco, California. The term of the lease is from July 5, 2021 to August 31, 2026, with early entry date of June 6, 2021. The lease does not provide an option to extend after it expires. The total lease payments for the life of the lease is approximately $2.0 million. The Company obtained the right to direct the usage of the office space on the early entry date, and therefore considered June 6, 2021 as the lease commencement date. The lease was evaluated as an operating lease. As of September 30, 2021, the Company had ROU asset and lease liability of approximately $1.7 million and $1.9 million, respectively, related to this lease.

The ROU assets recorded under the operating lease and finance lease were $1.9 million and $0.9 million, respectively, at September 30, 2021. The amounts were included in the other assets on the condensed consolidated balance sheet.

The following table presents the maturities and balance sheet information of the Company's operating and finance lease liabilities as of September 30, 2021 (in thousands, except lease term and discount rate):

	September 30, 2021	
	Operating Leases	Finance Leases
2021 (remaining three months)	$ 102	$ 108
2022	519	432
2023	482	288
2024	433	—
2025	446	—
Thereafter	301	—
Total lease payments	2,283	828
Less: imputed interest	(184)	(14)
Total lease liabilities	$ 2,099	$ 814
Lease liabilities: current (i)	$ 416	$ 429
Lease liabilities: non-current (ii)	1,683	385
Total lease liabilities	$ 2,099	$ 814
Weighted average remaining lease term (in years)	4.5	1.9
Weighted average discount rate	3.5%	1.7%

(i) Current lease liabilities are presented within accrued expenses and other current liabilities and payable and accrued liabilities due to related party of $0.7 million and $0.1 million, respectively, on the condensed consolidated balance sheet.

(ii) Non-current lease liabilities are presented within other non-current liabilities on the condensed consolidated balance sheet, which includes $0.1 million due to Tallac Therapeutics.

The following table presents the components of lease costs (in thousands):

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Operating lease cost	$ 132	$ 229
Variable lease cost and other, net (i)	22	61
Finance lease cost		
Amortization of right-of-use assets	112	257
Interest	3	10
Total lease cost	$ 269	$ 557

(i) The Variable lease cost and other, net is comprised primarily of common area maintenance charges for the operating lease, which is dependent on usage. These costs are classified as operating lease expense due to the election to not separate lease and non-lease components. These costs were not included within the measurement of the Company’s operating lease ROU assets and operating lease liabilities.

The following table presents supplemental cash flow information related to leases:

	Nine Months Ended September 30, 2021
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 141
Operating cash flows from finance leases	$ 7
Financing cash flows from finance leases	$ 177
Right-of-use asset acquired under leases	
Operating leases	$ 1,812
Finance leases	$ 834

ASC 840 Disclosures

The Company elected the alternative modified transition method, which applies ASC 842 as of the effective date on January 1, 2021. Prior to the adoption of ASC 842, the Company applied ASC 840 to its lease transactions.

The following table presents the future minimum lease commitments under the Company's operating leases as of December 31, 2020, as previously disclosed (in thousands):

	December 31, 2020
2021	140
2022-2023	206
Total future minimum lease payments	$ 346

Rent expense was $0.1 million and $0.5 million, respectively, for the three and nine months ended September 30, 2020.

(6) TERM LOAN AND RELATED DERIVATIVES

The Company's wholly-owned subsidiaries Alexo Therapeutics International and Sirpant Therapeutics, as borrowers, entered into a Loan and Security Agreement, or the Loan Agreement, dated as of December 20, 2019, with Silicon Valley Bank, or SVB, and WestRiver, collectively as lenders, and SVB, as administrative agent and collateral agent. On the closing date of the Loan Agreement in December 2019, $6.0 million was funded to the Company. In December 2020, the Company fully repaid the loan balance.

In conjunction with the Loan Agreement, the Company issued warrants to purchase Series B convertible preferred stock to SVB and WestRiver, and recorded a warrant liability of approximately $0.4 million at the date of issuance. The Company also determined that certain loan features were embedded derivatives requiring bifurcation and separate accounting, and recorded a term loan compound derivative liability of approximately $51,000. The Company measured its Series B convertible preferred stock warrant liability and term loan compound derivative liability at fair value on a recurring basis, which were classified as Level 3 liabilities. During the three and nine months ended September 30, 2020, the increases in fair value in warrant liability were approximately $263,000 and $658,000, respectively. During the three and nine months ended September 30, 2020, the decreases in fair value in compound derivative liability were approximately $21,000 and $8,000, respectively. Those amounts were recognized as a component of other income (expense), net in the condensed consolidated statement of operations and comprehensive loss. The Company reclassified the preferred stock warrant liability balance into additional paid-in capital in July 2020 with no further re-measurement required, as the common stock warrants are considered permanent equity effective with the completion of the initial public offering. The compound derivative liability was extinguished upon the extinguishment of the host instrument in December 2020.

(7) STOCKHOLDERS' EQUITY

On July 21, 2020, the Company's amended and restated certificate of incorporation became effective, authorizing 1,000,000,000 shares of common stock and 100,000,000 shares of undesignated preferred stock. As of September 30, 2021 and December 31, 2020, the Company had 40,486,287 and 39,844,522 shares of common stock outstanding, respectively.

Common Stock

Common stock reserved for future issuance as of September 30, 2021 and December 31, 2020, consists of the following:

	September 30, 2021	December 31, 2020
Stock options issued and outstanding	4,892,109	4,857,308
Restricted stock units issued and outstanding	15,075	—
Remaining shares available for future issuance under equity incentive plan	3,739,798	2,835,443
Employee Stock Purchase Plan shares authorized for future issuance	796,232	400,000
Total	9,443,214	8,092,751

(8) STOCK-BASED COMPENSATION

2020 Amended and Restated Equity Incentive Plan

On April 1, 2020, the board of directors approved a new equity incentive plan, or the 2020 Equity Incentive Plan, that replaced the 2015 Share Award Scheme. In July 2020, the Company adopted the Amended and Restated 2020 Equity Incentive Plan, or the 2020 Plan. The 2020 Plan replaced the Company's 2020 Equity Incentive Plan and a total of 7,874,862 shares were reserved under the 2020 Plan.

Unless the board of directors provides otherwise, beginning on January 1, 2021, and ending on (and inclusive of) January 1, 2030, the maximum number of shares available for issuance under the 2020 Plan automatically increases on the first day of each fiscal year by an amount equal to the least of:

- 4,000,000 shares;
- four percent of the outstanding shares of the Company's common stock on the last day of the immediately preceding fiscal year; or
- such number of shares as the board of directors may determine no later than the last day of the immediately preceding fiscal year.

Accordingly, on January 1, 2021, the number of shares available under the 2020 Plan was increased by 1,593,781 shares.

Employee Stock Purchase Plan

In July 2020, the Company's board of directors and stockholders approved the ALX Oncology Holdings Inc. 2020 Employee Stock Purchase Plan, or the ESPP. The ESPP allows eligible employees to have up to 15 percent of their eligible compensation withheld and used to purchase common stock, subject to a maximum of $25,000 worth of stock purchased in a calendar year or no more than 3,000 shares in a purchase period, whichever is less. The ESPP allows for offering periods of up to 27 months consisting of one or more purchase periods. In January 2021, the board of directors approved the first offering period with a simultaneous purchase period beginning February 1, 2021 and ending June 30, 2021. The board of directors delegated the Company's Chief Executive Officer and the Chief Financial Officer to administrate the ESPP for subsequent offering periods. Eligible employees can purchase the Company's common stock at the end of the purchase period at 85% of the lower of the closing price of the Company's common stock on the Nasdaq Global Select Market on the first day of the offering period and the last day of the purchase period**.**

The initial number of shares of common stock available for issuance under the ESPP was 400,000. Unless the board of directors provides otherwise, beginning on January 1, 2021, the maximum number of shares available for sale under the ESPP automatically increases on the first trading day in January of each calendar year during the term of the ESPP by an amount equal to the least of:

- 800,000 shares;
- one percent of the outstanding shares of the Company's common stock on the last day of the immediately preceding fiscal year; or
- such number of shares as the board of directors may determine no later than the last day of the immediately preceding fiscal year.

Accordingly, on January 1, 2021, the number of shares available under the ESPP was increased by 398,445 shares. As of September 30, 2021, 2,213 shares of common stock have been purchased under the ESPP, and the number of shares of common stock available for issuance under the ESPP was 796,232.

Stock-based Compensation Expense

Total stock-based compensation expense recognized in the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 1,519	$ (359)	$ 2,813	$ 2,008
General and administrative	2,672	1,048	5,415	1,685
	$ 4,191	$ 689	$ 8,228	$ 3,693

(9) RELATED-PARTY TRANSACTIONS

Related-party revenue

In June 2018, the Company entered into a Research and Development Services Agreement, or Tollnine Agreement, with Tollnine Therapeutics, Inc., or Tollnine, a related-party of the Company, to provide research and development services to Tollnine. The Company's Chief Executive Officer was the Chief Executive Officer of Tollnine until April 2020 but remains on the Board of Directors. In addition, two of the Company's investors were also investors in Tollnine. As such, Tollnine was deemed to be a related-party. The Tollnine Agreement had an initial term of 3 years. The services were provided at a price based on the costs incurred by the Company plus a mark-up equal to 10% of such costs. The Company recognized revenue when Tollnine, as the Company's customer, obtained control of promised goods or services, in an amount that reflects the consideration which the Company received in exchange for those goods or services.

The Company recognized related-party revenues of zero and $1.2 million for the three and nine months ended September 30, 2020, respectively, under the Tollnine Agreement. Effective as of July 1, 2020, the Company terminated the Tollnine Agreement and entered into the Tallac Services Agreement with Tallac Therapeutics (formerly known as Tollnine).

Tallac Service Agreement

The Company entered into a research and development services agreement, or the Tallac Services Agreement, with Tallac Therapeutics effective as of July 1, 2020. The Tallac Services Agreement provides that Tallac Therapeutics will provide certain preclinical research services to the Company for a service fee based on the costs incurred by Tallac Therapeutics plus a mark-up equal to 10% of such costs. The Tallac Services Agreement has an initial term of four years and is renewed automatically for additional one year terms thereafter. The Company records the payments for the research and development services as research and development costs within the condensed consolidated statement of operations and comprehensive loss. The Company recorded $0.1 million and $0.6 million, respectively, as research and development costs for the three and nine months ended September 30, 2021. The Company recorded $0.4 million as research and development costs for the three and nine months ended September 30, 2020.

Tallac Collaboration Agreement

On March 4, 2021, the Company entered into a Collaboration Agreement with Tallac Therapeutics to jointly develop, manufacture, and commercialize a novel class of cancer immunotherapeutics. The collaboration builds on the Company's expertise in developing therapies that block the CD47 checkpoint pathway and expands its immuno-oncology pipeline. The companies will leverage their respective scientific and technical expertise to advance an anti-SIRPα antibody conjugated to a Toll-like receptor 9, or TLR9, agonist for targeted activation of both the innate and adaptive immune systems. The key economic components of the collaboration transaction include that both parties will share equally (a) in the cost and expenses of research and development and (b) any profit or loss.

The Company accounts for research and development, or R&D, costs in accordance ASC 730, Research and Development, which states R&D costs must be charged to expense as incurred. Accordingly, the Company records its internal and third-party costs associated with the collaboration as R&D expenses as incurred. When the Company is entitled to reimbursement of the R&D expenses that it incurs under the collaboration, the Company records those reimbursable amounts as a reduction to R&D expenses. The Company also records as R&D expenses, the portion of Tallac's expenses that the Company is obligated to reimburse, in the period when Tallac incurs such expenses. During the three and nine months ended September 30, 2021, the Company recorded $0.8 million and $1.4 million, respectively, in R&D expenses related to the collaboration.

The Collaboration Agreement includes the right to set off clause, as such, the Company records the amount due to or reimbursable from Tallac on a net basis. As of September 30, 2021, the Company had $1.4 million of accrued expenses due to Tallac which was presented within the payable and accrued liabilities due to related party on the condensed consolidated balance sheet.

(10) NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (24,566)	$ (10,181)	$ (55,025)	$ (26,966)
Less: cumulative preferred dividends allocated to preferred stockholders	—	(578)	—	(5,202)
Net loss attributable to common stockholders	$ (24,566)	$ (10,759)	$ (55,025)	$ (32,168)
Denominator:				
Weighted-average shares of common stock outstanding	40,396,188	29,664,122	40,234,159	12,052,876
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (0.36)	$ (1.37)	$ (2.67)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods presented as the inclusion of all potential common stock outstanding would have been anti-dilutive.

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been anti-dilutive:

	September 30,	
	2021	2020
Convertible preferred stock	—	21,369,774
Warrants to purchase convertible preferred stock	—	61,292
Common stock subject to repurchase	—	3,908
Options issued and outstanding	4,892,109	3,874,815
Restricted stock units issued and outstanding	15,075	—
Estimated common stock issuable under the employee stock purchase plan	2,001	—
Total	4,909,185	25,309,789

(11) COMMITMENTS AND CONTINGENCIES

Guarantees and Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of September 30, 2021.

Contingencies

From time to time, the Company may be a party to various claims in the normal course of business. Legal fees and other costs associated with such actions will be expensed as incurred. The Company will assess, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates will be recorded when and if it is determined that a loss related

matter is both probable and reasonably estimable. For the nine months ended September 30, 2021 the Company had no pending or threatened litigation.

Leases

The Company has operating leases related to its office spaces and embedded finance leases related to a pharmaceutical support services agreement. See Note 5 "Leases" for details of related commitments.

License Agreements

In March 2015, the Company entered into a license agreement, or the Stanford Agreement, with the Board of Trustees of the Leland Stanford Junior University, or Stanford, under which the Company obtained a worldwide, royalty-bearing, sublicensable license under certain patents relating to the Company's current product candidates, to develop, manufacture and commercialize products for use in certain licensed fields, the scope of which would include the application of the licensed intellectual property in oncology. The Company paid Stanford a nonrefundable license royalty and reimbursed Stanford for past patent expenses, together totaling less than $0.1 million, and granted Stanford a specified number of shares of common stock of the Company. The Company is required to make milestone payments up to an aggregate of $5.0 million in respect of a specified number of licensed products that successfully satisfy certain clinical and regulatory milestones. The Company recorded the first milestone payment of $0.2 million during the three months ended June 30, 2021. The Company did not record any other milestone payments during the three months ended September 30, 2021.

In June 2016, the Company entered into a license agreement with Selexis SA, or Selexis, under which the Company obtained a worldwide, royalty-bearing, sublicensable license under certain patents, know-how and other intellectual property, to use Selexis generated cell lines to manufacture evorpacept (also known as ALX148), and to make, use and sell licensed product containing such compound in all fields of use. The Company paid Selexis a nominal one-time fee and will pay Selexis an annual maintenance fee. The Company also agreed to pay Selexis milestone payments up to an aggregate of 1.2 million Swiss Francs in respect of all licensed products developed and/or commercialized under the grant that successfully satisfies certain milestone events. The Company recorded a milestone payment of $0.1 million during the three months ended June 30, 2021. The Company did not record any other milestone payments during the three months ended September 30, 2021.

In March 2017, the Company entered into an agreement with Crystal Bioscience Inc. (now a subsidiary of Ligand Pharmaceuticals Incorporated), or Crystal, under which the Company obtained an assignment of certain patents, covering certain SIRPα antibodies. Under this agreement, the Company also received a worldwide, royalty-bearing non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicenses, under certain of Crystal's background patents and know-how necessary to commercialize the rights under the assigned patents. The Company agreed to pay Crystal milestone payments up to $11.1 million in respect of all licensed products developed under the assigned patents, that successfully satisfy certain clinical and regulatory milestones, each milestone being paid only once for all products. No milestone payments have been recorded as of September 30, 2021.

Other Contractual Obligations and Other Commitments

In November 2015, the Company entered into a Master Service Agreement, or the MSA, with KBI Biopharma, Inc. relating to formulation development, process development and current good manufacturing practices, or cGMP, manufacturing of evorpacept for use in clinical trials on a project basis. The MSA had an initial term of three years with successive one-year renewal periods, is cancellable upon notice and is non-exclusive. Statements of work under the MSA commit the Company to certain future purchase obligations of approximately $24.1 million. In addition, the Company has commitments with two other drug product manufacturers that commit the Company to certain future purchase obligations of approximately $0.9 million. The Company expects to make payments for these commitments through 2025 based on non-cancellable commitments and forecasts that include estimates of future market demand, quantity discounts and manufacturing efficiencies that may impact timing of purchases.

The Company enters into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation.

(12) SUBSEQUENT EVENT

On October 4, 2021, the Company entered into a stock purchase agreement with ScalmiBio, Inc., or ScalmiBio, as the Company expands its pipeline with plans to develop new anti-cancer drug candidates based on ScalmiBio's platform. Under the terms of the stock purchase agreement, the Company made an initial payment to the stockholders of ScalmiBio at closing on October 4, 2021 of approximately $4.5 million in cash, net of certain expenses and adjustments, and will make an additional payment of $2.0 million at the one-year anniversary of the transaction subject to certain conditions. In addition, the Company has agreed to pay up to $35 million, in aggregate, in certain milestones based on the clinical development of the acquired ScalmiBio technology and has also agreed to pay a low single digit royalty on net sales of any products developed from the ScalmiBio acquired technology for a defined term. The Company has the option to buy-out the royalty payment, prior to the first marketing approval of the developed product.

Dr. Jaume Pons, the Company's CEO and President, and a director, was also a director of ScalmiBio prior to the acquisition, and owned 31.7% of ScalmiBio stock. As a result, Dr. Pons received or will receive his proportional share of the consideration to ScalmiBio stockholders as described above. Dr. Pons also received approximately $87,000 out of the closing proceeds for the repayment of a note and accrued interest he had loaned to ScalmiBio.

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 checkpoint pathway and bridge the innate and adaptive immune system. Cancer cells leverage CD47, a cell surface protein, as a "don't eat me" signal to evade detection by the immune system. Our company is developing a next-generation checkpoint inhibitor designed to have a high affinity for CD47 and to avoid the limitations caused by hematologic toxicities inherent in other CD47 blocking approaches. We believe our lead product candidate, evorpacept (also known as ALX148), will have a wide therapeutic window to block the "don't eat me" signal on cancer cells, and to leverage the immune activation of broadly used anti-cancer agents through combination strategies. As of September 30, 2021, we had dosed over 185 subjects with evorpacept across a range of hematologic and solid malignancies in combination with a number of leading anti-cancer agents. We plan to initiate additional studies in combination with leading anti-cancer agents. In hematologic malignancies, we have dosed 13 subjects for the treatment of myelodysplastic syndromes, or MDS, and intend to advance evorpacept into clinical development for the treatment of acute myeloid leukemia, or AML, in the fourth quarter of 2021. In solid tumors, we have initiated two randomized Phase 2 trials of evorpacept for the treatment of first-line head and neck squamous cell carcinoma, or HNSCC, and dosed the first subject in the first trial in May 2021, and dosed the first subject in the second trial in July 2021, and we also initiated a Phase 1 trial in collaboration with Zymeworks for the treatment of breast cancer and dosed the first subject in October 2021. We intend to initiate a randomized Phase 2 trial of evorpacept for the treatment of second line gastric/gastroesophageal junction, or GEJ, cancer in the fourth quarter of 2021. Based on our clinical results to date in multiple oncology indications showing encouraging anti-tumor activity and tolerability and our clinical development plans, our strategy is to pursue evorpacept as a potentially critical component for future combination treatments in oncology.

Our predecessor company, ALX Oncology Limited, an Irish private company limited by shares, was initially incorporated in Ireland on March 13, 2015 under the name Alexo Therapeutics Limited and changed its name to ALX Oncology Limited on October 11, 2018. We were then incorporated in Delaware on April 1, 2020 under the name ALX Oncology Holdings Inc. and completed an internal reorganization effective as of the same date whereby ALX Oncology Limited became our wholly-owned subsidiary and all of the stockholders, warrant holders and option holders of ALX Oncology Limited became our stockholders, warrant holders and option holders, holding the same number of corresponding shares, warrants and/or options in us as they did in ALX Oncology Limited immediately prior to the internal reorganization. The information included herein are presented as that of ALX Oncology Holdings Inc., unless such information refers to a date prior to April 1, 2020, in which case it will reflect that of our predecessor company.

Since our founding, we have devoted substantially all of our resources to identifying and developing evorpacept, advancing preclinical programs, scaling up manufacturing, conducting clinical trials and providing general and administrative support for these operations. We have no products approved for marketing and we have never received any revenue from drug product sales.

In July 2020, we consummated our initial public offering, raising net proceeds of $169.5 million, after deducting underwriting discounts and commissions of $13.0 million and offering-related expenses of $3.2 million. In December 2020, we consummated a follow-on public offering, raising net proceeds of $194.9 million, after deducting underwriting discounts and commissions of $12.5 million and offering-related expenses of $0.7 million. From inception through September 30, 2021, we have raised an aggregate of $545.3 million to fund our operations, of which $175.1 million were net proceeds from sales of our convertible preferred stock, $5.8 million were net proceeds from borrowings under a term loan, $169.5 million were net proceeds from our initial public offering and $194.9 million were net proceeds from our follow-on public offering.

We have incurred net losses in each year since inception. Our net losses were $24.6 million and $10.2 million for the three months ended September 30, 2021 and 2020, respectively, and $55.0 million and $27.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $173.5 million. Substantially all of our operating losses are a result of expenses incurred in connection with our research and development programs, primarily evorpacept, and from general and administrative expenses associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses over at least the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance evorpacept through multiple clinical trials in multiple indications;
- pursue regulatory approval of evorpacept in hematological malignancies and solid tumors;
- continue our discovery and preclinical and clinical development efforts, including our collaborations with Tallac Therapeutics and Zymeworks and our recent acquisition of ScalmiBio;
- obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- manufacture supplies for our preclinical studies and clinical trials; and
- continue to add operational, financial and management information systems to support ongoing operations as a public company.

Components of Results of Operations

Related-Party Revenue

To date, we have not generated any revenue from product sales, licenses or collaborations and do not expect to generate any revenue from the sale of products in the foreseeable future. We recognized related-party revenue related to research and development services to Tallac Therapeutics, which ceased as of July 1, 2020. If our clinical development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for any of our product candidates or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates including evorpacept. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, evorpacept, which include:

- expenses incurred in connection with the preclinical and clinical development, including expenses incurred under agreements with contract research organizations, or CROs;
- expenses incurred in connection with the preclinical and clinical development, including expenses incurred under collaboration agreements;
- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- expenses related to production of clinical materials, including fees paid to contract manufacturing organizations, or CMOs;
- laboratory and vendor expenses related to the execution of preclinical studies and clinical trials; and
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

We expense research and development costs as incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered or as services are performed. We record accruals for estimated costs of research, preclinical studies and clinical trials and manufacturing development, which are a significant component of research and development expenses. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

Our research and development expenses consist primarily of costs associated with the development of our lead product candidate evorpacept and include external costs, such as fees paid to consultants, central laboratories, contractors, collaborators, CMOs and CROs in connection with our preclinical and clinical development activities.

Almost all of our research and development expenses to date related to the clinical development of our lead product candidate, evorpacept. 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 progress on our existing product candidates and developing new product candidates. As our product candidates advance into later stages of development, we begin to conduct larger clinical trials. The process of conducting the necessary clinical trials 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. In addition, we will incur expenses related to the preclinical research conducted internally and through the contract with Tallac Therapeutics, as further described in Note 9 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

The successful development of our current and future product candidates is highly uncertain. This is due to the numerous risks and uncertainties, including the following:

- successful completion of preclinical studies and clinical trials;
- delays in regulators or institutional review boards authorizing us or our investigators to commence our clinical trials or in our ability to negotiate agreements with clinical trial sites or CROs;
- the number and location of clinical sites included in the trials;
- raising additional funds necessary to complete clinical development of our product candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- contracting with third-party manufacturers for clinical supplies of our product candidates;
- protecting and enforcing our rights in our intellectual property portfolio, including, if necessary, litigation; and
- maintaining a continued acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates may significantly impact the costs and timing associated with the development of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact the success, cost or timing of our clinical development programs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, business development expenses, facilities expenses, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit, accounting and tax-related services, and directors and officers liability insurance premiums. Personnel and related costs primarily consist of salaries, benefits and stock-based compensation expense. Facilities costs primarily consist of rent and maintenance of facilities.

We anticipate that our general and administrative expenses will continue to increase as a result of increased headcount, expanded infrastructure and higher consulting, legal, tax and regulatory-related services associated with maintaining compliance with stock exchange listing and SEC requirements, audit and investor relations costs, director and officer insurance premiums and other costs associated with being a public company.

Cost of Services for Related-Party Revenue

We previously incurred costs associated with related-party contract research services including direct labor and associated employee benefits, laboratory supplies and other expenses. These costs were recorded in cost of services for related-party transactions as a component of total operating expenses in the accompanying condensed consolidated statements of operations and comprehensive loss.

Interest Expense

Historically, our interest expense consisted primarily of interest expense on the term loan, amortization of deferred debt issuance costs, and interest related to finance leases.

Other Income (expense), Net

Our other income (expense), net, consists of interest income on cash balances, changes in the fair value of our convertible preferred stock warrant liability and compound derivative liability, and foreign currency re-measurement and transaction gains and losses. Prior to our initial public offering, the underlying shares of our Series B convertible preferred stock warrants were contingently redeemable, and we accounted for these warrants as a liability at fair value and re-measured the fair value at each balance sheet date. As a result of the completion of our initial public offering, the Series B convertible preferred stock warrant liability was reclassified to stockholders' equity and re-measurement was no longer required. The compound derivative liability was extinguished upon the extinguishment of the host instrument in December 2020.

Results of Operations and Net Loss

The following table summarizes our results of operations for the three and nine months ended September 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2021	2020	$	%	2021	2020	$	%
Related-party revenue	$ —	$ —	$ —	NM %	$ —	$ 1,182	$ (1,182)	(100) %
Operating expenses								
Research and development	18,214	5,328	12,886	242 %	39,276	16,819	22,457	134 %
General and administrative	6,362	4,481	1,881	42 %	15,807	9,126	6,681	73 %
Cost of services for related party revenue	—	—	—	NM %	—	1,075	(1,075)	(100) %
Total operating expenses	24,576	9,809	14,767	151 %	55,083	27,020	28,063	104 %
Loss from operations	(24,576)	(9,809)	(14,767)	151 %	(55,083)	(25,838)	(29,245)	113 %
Interest expense	(4)	(226)	222	(98) %	(10)	(660)	650	(98) %
Other income (expense), net	14	(111)	125	(113) %	68	(409)	477	(117) %
Loss before income taxes	(24,566)	(10,146)	(14,420)	142 %	(55,025)	(26,907)	(28,118)	105 %
Income tax provision	—	(35)	35	(100) %	—	(59)	59	(100) %
Net loss and comprehensive loss	(24,566)	(10,181)	(14,385)	141 %	(55,025)	(26,966)	(28,059)	104 %
Cumulative dividends allocated to preferred stockholders	—	(578)	578	(100) %	—	(5,202)	5,202	(100) %
Net loss attributable to common stockholders	$ (24,566)	$ (10,759)	$ (13,807)	128 %	$ (55,025)	$ (32,168)	$ (22,857)	71 %

Related-Party Revenue

Related-party revenue for the three and nine months ended September 30, 2020 was zero and $1.2 million, respectively, which was generated solely from payments received for reimbursement of research and development expenses pursuant to the Tollnine Agreement, as further described in Note 9 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. Related-party revenue for the three and nine months ended September 30, 2021 was zero due to the termination of the Tollnine Agreement as of July 1, 2020.

Research and Development Expenses

The following table summarizes our research and development expenses incurred for the three and nine months ended September 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2021	2020	$	%	2021	2020	$	%
Clinical development costs	$ 14,618	$ 4,612	$ 10,006	217 %	$ 30,724	$ 11,913	$ 18,811	158 %
Personnel and related costs	1,936	1,039	897	86 %	5,146	2,741	2,405	88 %
Stock-based compensation expense	1,519	(359)	1,878	(523) %	2,813	2,008	805	40 %
Other research and development costs	141	36	105	292 %	593	157	436	278 %
Total research and development expense	$ 18,214	$ 5,328	$ 12,886	242 %	39,276	16,819	$ 22,457	134 %

Research and development expenses for the three months ended September 30, 2021 was $18.2 million, compared to $5.3 million for the three months ended September 30, 2020. The increase of $12.9 million was primarily attributable to (i) an increase of $10.0 million in clinical and development costs due to $8.7 million higher expenses associated with increased clinical costs mainly associated with a higher number of active clinical trials and increased patient enrollment and other research costs in advancement of our current lead product candidate, evorpacept, $0.8 million related to collaborations, of which $0.6 million was related to the Tallac Collaboration, and $0.3 million related to regulatory consulting expenses, (ii) an increase of $1.9 million in stock-based compensation expense mainly due to additional stock option awards granted in 2021 at higher fair values and negative stock-based compensation expense due to a reduction recorded in the corresponding prior period, (iii) an increase of $0.9 million in personnel expense due to $0.7 million increase driven by headcount growth and our share of Tallac's personnel expenses of $0.2 million related to the collaboration and (iv) an increase of $0.1 million in other research and development costs due to increase in clinical trial insurance as we continue to initiate new trials.

Research and development expenses for the nine months ended September 30, 2021 was $39.3 million, compared to $16.8 million for the nine months ended September 30, 2020. The increase of $22.5 million was primarily attributable to (i) an increase of $18.8 million in clinical and development costs due to $16.4 million higher expenses associated with increased pre-clinical costs, increased clinical costs mainly associated with a higher number of active clinical trials and increased patient enrollment and other research costs in advancement of our current lead product candidate, evorpacept, $1.6 million related to collaborations, of which $1.0 million was related to the Tallac Collaboration, and an increase of $0.5 million in regulatory consulting expenses, (ii) an increase of $2.4 million in personnel and related costs due to $2.0 million higher expense driven by headcount growth and recruiting expenses and our share of Tallac's personnel expenses of $0.4 million related to the collaboration, (iii) an increase of $0.8 million in stock-based compensation expense mainly due to an increase of $3.1 million in stock-based compensation expense driven by additional stock option awards granted in 2021 at higher fair values, offset by a decrease of $2.3 million expense as we modified stock option awards for former employees who transferred to Tallac Therapeutics in the nine months ended September 30, 2020 and (iv) an increase of $0.4 million in other research and development costs due to an increase of $0.3 million milestone payments triggered by the initiation of our Phase 2 trials and an increase of $0.1 million clinical trial insurance as we continue to initiate our trials.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred for the three and nine months ended September 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2021	2020	$	%	2021	2020	$	%
Personnel and related costs	$ 1,444	$ 1,339	$ 105	8 %	$ 3,839	$ 2,577	$ 1,262	49 %
Stock-based compensation expense	2,672	1,048	1,624	155 %	5,415	1,685	3,730	221 %
Other general and administrative costs	2,246	2,094	152	7 %	6,553	4,864	1,689	35 %
Total general and administrative expenses	$ 6,362	$ 4,481	$ 1,881	42 %	$ 15,807	$ 9,126	$ 6,681	73 %

General and administrative expenses for the three months ended September 30, 2021 was $6.4 million, compared to $4.5 million during the three months ended September 30, 2020. This increase of $1.9 million was primarily attributable to (i) an increase of $1.6 million in stock-based compensation driven by $1.8 million increase due to additional stock option awards granted in 2021 at higher fair values, offset by a decrease of $0.2 million as we recorded additional expense related to the modification of stock option awards for a former employee in the three months ended September 2020, (ii) an increase of $0.1 million other general and administrative costs primarily driven by an increase of $0.5 million due to corporate legal fees, general business insurance fees, SOX and compliance fees, partially offset by a decrease of $0.4 million in accounting and consulting service fees, which were higher in the three months ended September 30, 2020 due to the IPO and (iii) an increase of $0.1 million in personnel and related costs mainly driven by the headcount growth.

General and administrative expenses for the nine months ended September 30, 2021 was $15.8 million, compared to $9.1 million during the nine months ended September 30, 2020. This increase of $6.7 million was primarily attributable to (i) an increase of $3.9 million in stock-based compensation expense driven by additional stock option awards granted in 2021 at higher fair values, offset by a decrease of $0.2 million as we recorded additional expense related to the modification of stock option awards for a former employee in the nine months ended September 2020 while we did not have any such modification in the nine months ended September 30, 2021, (ii) an increase of $1.7 million in other general and administrative costs primarily driven by $2.2 million increase due to general business insurance fees, corporate legal fees, SOX and compliance fees, and filing fees, partially offset by a decrease of $0.5 million in accounting and consulting service fees, which were higher in the nine months ended September 30, 2020 due to the IPO, and (iii) an increase of $1.3 million personnel and related costs primarily driven by headcount growth.

Cost of Services for Related-Party Revenue

Cost of services for related-party revenue for the three and nine months ended September 30, 2020 was zero and $1.1 million, respectively, which are attributable to fee-for-service hours provided to Tallac Therapeutics. Cost of services for related-party revenue for the three and nine months ended September 30, 2021 was zero due to the termination of the Tollnine Agreement as of July 1, 2020.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

Since our inception, we have incurred significant operating losses and have not generated any product revenue. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all, subject to marketing approval of any of our product candidates. To date, we have funded our operations with proceeds from the sales of shares of our common stock and convertible preferred stock and borrowings under our term loan. Through September 30, 2021, we have received net proceeds from sales of our convertible preferred stock, borrowings under our term loan, our initial public offering and our follow-on public offering of $175.1 million, $5.8 million, $169.5 million and $194.9 million, respectively. As of September 30, 2021, we had cash and cash equivalents of $385.1 million.

Debt Extinguishment

In December 2020, we used approximately $6.5 million of the net proceeds from our follow-on public offering to repay the outstanding principal amount of $6.0 million and early extinguish the outstanding Term Loan with SVB and WestRiver. As a result, we recognized a $0.6 million loss on early debt extinguishment, representing the difference between the reacquisition price of debt and the net carrying amount of the loan as of the date of the payoff.

Funding Requirements

We have incurred losses and negative cash flows from operations since inception and anticipate that we will continue to incur net losses for the foreseeable future. As of September 30, 2021, we had an accumulated deficit of $173.5 million. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. In addition, we expect to incur additional costs associated with operating as a public company. Management recognizes the need to raise additional capital to fully implement its business plan. The timing and amount of such future capital requirements are difficult to forecast and will depend on many factors, including:

- the timing and progress of preclinical and clinical development activities;
- successful enrollment in and completion of clinical trials;
- the timing and outcome of regulatory review of our product candidates;

- our ability to establish agreements with third-party manufacturers for clinical supply for our clinical trials and, if any of our product candidates are approved, commercial manufacturing;
- addition and retention of key research and development personnel;
- our efforts to enhance operational, financial and information management systems, and hire additional personnel, including personnel to support development of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval;
- the legal patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone and royalty payments thereunder; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 drug candidates that we would otherwise prefer to develop and market ourselves.

In July 2020, we completed our initial public offering pursuant to a registration statement on Form S-1. In the initial public offering, we issued and sold an aggregate of 9,775,000 shares of common stock, including the underwriters' exercise in full of their overallotment option, under the registration statement at a public offering price of $19.00 per share. Net proceeds were approximately $169.5 million, after deducting underwriting discounts and commissions of $13.0 million and offering-related expenses of $3.2 million.

In December 2020, we completed our follow-on public offering pursuant to a registration statement on Form S-1. In the follow-on public offering, we issued and sold an aggregate of 2,737,000 shares of common stock, including the underwriters' exercise in full of their overallotment option, under the registration statement at a public offering price of $76.00 per share. Net proceeds were approximately $194.9 million, after deducting underwriting discounts and commissions of $12.5 million and offering-related expenses of $0.7 million.

We believe our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2024. We have based these estimates on assumptions in which actuals may materially differ, and we could utilize our available capital resources sooner than we expect.

Cash Flows

The following table presents a summary of the net cash flow activity for each of the periods set forth below:

	Nine Months Ended September 30,	
	2021	**2020**
	(in thousands)	
Net cash (used in)/provided by:		
Operating activities	$ (50,613)	$ (24,674)
Investing activities	(405)	621
Financing activities	1,948	274,520
Net (decrease)/increase in cash and cash equivalents	$ (49,070)	$ 250,467

Operating Activities

In the nine months ended September 30, 2021, cash used in operating activities of $50.6 million was attributable to a net loss of $55.0 million and a net change of $4.3 million in our operating assets and liabilities, partially offset by $8.7 million in non-cash charges. The change in operating assets and liabilities was primarily due to $3.6 million increase in accounts payable due to timing of invoice and payments, offset by $6.6 million increase in other assets related to long-term prepaid clinical costs and $2.0 million increases in prepaid expenses and other current assets. The non-cash charges mainly consisted of stock-based compensation of $8.2 million and non-cash lease costs of $0.4 million.

In the nine months ended September 30, 2020, cash used in operating activities of $24.7 million was attributable to a net loss of $27.0 million and a change of $2.5 million in our net operating assets and liabilities, partially offset by $4.8 million in non-cash charges. The non-cash charges consisted of stock-based compensation of $3.7 million, change in fair value of Series B convertible preferred stock warrant liability and term loan compound derivative of $0.7 million, depreciation and amortization of $0.2 million and amortization of term loan discount and issuance costs of $0.3 million, partially offset by a gain on assignment of lease of $0.1 million. The change in operating assets and liabilities was primarily due to a $2.3 million decrease in accounts payable, $2.1 million increase in prepaid expenses and other current assets, partially offset by a $2.0 million increase in accrued expenses and other current liabilities. This is primarily due to timing of cash payments for clinical-related activities.

Investing Activities

In the nine months ended September 30, 2021 cash used in investing activities was $0.4 million for purchases of property and equipment.

In the nine months ended September 30, 2020, cash provided by investing activities was $0.6 million, primarily due to proceeds from assets held for sale.

Financing Activities

In the nine months ended September 30, 2021, cash provided by financing activities was $1.9 million, which were driven by $2.0 million proceeds from exercise of common stock under equity incentive plans and $0.1 million proceeds from issuance of common stock pursuant to employee stock purchase plan, offset by $0.2 million of principal payments on finance leases.

In the nine months ended September 30, 2020, cash provided by financing activities was $274.5 million, primarily from the net proceeds of our initial public offering of $172.7 million, after deducting underwriting commissions and discounts, the sale and issuance of Series C convertible preferred stock with gross proceeds of $105.0 million, net of $0.3 million in issuance costs, and proceeds from the exercise of common stock under equity incentive plans of $0.3 million, partially offset by payment of offering costs of $3.2 million.

Contractual Obligations and Commitments

We have contractual obligations from our operating lease, finance leases, manufacturing and service contracts, and other research and development activities. The following table aggregates our material expected contractual obligations and commitments as of September 30, 2021 (in thousands):

	Payments Due By Period				
	Total	2021 (4)	2022 - 2023	2024 - 2025	Thereafter
Operating lease obligations (1)	$ 2,283	$ 102	$ 1,001	$ 879	$ 301
Finance lease obligations (2)	828	108	720	—	—
Manufacturing and service contracts (3)	25,006	7,481	17,297	198	30
Total	$ 28,117	$ 7,691	$ 19,018	$ 1,077	$ 331

(1) The payments consist of (i) payments due for the office space in Burlingame, California under a single operating sub-lease agreement that expires in 2023, and (ii) payments due for the office space in South San Francisco, California under a single operating lease agreement that expires in 2026. See Note 5 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for details of related commitments.

(2) Payments due for embedded finance leases related to a pharmaceutical support service contract. See Note 5 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for details of related commitments.

(3) In November 2015, we entered into a Master Service Agreement, or the MSA, with KBI Biopharma, Inc. relating to formulation development, process development and cGMP manufacturing of evorpacept for use in clinical trials on a project basis. The MSA had an initial term of three years with successive one-year renewal periods, is cancellable upon notice and is non-exclusive. Statements of work under the MSA commit us to certain future purchase obligations of approximately $24.1 million. In addition, we have commitments with two other drug product manufacturers that commit us to certain future purchase obligations of approximately $0.9 million. These amounts are based on non-cancellable commitments and forecasts that include estimates of future market demand, quantity discounts and manufacturing efficiencies that may impact timing of purchases.

(4) Remaining three months.

We enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments are not included in the table of contractual obligations above.

Off-Balance Sheet Arrangements

During the period presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and the disclosure of our contingent liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may materially differ from these estimates under different assumptions or conditions.

Our critical accounting policies are more fully described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. During the three and nine months ended September 30, 2021, there were no material changes to our critical accounting policies from those discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 18, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of September 30, 2021, we had cash and cash equivalents of $385.1 million. We generally hold our cash and cash equivalents in interest-bearing bank accounts and money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. An immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents.

Financial Institution Risk

Substantially all of our cash and cash equivalents is held with a single financial institution. Due to its size, this financial institution represents a minimal credit risk. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation up to $250,000. At September 30, 2021, we had $384.9 million in excess of this insured limit.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for services with payments denominated in foreign currencies, primarily the Euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our condensed consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. A 10.0% increase or decrease in current exchange rates would not have a material effect on our financial results.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer and our Chief Financial Officer, who is the principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

In connection with that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms as of September 30, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, growth prospects or 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 also may impair our business operations and the market price of our common stock.

Risk Factors Summary

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. These risks include, but are not limited to, the following:

- We have incurred significant net losses since our 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, such capital may not be available to us or may only be available on terms that are unfavorable to us;
- We have a limited operating history and have no products approved for commercial sale;
- The price of our stock may be volatile, and you could lose all or part of your investment;
- We are substantially dependent on the success of our lead product candidate, evorpacept (also known as ALX148), which is in clinical development and which has not completed a pivotal trial;
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities;
- Our product candidates may cause significant adverse events or other undesirable side effects when used alone or in combination with other treatments;
- Clinical trials of our product candidates are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety, efficacy and potency of our product candidates or provide the basis for marketing approval;
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, which could lead to our inability to generate product revenue;
- If we are unable to obtain, maintain and enforce patent protection and other intellectual property for our product candidates and related technology, our business could be materially harmed;
- We are highly dependent on our key personnel, and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy;
- Our preclinical research is conducted solely by a third party service provider, Tallac Therapeutics, Inc. (formerly known as Tollnine, Inc.), or Tallac Therapeutics, and we are dependent on Tallac Therapeutics to perform its contractual research obligations on an effective and timely basis;

- The COVID-19 pandemic could adversely impact our business including our ongoing and planned clinical trials and preclinical research; and
- In the past, we have identified material weaknesses in our internal control over financial reporting. If remediation measures we implemented are not effective, investors may lose confidence in our financial reports.

Risks Related to Our Financial Position and Need for Additional Capital

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

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue from product sales, licenses or collaborations to date and have financed our operations principally through public offerings of our common stock and private placements of our convertible preferred stock. Our net loss was $24.6 million and $10.2 million for the three months ended September 30, 2021 and 2020, respectively, and $55.0 million and $27.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $173.5 million. We have devoted substantially all of our resources and efforts to research and development. Our lead product candidate, evorpacept, is in early-stage clinical trials. Our other programs are in preclinical discovery and research stages. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing 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 discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

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 or future commercialization efforts.

Developing pharmaceutical 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, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for evorpacept and advance our other programs. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We have incurred and expect to continue to incur additional costs associated with operating as a public company and comply with legal, accounting and other regulatory requirements. 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 and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of September 30, 2021, we had cash and cash equivalents of $385.1 million. Based on our current operating plan, we believe that our existing cash and cash equivalents, will be sufficient to fund our operations through 2024. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our cash and cash equivalents to advance the clinical development of evorpacept, as well as for working capital and other general corporate purposes. This may include additional pre-clinical research, clinical development, hiring additional personnel, capital expenditures, the potential acquisition of businesses or assets and the costs of operating as a public company, as well as for working capital and other general corporate purposes. Advancing the development of evorpacept and our other programs will require a significant amount of capital. Our current cash and cash equivalents on hand, may not be sufficient to fund all of the actions that are necessary to complete the development of evorpacept or our other programs.

We expect to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed

external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. 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 may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We were incorporated and commenced operations in 2015, have no products approved for commercial sale and have not generated any revenue from product sales, licenses or collaborations. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying and developing potential product candidates and conducting preclinical and clinical trials of our product candidates, including Phase 1 and Phase 2 clinical trials of evorpacept. We have not yet demonstrated our ability to successfully complete any large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale drug or arrange for a third party to do so on our behalf or conduct sales and marketing activities. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history. 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. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from any product sales, licenses or collaborations and do not expect to generate any revenue from the sale of product candidates in the foreseeable future. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- successful and timely completion of preclinical and clinical development of our lead product candidate, evorpacept, and our other future product candidates;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of evorpacept and our other future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for evorpacept and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance of evorpacept and any future product candidates as viable treatment options by patients, the medical community and third-party payors;
- obtaining favorable coverage and adequate reimbursement by third-party payors for our product candidates;

- addressing any competing therapies and technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio, including our licensed intellectual property;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidate; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and/or continue our operations.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, evorpacept, which is in clinical development and which has not completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize evorpacept in one or more indications, or we experience significant delays in doing so, we may never generate any revenue or become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of our lead product candidate, evorpacept, in our ongoing clinical trials. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of evorpacept in one or more of these indications, such as MDS, AML, HNSCC, or gastric/ GEJ carcinoma. We cannot be certain that evorpacept will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, testing, manufacturing, safety, efficacy and potency, labeling, approval, sale, marketing and distribution of evorpacept is, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Our failure to timely complete clinical trials, obtain regulatory approval or, if approved, commercialize evorpacept or any of our future product candidates, would materially harm our business, financial condition and results of operations. We are not permitted to market or promote evorpacept, or any other product candidate, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. If we do not receive marketing approvals for evorpacept, we may not be able to continue our operations.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. The clinical trials of our product candidates may not produce positive results or demonstrate adequate safety, purity and efficacy and potency to the satisfaction of regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy/potency of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain approval of their drugs.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety, purity and efficacy and potency to the satisfaction of the FDA or comparable international regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. In addition, the FDA or any comparable international regulatory authorities may conclude that the results from our clinical trials are insufficient to support any accelerated approval that we may seek with respect to evorpacept or any of our future product candidates in general or with respect to any specific indications. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical

trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Clinical trials of our product candidates are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety, purity and efficacy and potency of our product candidates or provide the basis for marketing approval.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials to demonstrate their safety, purity and efficacy and potency. Clinical trials are expensive and difficult to design and implement. Clinical trials can take many years to complete, and their ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe, pure and effective or potent for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing.

We do not know whether our future clinical trials will begin on time or enroll subjects on time or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining institutional review board approval at each clinical trial site;
- adding necessary new clinical trial sites;
- recruiting suitable subjects to participate in a trial; failing in having clinical trial sites or subjects comply with trial protocols;
- suffering clinical trial sites or subjects dropping out of trials; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:

- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of subjects required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or subjects dropping out of these clinical trials at a higher rate than anticipated;
- delays in clinical trials due to outbreaks or public health crises, such as the COVID-19 pandemic, that impact both trial site operations and subject selection;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates are greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving our product candidates.

As a result of any of these delays or other circumstances, we may incur unplanned costs, not obtain or be delayed in obtaining marketing approval, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have our drug removed from the market after obtaining marketing approval.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate safety, purity and efficacy and potency sufficient to obtain marketing approval or our product candidates or to market our drugs after any such approval.

In December 2020, the FDA verbally informed us, that given our planned initiation of two Phase 2 HNSCC clinical trials that could be potentially registrational, they require completion of a routine non-clinical safety study. The FDA noted that for any drug development program moving swiftly through development, this non-clinical study is still required prior to the initiation of a clinical trial that could be considered pivotal. We were allowed to initiate both Phase 2 HNSCC clinical trials with the enrollment capped at a total of 50 subjects treated with evorpacept across both trials (excluding safety lead-in cohorts). In June 2021, the FDA informed us that it reviewed our standard non-clinical safety study and has removed the partial clinical hold and patient cap on our two Phase 2 studies in patients with HNSCC.

If we experience delays or difficulties in the enrollment of subjects in clinical trials and/or retention of subjects in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or comparable international regulatory authorities. Subject enrollment is a significant factor in the timing of clinical trials. In particular, because certain of our clinical trials of evorpacept are focused on indications with small patient populations, our ability to enroll eligible subjects may be limited or may result in slower enrollment than we anticipate.

Enrollment of subjects in our clinical trials may be delayed or limited if our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic. In addition, subjects may not be able to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or subjects' reluctance to visit the clinical trial sites during the pandemic. The drop-out rates in our clinical trials may be increased during the pandemic. Subjects who enroll in our clinical trials and then who become infected with the COVID-19 virus may complicate the clinical trial data, procedures and analysis. These factors resulting from the COVID-19 pandemic could delay the anticipated readouts from our clinical trials and our regulatory submissions and increase the costs associated of the clinical trials.

Subject enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Subject enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy or potency of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials by us and the clinical trial sites;
- patient referral practices of physicians;
- the ability to monitor subjects adequately during and after the clinical trial;
- proximity of clinical trial sites to prospective subjects;
- risk of subjects enrolled in clinical trials dropping out before completion; and
- inability or delay in enrollment of subjects due to a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic.

Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our drugs.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Further, interim, topline and preliminary data include certain assumptions, estimations, calculations and conclusions as part of our analyses of data available at that time, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If evorpacept or any of our other product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. For example, we have observed single-digit incident rates of treatment-related grade three and higher cytopenias across each of the trial cohorts in our evorpacept combination clinical trials with pembrolizumab, trastuzumab and rituximab in a heavily pre-treated group of subjects who are typical participants in early stage cancer trials and are often hematologically fragile at baseline. Subjects in our evorpacept combination clinical trials experienced a number of treatment-related adverse events that were low-grade and manageable, including fatigue, rash, aspartate aminotransferase, or AST, increase, platelets decrease, alanine aminotransferase, or ALT, increase, pruritus, pyrexia, decreased appetite, anemia, infusion reaction, neutropenia, nausea, alkaline phosphate increase, arthralgia, white blood cell decrease and myalgia. Treatment-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any adverse events as a result of evorpacept or any of our future product candidates, including in combination therapy, may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

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

The development and commercialization of new product candidates is highly competitive. We face competition with respect to evorpacept and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immuno-oncology therapies for the treatment of cancer. There are other companies working to develop immuno-oncology therapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. The large pharmaceutical and biotechnology companies that have commercialized and/or are developing immuno-oncology treatments for cancer include AstraZeneca, Bristol Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer and Roche/Genentech.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, including with respect to the targeting of CD47 pathway and others are based on entirely different approaches. We are aware that Apexigen, Arch Therapeutics, Bristol Myers Squibb, Gilead Sciences (through its acquisition of Forty Seven), I-Mab, Innovent, Kahr, Novimmune, OSE Immunotherapeutics and Trillium Therapeutics, among others, are developing drugs targeting the CD47 pathway that may have utility for the treatment of indications that we are targeting. 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 already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if evorpacept and any of our other future product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller 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, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Even after approval, our manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our approved products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Regulatory approvals may contain significant limitations related to use restrictions for specific target population subsets, *e.g.*, age groups, warnings, precautions or contraindications, or may include costly and burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS as a condition for approval of our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk mitigation tools.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with a contract supplier, vendor, or facility where the product is manufactured or processed, a regulatory agency may impose restrictions on that product, the manufacturing facility or contractor, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions or enforcement actions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;

- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any of these sanctions, enforcement actions or penalties described above may inhibit our ability to commercialize our product candidates, even if approved, and generate revenue.

We rely on Tallac Therapeutics, a third-party service provider, to conduct substantially all of our preclinical research activities. If Tallac Therapeutics does not successfully carry out its contractual duties or meet expected deadlines, there may be disruptions or delays to our development pipeline and our business could be substantially harmed.

We do not have the ability to independently conduct our preclinical research activities as we rely on a third-party service provider to conduct all of our preclinical research activities. Effective as of July 1, 2020, we transferred all of our preclinical research capabilities and nine of our employees, including our former Chief Scientific Officer, Dr. Hong Wan, to Tallac Therapeutics, and entered into a research and development services agreement, or the Tallac Services Agreement, with Tallac Therapeutics. Under the terms of the Tallac Services Agreement, Tallac Therapeutics will provide preclinical research services to us for the cost of these services plus a mark-up equal to 10.0% of such costs.

If Tallac Therapeutics does not successfully carry out its contractual obligations or meet expected deadlines, if Tallac Therapeutics needs to be replaced or if the quality or accuracy of the preclinical data Tallac Therapeutics obtains is compromised due to its failure to adhere to its or our preclinical protocols, regulatory requirements or for other reasons, our preclinical research efforts and studies may be extended, delayed or terminated, and there may be disruptions or delays to our development pipeline. As a result, our product candidate research and development efforts may be delayed or harmed, and our costs could increase and our future ability to generate revenues could be delayed.

Further, Tallac Therapeutics' employees are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to our preclinical research efforts and studies. If Tallac Therapeutics fails to devote sufficient resources to the research and development of our preclinical research programs and studies, or if its performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, we must disclose our proprietary information to Tallac Therapeutics, which could increase the risk that this information will be misappropriated or that disputes related to our intellectual property with Tallac Therapeutics may occur, including the risks discussed below related to intellectual property matters.

If our relationship with Tallac Therapeutics terminates, we may not be able to enter into arrangements with alternative providers or do so in a timely manner or on commercially reasonable terms. If the Tallac Services Agreement is terminated, replacing Tallac Therapeutics or adding additional preclinical research providers will involve additional costs and divert our management's time and focus. In addition, there is a natural transition period when a new service provider commences work. As a result, delays may occur, which can materially impact our ability to meet our desired preclinical timelines. Since Tallac Therapeutics is an early-stage company with a limited operating history, it may face challenges to its business and cease to operate, and we may need to engage replacement service providers on an accelerated timeline and on even less favorable terms. 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 results of operations.

Our commercial success depends, in part, on our ability to conduct our research and develop our product pipeline without infringing the intellectual property and other proprietary rights of third parties. If we ever become involved in any dispute with Tallac Therapeutics over ownership of intellectual property or proprietary rights in the future because of the access that Tallac Therapeutics had to our intellectual property, including trade secrets, we may need to negotiate or engage in litigation to preserve our intellectual property rights, which may be time-consuming, expensive and ultimately unsuccessful. In addition, our former employees who are now employees of Tallac Therapeutics may possess our proprietary information. Although these former employees have signed confidentiality and invention assignment agreements with us, we cannot guarantee that they will not breach these agreements in the future. If these former employees disclose our proprietary information to Tallac Therapeutics or other third parties, we may not be able to obtain adequate remedies for such breaches.

We contract with third parties for the manufacture of our product candidates for preclinical development and clinical trials, and we expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical

development and clinical testing, as well as for the commercial manufacture of our drugs if any of our product candidates receive marketing approval. No assurance can be given that long-term, scalable manufacturers can be identified or that they can make clinical and commercial supplies of our product candidates that meet the product specifications of previously manufactured batches, or are of a sufficient quality, or at an appropriate scale and cost to make it commercially feasible. Such third-party manufacturers may also be subject to delays due to circumstances outside of their control for a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic, that could shut down or cause limited staffing of their facilities. Our reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. If they are unable to do so, it could have a material adverse impact on our business.

The facilities used by contract manufacturers to manufacture our product candidates must be approved by the FDA or any applicable foreign regulatory authority pursuant to inspections that may be conducted after we submit our marketing applications to the FDA or any such foreign regulatory authority. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any applicable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact, including causing substantial delay, in our ability to develop, obtain regulatory approval for or market our product candidates. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

Our product candidates and any drugs that we may develop may compete with other product candidates and approved drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

We also expect to rely on other third parties to store and distribute product candidate supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any future product candidates or commercialization of our products, producing additional losses and depriving us of potential drug revenue.

Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval or commercial drug supply after marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement.

Material modifications in the methods of product candidate manufacturing or formulation may result in additional costs or delay.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented. Also, as product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing, suppliers and formulation, are altered in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. 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 modified manufacturing, materials or process. This could delay completion of clinical trials, require the conduct of additional clinical trials, such as bridging studies to demonstrate the product is substantially equivalent to product used during earlier 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, if approved, and generate revenue.

Lack of third-party combination drugs may materially and adversely affect demand for our product candidates.

Our product candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. In addition, we currently use, and plan to use in the future, third-party drugs in our development and clinical trials as controls for our studies, such as conducting Phase 2 clinical trials of evorpacept in combination with pembrolizumab for HNSCC and trastuzumab for gastric/GEJ carcinoma. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. For instance, we entered into clinical trial collaboration and supply agreements with Merck, Eli Lilly and Zymeworks, pursuant to which our collaboration counterparties will supply doses of pembrolizumab, ramucirumab, and zanidatamab, respectively, for use in certain of our clinical trials. If the agreements with Merck and Eli Lilly are terminated before our trials are

completed, we may need to find another source of pembrolizumab and ramucirumab, respectively, in order to continue our trial. Zanidatamab is not approved for commercial use by the FDA or any comparable regulatory authority, and as a result, no alternative source of zanidatamab exists. As such, if the agreement with Zymeworks is terminated before our trials are completed, our ability to continue our trials would be limited.

If other pharmaceutical companies discontinue these drugs for combination therapies in the future, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs at all or in a timely manner and on a cost-effective basis. Use of new combination drugs with our approved product candidates will require further regulatory approval before we can promote such new combination therapies. As a result, demand for our product candidates may be lowered, which would in turn materially and adversely affect our business and results of operations.

We may not be able to obtain regulatory approval for our product candidates or commercialize any product candidates that may result from our development efforts, or may miss expected deadlines, if we are not able to maintain or secure agreements with the third parties that conduct the activities related to our clinical trials on acceptable terms, if these third parties do not perform their services as contractually required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll subjects on a timely basis or otherwise conduct our clinical trials as planned. In addition, there is no guarantee that these third parties will devote adequate time and resources to our clinical trials or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. For example, these third parties may be adversely impacted by the COVID-19 pandemic. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA or other regulatory agencies. Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCPs, regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed, or the FDA or foreign regulatory authority may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA or foreign regulatory authority could determine that any of our clinical trials fail or have failed to comply with applicable cGCPs.

Our business also may be implicated if any of our CROs violates fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our third-party clinical trial sites terminate for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer the care of those subjects to another qualified clinical trial site. Further, our CROs are not required to work indefinitely or exclusively with us. Our existing agreements with our CROs may be subject to termination by the counterparty upon the occurrence of certain circumstances. If any CRO terminates its agreement with us, the research and development of the relevant product candidate would be suspended, and our ability to research, develop and license future product candidates would be impaired. We may be required to devote additional resources to the development of our product candidates or seek a new CRO partner, and the terms of any additional arrangements that we establish may not be favorable to us. Switching or adding CROs or other service providers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or service provider commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative arrangements, the resulting delays and potential inability to find suitable replacements could materially and adversely impact our business.

Even if we receive marketing approval for any of our product candidates, we may not achieve market acceptance, which would limit the revenue that we can generate from sales of any of our approved product candidates.

Even if the FDA and applicable foreign regulatory authorities approve the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use our product candidates. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Market acceptance of evorpacept and any other product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of evorpacept and our other product candidates to treat cancer or other applicable targeted diseases, as compared with other available drugs, treatments or therapies;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- the approval of other new therapies for the same indications;
- the prevalence and severity of any adverse side effects associated with evorpacept and our other product candidates;
- limitations or warnings contained in the labeling approved for evorpacept or our other product candidates by the FDA or foreign regulatory authorities;
- availability of alternative treatments and the potential and perceived advantages of our product candidates over alternative treatments;
- the size of the target patient population and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength and effectiveness of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost-effectiveness in relation to alternative treatments;
- relative convenience and ease of administration;
- our ability to obtain sufficient third-party coverage or reimbursement, and the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- the likelihood that the FDA or any foreign regulatory authority may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

Adverse events in clinical trials for our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for evorpacept or any other product candidate that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry generally could also result in greater governmental regulation and stricter labeling requirements.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by patients, physicians and third-party payors, we may not generate sufficient revenue to become or remain profitable and our business may be harmed.

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval.

We currently have no marketing and sales organization and we have never commercialized a product candidate. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party.

If any of our product candidates ultimately receives regulatory approval, we may choose to establish an internal 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. Factors

that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

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 revenue 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. We have no internal sales, marketing or distribution capabilities.

The market opportunities for the product candidates we develop, if approved, may be limited to certain smaller patient subsets.

There is no guarantee that the product candidates we develop, even if approved, would be approved for the currently proposed indications. We may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk. Regulators, like FDA, may require us to narrow our indications to smaller patient subsets, and the number of patients in such subsets may turn out to be lower than expected.

Our current and future product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe, pure, potent or effective for use by the target patient population for any indication.

Our lead product candidate, evorpacept, is at an early stage of clinical development and not all adverse effects can be predicted or anticipated. Unforeseen side effects from evorpacept or any of our future product candidates may arise at any time during clinical development or, if approved by regulatory authorities, after the approved drug product has been marketed. Any undesirable or unacceptable side effects of evorpacept or our future product candidates could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or comparable international regulatory authorities, or result in marketing approval from the FDA or comparable international regulatory authorities with restrictive label warnings or for limited patient populations. Ultimately, such side effects could result in product liability claims. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication.

Even if any of our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindication, precaution or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, limit the patient population who can use the product or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future product candidates.

Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Coverage under certain government programs, such as Medicare, Medicaid and TRICARE, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy and potency or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

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. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain and maintain coverage and adequate reimbursement for a product;
- our ability to generate revenue and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates manufacturers' promotional claims of drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the FDA-approved labeling. The FDA, the Department of Justice, the Inspector General of the Department of Health and Human Services, or HHS, among other government 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, including large civil and criminal fines, penalties and enforcement actions. The FDA has also imposed consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed for companies that engaged in such prohibited activities. If we cannot successfully manage the promotion of our approved product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to Government Regulation

Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review with respect to our drugs, which will result in significant additional expense.

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 subject to certain conditions of approval and may contain requirements for potentially costly post-approval trials and surveillance to monitor the safety, purity and efficacy/potency of the marketed product. For any approved drug, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug;
- withdrawal of the drug from the market or voluntary or mandatory product recalls;
- adverse publicity, fines, warning letters or holds on clinical trials;
- refusal by the FDA or any other applicable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- drug product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the policies of the FDA or other comparable foreign regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates or impact any already approved drugs. 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, which would adversely affect our business, prospects and ability to generate revenue or achieve or sustain profitability.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, which could lead to our inability to generate product revenue. 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.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. 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 product candidates in those countries. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. Our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA and comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for or obtained regulatory approval for any product candidate and it is possible that evorpacept or any product candidates we may seek to develop in the future will ever obtain regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable international regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or comparable international regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and potency and safety in the full population for which we seek approval;
- the FDA or comparable international regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, New Drug Application or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable international regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable international regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or international foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In order to market any product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and potency and approval standards. 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.

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, government shutdowns, including as a result of budget delays or other circumstances like the COVID-19 pandemic and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

While we have received certain FDA Fast Track designations, such Fast Track designations may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that the drug will receive marketing approval.

In February 2020, the FDA granted Fast Track designations to evorpacept for first-line HNSCC and for second-line treatment of advanced HER2-positive gastric/GEJ carcinoma. If a product candidate is intended for the treatment of a serious condition and preclinical or clinical data demonstrate the potential to address unmet medical need for such condition, a sponsor may apply for FDA Fast Track designation. Even though we received these Fast Track designations for evorpacept, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with such orphan drug designation.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We may seek Orphan Drug Designation for certain indications for our product candidates in the future. Orphan Drug Designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process. Generally, if a product candidate with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period

of marketing exclusivity that precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. Therefore, if our competitors are able to obtain orphan product exclusivity for their product candidates in the same indications we are pursuing, we may not be able to have competing product candidates approved in those indications by the FDA for a significant period of time. There are also limited circumstances where the FDA may reduce the seven-year exclusivity for a product candidate with an orphan drug designation where other product candidates show clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. However, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture a sufficient supply of our product.

Current and future legislation may increase the difficulty and cost for us to commercialize our products, if approved, and affect the prices we may obtain. We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies 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.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our drugs, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our drugs;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively ACA, was enacted in 2010 and includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. The ACA continues to impact the U.S. pharmaceutical industry. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. In December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans, or QHPs, and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. Further, in December 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by the U.S. Congress as part of a tax act. Additionally, in December 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. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. Additionally, it is possible that additional governmental action is taken in response to the COVID-19 pandemic, resulting in a material adverse effect on our business. For example, on August 6, 2020, the Trump administration issued another executive order that instructs the federal government to develop a list of "essential" medicines and then buy them and other medical supplies from U.S.

manufacturers instead of from companies around the world, including China. The order is meant to reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and the production of drug products in the United States.

There also has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their drugs, which has resulted in several U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020, codifying a policy change that was effective January 1, 2019. In 2020, the U.S. Department of Health and Human Services and CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, importation of prescription drugs from Canada and other countries, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of these new rules. In January 2021, the Biden administration issued a “regulatory freeze” memorandum that directs department and agency heads to review new or pending rules of the prior administration. It is unclear whether these new regulations will be withdrawn or when they will become fully effective under the current administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the current administration on us and the biopharmaceutical industry as a whole is unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Programs rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have material impact on our business.

The ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved drug product. Any denial in coverage or reduction in reimbursement from Medicare or other government funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices, price controls and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future product candidates, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such product candidates and third-party payors’ reimbursement policies might adversely affect our ability to sell any future product candidates profitably.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay the commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower-priced cross-border sales, our profitability will be negatively affected.

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, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, our operations may be directly, or indirectly through our prescribers, consultants, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate are described in the following paragraphs:

- The U.S. federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, 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 U.S. federal and state healthcare programs such as Medicare and Medicaid. Moreover, the ACA provides that the government may assert that a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the civil FCA.
- The federal civil and criminal false claims, including the civil FCA, that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. No specific intent to defraud is required under the civil FCA. The criminal FCA provides for criminal penalties for submitting false claims, including imprisonment and criminal fines.
- The Civil Monetary Penalty Act of 1981 and implementing regulations impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.
- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act and Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, impose certain obligations, including mandatory contractual terms, on covered entities subject to the Final HIPAA Omnibus Rule, *i.e.*, health plans, healthcare clearinghouses and healthcare providers, and their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The U.S. Federal Food, Drug and Cosmetic Act prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. Additionally, President Trump signed into law in 2018 the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which, under the provision entitled "Fighting the Opioid Epidemic with Sunshine," in part, extends the reporting and transparency requirements under the Physician Payments Sunshine Act to physician assistants, nurse

practitioners and other mid-level practitioners, with reporting requirements beginning in 2022 for payments made or ownership or investment interests held in 2021.

- The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, price reporting, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.
- Analogous state laws and regulations impose additional obligations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state 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.
- European and other foreign law equivalents of each of the laws also impose legal requirements, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight, and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

If we, our employees, independent contractors, principal investigators, consultants, vendors or agents acting on our behalf fail to comply with healthcare laws and regulatory requirements, we could be subject to fines, penalties or enforcement actions, or incur costs that could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct as well as risks of noncompliance by contractors or agents acting on our behalf. Misconduct by employees and independent contractors, such as principal investigators, consultants and vendors, could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with health care fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of research, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a written code of business conduct and ethics, but it is not always possible to identify and deter employee or independent contractor misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. 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 fines, exclusion from participation in government-funded healthcare programs, or other sanctions.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

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 involve, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the State of California to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional laws and regulations affecting our operations may be adopted in the future. Current or future laws and regulations may impair our research, development or commercialization efforts. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

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 and the ability to hire and retain key personnel. 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, such as recent furloughs or government shutdowns, 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.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations, all of which can subject us to criminal liability and other serious consequences for violations.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. These laws generally prohibit companies and their employees and third party business partners, representatives and agents from engaging in corruption and bribery, including offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a government official or commercial party in order to influence official action, direct business to any person, gain any improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with government officials, including officials of non-U.S. governments.

Additionally, in many countries, healthcare providers are employed by the government, and the purchasers of biopharmaceuticals are government entities. As a result, our dealings with these providers and purchasers are subject to regulation and such healthcare providers and employees of such purchasers may be considered "foreign officials" as defined in the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology companies. In addition to our own employees, we leverage third parties to conduct our business abroad, such as obtaining government licenses and approvals. We and our third-party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies, state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of our employees, our third-party business partners, representatives and agents, even if we do not explicitly authorize such activities. There is no certainty that our employees or the employees of our third-party business partners, representatives and agents will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, debarment from U.S. government contracts, substantial diversion of management's attention, significant legal fees and fines, severe criminal or civil sanctions against us, our officers or our employees, disgorgement and other penalties and remedial measures and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, financial condition and stock price.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization

for our products, when applicable, could harm our business. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges.

Data collection under European and U.S. laws is governed by restrictive regulations addressing the collection, use, processing and, in the case of Europe, cross-border transfer, of personal information.

We may collect, process, use or transfer personal information from individuals located in the European Union, the European Economic Area, and their respective member states, Switzerland and the United Kingdom in connection with our business, including in connection with conducting clinical trials in these regions. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Union. The collection and use of personal health data in the European Union is governed, in part, by the provisions of the General Data Protection Regulation (EU) 2016/679, or the GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal information, 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 imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

European data protection laws also generally prohibit the transfer of personal data from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data from the European Union to the United States, namely, the Privacy Shield framework administered by the U.S. Department of Commerce, was recently invalidated by a decision of the European Union's highest court. The same decision also cast doubt on the ability to use one of the primary alternatives to the Privacy Shield, namely, the European Commission's Standard Contractual Clauses, to lawfully transfer personal data from Europe to the United States and most other countries. However, a new set of Standard Contractual Clauses have been adopted by the European Commission that will be used going forward. In addition, the existing data transfer arrangement that relied on the previous version of the Standard Contractual Clauses needs to be updated by December 27, 2022, which could increase our costs.

Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. Although the European Commission has granted "adequacy status" to the United Kingdom, and personal data can flow from the European Union to the United Kingdom and back, the United Kingdom is expected to change its policy with respect to the export of personal data to third countries, such as the United States. The United Kingdom may require Standard Contractual Clauses that are different from (or require amendment to) the European Commission's version of these clauses. We may, therefore, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable European Union Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

In addition, U.S. states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements related to personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, in 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. 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 by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and which can include any of our current or future employees who may be California residents or any other California residents whose data we collect or process) and provide such residents new ways to opt out of certain sales of personal information. 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. Additionally, a new privacy law, the California Privacy Rights Act, or the CPRA, was approved by California voters in the election on November 3, 2020. The CPRA will modify the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. As we expand our operations, preclinical studies and clinical trials, the CCPA and CPRA may increase our compliance costs and potential liability. Other states are beginning to consider and pass similar laws.

Privacy and data security laws and regulations are not consistent across jurisdictions, and they may impose conflicting or uncertain obligations. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous, costly and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with new and changing data protection obligations under these laws and regulations. Actual or alleged noncompliance with any such laws and

regulations may lead to regulatory investigations, enforcement actions, claims and litigation, and if we fail to comply with any such laws or regulations, we may face significant fines and penalties. Any of these could adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our product candidates and related technology, our business could be materially harmed.

Our strategy depends on our ability to identify, seek, obtain and maintain patent protection for our product candidates and other research and development discoveries. Our patent portfolio is relatively small compared to many large and more established pharmaceutical and biotechnology companies. As our patent portfolio grows, we expect patent protection will continue to be an important part of our strategy. The patent protection process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development discoveries in a timely manner 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 have licensed from third parties. Therefore, our in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in foreign countries or may fail to effectively prevent third parties from commercializing competitive product candidates.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, and such prior art may affect the scope of any allowable claims or it may prevent our patent applications from issuing as patents. Further, the issuance of a patent does not ensure that it is valid or enforceable, nor is the issuance conclusive as to inventorship or the scope of any claims. Third parties may challenge the validity, enforceability or scope of our issued patents or claim that they should be inventors on such patents, and such patents may be narrowed, invalidated, circumvented or deemed unenforceable and such third parties may gain rights to such patents. We could also become involved in reexamination, *inter partes* review, post-grant review, opposition or derivation proceedings challenging our patent rights or the patent rights of others.

In addition, changes in law may introduce uncertainty in the enforceability or scope of patents owned by us. If our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is no prior art that may ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions.

For all of the foregoing reasons, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

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

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 to develop their own products in jurisdictions where we have not obtained patent protection and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be valid 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 patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. 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.

Additionally, the requirements for patentability may differ in certain countries. For example, in India, unlike the United States, there is no link between regulatory approval of a drug and its patent status, and patenting of medical uses of a claimed drug are prohibited. In addition to India, certain countries in Europe and other countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees automatically when due, but we must notify the provider of any new patents or applications. Additionally, the USPTO and various foreign patent offices require compliance with many procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents or in third-party patents. The United States has enacted and implemented wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a higher level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The AIA and its implementation may 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 an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or does file a patent application in the USPTO after March 16, 2013 but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to file third party submissions of prior art to the USPTO during patent prosecution and to challenge any issued patent in the USPTO (*e.g.*, via post-grant reviews or *inter partes* reviews). Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court 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.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Our patents covering one or more of our product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which the patent examiner and we were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

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 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, including biosimilars. 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.

Patent protection, prosecution, assertion and defense for some of our product candidates may be dependent on third parties.

There may be times in the future when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors, such as with respect to our Stanford license agreements. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers. If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability

to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

If we are unable to protect the confidentiality of our trade secrets and proprietary information or obtain proper assignment of such intellectual property, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets and other proprietary information. Trade secrets and know-how can be difficult to protect. Trade secrets and know-how can also in some instances be independently derived or reverse-engineered by a third party. We maintain the confidentiality of trade secrets and proprietary information in part by entering into confidentiality agreements with our employees, consultants, other service providers, including Tallac Therapeutics, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies in addition to our service provider agreements, such as the Tallac Services Agreement, also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and even when we obtain these agreements, individuals with whom we have these agreements may not comply with their terms. Any of the parties to these agreements may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also become involved in inventorship disputes relating to inventions and patents developed by our employees, consultants, contractors and other service providers, such as Tallac Therapeutics, under such agreements. To the extent that our employees, consultants, contractors or other service providers use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced, and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time-consuming and unsuccessful.

Third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates or biosimilar versions of any approved product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for an invalidity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. 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.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition or other proceedings challenging the validity or scope of our patent rights, requiring us and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us, including disputes that may arise from our reliance on Tallac Therapeutics as the current sole provider of our preclinical research services and the intellectual property generated under the Tallac Services Agreement; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to the expiration of relevant patents owned by or licensed to us under the Biologics Price Competition and Innovation Act of 2009, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

Any litigation or other proceedings would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved drug. In addition, there is a risk that a court will order us to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

In addition, 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. There could also 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 an adverse effect on the price of our common stock. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or on our business, results of operations, financial condition and prospects. Any of these outcomes could have a material adverse effect on our business.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

We employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such license may not be available on commercially reasonable terms or at all. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against these claims, litigation would expose us to the risk described above under "— We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful."

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties.

We are aware of third-party patents and patent applications containing claims in the immuno-oncology field based on scientific approaches that are the same as or similar to our approach, including with respect to the targeting of the CD47 and signal regulatory protein alpha, or SIRPα, pathways, and others that are based on entirely different approaches. These patents and applications could potentially be construed to cover our product candidates and their use. For example, we are aware of U.S. patent 10,907,209 and U.S. patent application 16/118,038 (and related applications in other jurisdictions) owned by University Health Network, or UHN, and The Hospital for Sick Children that may encompass certain therapies for the treatment of cancer using polypeptides comprising soluble human SIRPα. This patent and patent application relate to the treatment of cancer with polypeptides comprising soluble human SIRPα. Trillium Therapeutics, our competitor, has an exclusive license to the U.S. patent and application. The European counterpart patent (EP 2 429 574) was revoked by the European Patent Office and UHN and The Hospital for Sick Children have appealed the decision. The patent claims under the European patent, if the appeal by UHN and The Hospital for Sick Children is successful, could potentially limit our ability to pursue evorpacept in certain new indications or geographies in the future. However, we believe that we do not infringe claims listed in U.S. patent 10,907,209. As the biotechnology industry expands and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that there are not third-party patents or patent applications of which we are aware, but which we do not believe are relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates. These patents may not expire before we receive any marketing approval for our product candidates, and they could delay the commercial launch of one or more future product candidates. If our product candidates were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms or at all, our business, financial condition and results of operations could be materially harmed. Furthermore, even if a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Our failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations, and we would be exposed to a threat of litigation.

Any litigation resulting from claims of infringement or failure to license patents and proprietary rights of others would expose us to the risk described above under "—We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful." Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

Our intellectual property rights will not necessarily provide us with competitive advantages.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for product candidates many years before we obtain marketing approval for such product candidates and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;

- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with product candidate name approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names and potential pharmacy dispensing errors. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our rights to develop and commercialize our product candidates may be subject, in part, to the terms and conditions of agreements with others.

Our current agreements do not, and future agreements we may enter into in the future may not, provide exclusive rights to use certain intellectual property and technology retained by a collaborator in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that utilize technology retained by such collaborators to the extent such products are not also covered by our intellectual property.

We may need to obtain additional intellectual property rights from others to advance our research or allow commercialization of product candidates we may develop. We may be unable to obtain additional intellectual property rights at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Furthermore, our current or our future collaborators' patents may be subject to a reservation of rights by one or more third parties. The U.S. government may have certain rights to resulting intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of the government funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in facilities in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third-party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in agreements under which we option or license intellectual property rights from collaborators or licensors or otherwise experience disruptions to our business relationships with future collaborators or licensors, we could lose intellectual property rights that are important to our business.

Our current agreements do and our future agreements may impose various economic, development, diligence, commercialization and other obligations on us. Such agreements may also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products. It might be concluded that we have materially breached our obligations under such agreements and licensors or collaborators might therefore terminate or seek damages under the agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. Termination of these agreements could cause us to lose the rights to certain patents or other intellectual property, or the underlying patents could fail to provide the intended exclusivity, and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products similar to or identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

Moreover, disputes may arise regarding intellectual property subject to a collaboration agreement, including:

- the scope of the option or license rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the collaborator that is not subject to the option or license rights granted under the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the 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 collaborators and us and our other partners; and
- the priority of invention of patented technology.

We may enter into agreements to option or license intellectual property or technology from third parties that 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 growth prospects. Moreover, if disputes over intellectual property that we have optioned or licensed prevent or impair our ability to maintain such 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 growth prospects.

Risks Related to Our Operations

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2021, we had 32 employees, including 21 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we continue to transition into operating as a public company, we expect to need additional managerial, scientific, technical, medical, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to successfully develop and, if approved, commercialize evorpacept and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and 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 specific independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical management and manufacturing. We

cannot assure you 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 or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of evorpacept and any other future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers 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/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize evorpacept and other future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated our product research and development efforts on our novel immuno-oncology approach, and our future success depends on the successful development of our lead product candidate, evorpacept, and any future product candidates that we develop. There can be no assurance that any development problems we experience in the future related to our novel immuno-oncology approach will not cause significant delays or unanticipated costs or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and life science industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and our scientific, technical, business and medical personnel. The loss of the services provided by 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 the development of our product candidates and harm our business.

We conduct our operations at our facility in the San Francisco Bay Area of California, a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, manufacturing and sales and marketing personnel, and we face significant competition for experienced personnel. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region and doing so may be costly and difficult.

Many of the other biotechnology companies that we compete against for qualified personnel have considerably more financial and other resources, different risk profiles and a more extended history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we can offer. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity grants that vest over time. The value to employees of these equity grants 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. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our predecessor company, which after our internal reorganization is now our wholly-owned subsidiary, was an Irish private company limited by shares. Our business is subject to risks associated with conducting business internationally. Some of our subsidiaries and operations, in addition to suppliers, industry partners and clinical study centers, are located outside of the United States. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we expect to hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks and complexities, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses, including within the European Union and in the United Kingdom as a result of Brexit;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property, including as a result of potentially relevant third-party patent rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our drugs;
- exposure to foreign currency exchange rate fluctuations;
- political and economic instability, including wars, terrorism and political unrest, boycotts, curtailment of trade and other business restrictions;
- natural disasters, outbreaks or public health crises, such as the COVID-19 pandemic;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the FCPA, its accounting provisions or its anti-bribery provisions, or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

If any of the third parties that we rely on for various operational and administrative aspects of our business fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third-party consultants and contractors to provide specific operational and administrative services, including research and clinical consultation and management. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on cloud-based platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

We may become exposed to costly and damaging product liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. In addition, we have agreed to indemnify various counterparties related to our product candidates against certain liability claims and any agreements or collaborations in the future may include such indemnification obligations. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects or that certain patients should not use our drugs for various reasons.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities.

Our spending on current and future research and development programs, such as evorpacept, for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The COVID-19 pandemic could adversely impact our business including our ongoing and planned clinical trials and preclinical research.

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. Since then, the virus has spread across the world, including all 50 states within the United States, resulting in the World Health Organization characterizing COVID-19 as a pandemic. Currently, the Delta variant of COVID-19 continues to spread as another wave of the pandemic. As a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools have been suspended as part of quarantines and other measures intended to contain this pandemic. The extent to which the COVID-19 pandemic ultimately impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the outbreak, 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 and to address its impact, including on financial markets or otherwise. As the COVID-19 pandemic continues, we may experience disruptions that could severely impact our business, current and planned clinical trials and preclinical research, including:

- delays or difficulties in enrolling and retaining subjects, particularly elderly subjects, who are at a higher risk of severe illness or death from COVID-19, in our ongoing clinical trial of evorpacept and our future clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- difficulties interpreting data from our clinical trials due to the possible effects of COVID-19 on subjects;

- 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 clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in resources, including our employees, that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people, or restrictions on movement or access to our facility as a result of government-imposed "shelter in place" or similar working restrictions;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of all of our employees working remotely, including those hired during the COVID-19 pandemic;
- delays in receiving approval from regulatory authorities to initiate our clinical trials;
- interruptions in preclinical studies due to restricted or limited operations at the CROs conducting such studies;
- interruptions or delays in the operations of the FDA or other domestic or foreign regulatory authorities, which may impact review and approval timelines;
- delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical research;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or require us to discontinue the clinical trial altogether;
- interruptions or delays to our development pipeline;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside of the United States.

The COVID-19 pandemic continues to pose a threat on our ability to effectively conduct our business operations as planned and there can be no assurance that we will be able to avoid a material impact on our business from the spread of COVID-19 or its consequences, including disruption to our business and downturns in business sentiment generally or in our industry or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. For example, many of our employees continue to telecommute, which may impact certain of our operations over the near term and long term.

Additionally, certain third parties with whom we engage or may engage, including collaborators, contract organizations, third-party manufacturers, suppliers, clinical trial sites, regulators and other third parties are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties experience shutdowns or continued business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, as a result of the COVID-19 pandemic, there could be delays in the procurement of materials or manufacturing supply chains for one or more of our product candidates, which could delay or otherwise impact our preclinical studies and our planned clinical trials. Additionally, all of our preclinical studies are conducted by CROs, which could be discontinued or delayed as a result of the pandemic. It is also likely that the disproportionate impact of COVID-19 on hospitals and clinical sites will have an impact on recruitment and retention for our planned clinical trials. CROs have also made certain adjustments to the operation of such trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA and may need to make further adjustments in the future that could impact the timing or enrollment of our clinical trials. Many of these adjustments are new and untested, may not be effective, may increase costs and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. While we are currently continuing our clinical trials and preclinical studies, we may experience delays in the completion of our clinical trials, preclinical activities and subject enrollment, may need to suspend our clinical trials and may encounter other negative impacts to such trials due to the effects of the COVID-19 pandemic.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus, which may include using telemedicine visits, remote monitoring of subjects and clinical sites and measures to ensure that data from clinical trials that may be disrupted as a result of the pandemic are collected pursuant to the study protocol and consistent with GCPs, with any material protocol deviation reviewed and approved by the site Institutional Review Board. Subjects who may miss scheduled appointments, any interruption in study drug supply, or other consequences that may result in incomplete data being generated during a clinical trial as a result of the pandemic must be adequately documented and justified. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the trial, and any disruption of the trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site and a

description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (*e.g.*, participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the clinical trial. In June 2020, the FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs.

The COVID-19 pandemic continues to rapidly evolve. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section and in this "Risk Factors" section.

We may seek to enter into collaborations, including strategic collaborations, licenses and other similar arrangements related to our product candidates and may not be successful in doing so, and even if we are, we may not be able to maintain or realize the benefits of such relationships. If we are not able to establish future collaborations, we may have to alter some of our future development and commercialization plans and our business could be adversely affected.

We may seek to enter into collaborations, licenses and other similar arrangements for the development or commercialization of our product candidates, due to strategic advantages to partnering with third parties and capital costs required to develop or commercialize the product candidate in such markets. For instance, we recently entered into a collaboration agreement with Tallac Therapeutics pursuant to which we expect to jointly develop, manufacture, and commercialize a novel class of cancer immunotherapeutics. We may not be successful in our efforts to establish such collaborations for our product candidates because our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product are unsatisfactory. We also may not be able to realize the benefit of such collaborations if we are unable to successfully integrate them with our existing operations and company culture. In any such collaborations, we may likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we may enter into.

We face significant competition in seeking appropriate collaborators and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. We also may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our future collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program, or delay its potential commercialization. Further, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of such 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. Any of the foregoing factors would likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our

own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may acquire businesses or assets and we may not realize the benefits of such acquisitions.

We may acquire businesses or assets or create joint ventures with third parties that we believe may complement our existing product candidates. For example, on October 4, 2021, we entered into a share purchase agreement with ScalmiBio, Inc., or ScalmiBio, with plans to develop new anti-cancer drug candidates based on ScalmiBio's platform. We may not be able to realize the benefit of acquiring such businesses or joint ventures if we are not able to successfully integrate them with our existing operations and company culture. We may encounter difficulties in developing, manufacturing and marketing any new product candidates resulting from an acquisition or that delay or prevent us from realizing their expected benefits.

Also, the anticipated benefit of any joint venture or acquisition may not materialize or such joint venture or acquisition may be prohibited. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

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

Under the U.S. Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future, in either case as a result of subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2020, we had net operating loss carryforwards of approximately $7.9 million and $71.4 million for U.S. federal and state income tax purposes, respectively. 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 our company. The federal net operating losses carries forward indefinitely while the state net operating loss will begin to expire beginning in 2038.

As of December 31, 2020, we had Irish net operating loss carryforwards of approximately $5.1 million. These Irish net operating loss carryforwards do not expire but may not be fully utilized unless we generate sufficient income in Ireland. Under Irish law, where a company makes a loss in its trade, it can carry that loss forward to subsequent accounting periods and offset the loss against profits or gains of the same trade. The utilization of carried forward losses is disallowed where (i) the trade that gave rise to the losses is discontinued or (ii) within any period of three years, there is both a change in the ownership of a company and (whether earlier or later in that period or at the same time) a major change in the nature or conduct of a trade carried on by the company or (iii) at any time after the scale of the activities in a trade carried on by a company has become small or negligible and before any considerable revival of the trade, there is a change in ownership of the company. There are no legislative explanations of what constitutes a major change in the nature or conduct of a trade. Relevant case law indicates that there must be a difference in the kind of trade/goods (and not just a quantitative difference) or a major difference in client outlets or markets of the trade but whether there has been a major change in the nature or conduct of a trade is a qualitative matter, and one which is to be judged on the facts of any particular set of circumstances. We may experience ownership changes in the future as a result of subsequent movements in our share ownership, some of which are outside of our control. If we also experience a major change in the nature or conduct of our trade or our trade becomes small or negligible, we may be limited in the amount of loss carryforwards that we can use in the future to offset taxable income for Irish corporation tax purposes. Furthermore, in the event we incur net income in certain jurisdictions but incur losses (or have loss carryforwards) in other jurisdictions, we cannot offset the income from one jurisdiction with the loss from another, which could increase our effective tax rate.

Risks Related to Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will be sustained for our common stock.

Prior to our initial public offering, no market for shares of our common stock existed. Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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 may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to those discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- results and timing of our preclinical studies and clinical trials and studies and trials of our competitors;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or any future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- actual or anticipated changes in our growth and development relative to our competitors;
- developments or disputes concerning patents or other proprietary rights;
- introduction of new product candidates or technological innovations by us or our competitors;
- announcements by us, our future strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- actual or anticipated changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors such as macroeconomic, disasters, crises or health matters, including the impact of the COVID-19 pandemic;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of payment or receipt of any future milestone or other payments under commercialization or licensing agreements;
- announcements or expectations of additional financing efforts;
- overall fluctuations in U.S. equity markets, general market conditions and market conditions for biotechnology stocks; and
- other factors that may be unanticipated or out of our control.

In addition, the stock market has recently experienced significant volatility, particularly with respect to biotechnology and other life sciences company stocks as a result of the COVID-19 pandemic. The volatility of biotechnology and other life sciences company stock often does not relate to the operating performance of the companies presented by the stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that

issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time;
- our ability to enroll subjects in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of clinical trials for evorpacept, and any of our other product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with evorpacept and any of our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of evorpacept or any of our other product candidates;
- the level of demand for evorpacept and any of our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with evorpacept and any of our other product candidates;
- our ability to commercialize evorpacept and any of our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies;
- the COVID-19 pandemic; and
- the changing and volatile global economic and political environment.

The cumulative effect 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. Investors should not rely on our past results as an indication of our future performance. 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.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. As of September 30, 2021, we had 40,486,287 shares of our common stock outstanding. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amount of our common stock in the public market, the market price of our common stock could decline significantly.

Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act.

On July 17, 2020, we filed a registration statement on Form S-8 to register 3,563,962 shares of our common stock reserved for future issuance under our equity compensation plans. In addition, on March 18, 2021, we filed a registration statement on Form S-8 to register 1,992,226 shares of our common stock reserved for future issuance under our equity compensation plans. As a result, shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to the satisfaction of applicable vesting arrangements and the exercise of such options and, in the case of our affiliates, the restrictions of Rule 144.

Moreover, certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable coverage. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. If one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We have incurred and will continue to incur significant increased costs and management resources as a result of operating as a public company.

We have incurred and will continue to incur significant legal, accounting, compliance and other expenses as a public company and these expenses may increase even more after we are no longer an “emerging growth company”, which we expect to occur after December 31, 2021. Our management and other personnel need to devote a substantial amount of time and incur significant expense in connection with compliance initiatives. For example, as a public company, we must adopt additional internal controls and disclosure controls and procedures and have retained a transfer agent and adopted an insider trading policy. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, we implemented an enterprise resource planning, or ERP, system for our company. An ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. However, an ERP system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Additionally, in the future, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in using an ERP system could adversely affect our controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act, or SOX, and the related rules and regulations implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have and will continue to increase legal and financial compliance costs and make some compliance activities more time-consuming. We have invested and will continue to invest additional resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. In connection with our initial public offering, we increased our directors' and officers' insurance coverage, which substantially increased our insurance cost. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We currently are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we will not be an "emerging growth company" after December 31, 2021. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our common stock less attractive if we choose to rely on these exemptions. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to use this extended transition period. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates. If some investors find our common stock less attractive as a result of any of our reliance on these exemptions, there may be a less active trading market for our common stock and our share price may be more volatile.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 57.6% of our outstanding voting stock.

Therefore, this group of stockholders, if they act together, will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other material 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. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We do not anticipate paying cash dividends and, accordingly, stockholders must rely on share appreciation for any return on their investment.

We have never paid any dividends on our capital stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and do not anticipate that we will declare or pay any cash dividends on our capital stock in the foreseeable future. See the section titled "Dividend Policy." As a result, capital appreciation, if any, of our common stock will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

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

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 new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve fixed payment obligations or agreements that include 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 funds through partnerships, collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our clinical or discovery programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, with each class serving staggered three-year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of convertible preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on behalf of us;
- any action asserting a claim of breach of a fiduciary duty;

- any action asserting a claim against us arising under the Delaware General Corporation Law, or DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws (as either may be amended from time to time); and
- any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or Exchange Act, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by the Sarbanes-Oxley Act of 2002. During our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. In the past, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting, all of which have since been remediated. We did not identify any material weakness as of September 30, 2021.

Furthermore, if in the future, we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

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, 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(a) of SOX or any subsequent testing by our independent registered public accounting firm in connection with Section 404(b) of SOX, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. As discussed above, we have identified material weaknesses in the past which we are in the process of remedying. However, our efforts to remediate previous material weaknesses may not be effective or prevent any future deficiency in our internal control over financial reporting. 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 common stock.

In connection with our evaluation of our internal controls over financial reporting, we expect to upgrade our finance and accounting systems and team. If we are unable to accomplish these objectives in a timely and effective manner, our ability to comply with the financial reporting requirements and other rules that apply to reporting companies could be adversely impacted. Any failure

to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition and results of operations and the trading price of our common stock.

We will be required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. Beginning with our second annual report on Form 10-K after we become a public company, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, expected after December 31,2021, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

To achieve compliance with Section 404(a) within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively and implement a continuous reporting and improvement process for internal control over financial reporting.

We will cease being an “emerging growth company” after December 31, 2021. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not identify. Undetected material weaknesses in our internal controls could lead to consolidated financial statement restatements and require us to incur the expense of remediation.

We are organized in a holding company structure and we are, and will be, dependent upon the results of operations and cash flows of our subsidiaries and distributions we receive from our subsidiaries.

ALX Oncology Holdings Inc. is a holding company that currently has no material assets other than cash and our ownership of all of the equity issued by ALX Oncology Limited. As such, ALX Oncology Holdings Inc. will have no independent means of generating revenue or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, will be dependent upon the results of operations and cash flows of ALX Oncology Limited and its consolidated subsidiaries, including any distributions we receive from ALX Oncology Limited. There can be no assurance that our direct and indirect subsidiaries will generate sufficient cash flow to distribute funds to us or that applicable law and contractual restrictions, such as negative covenants in any debt instruments, will permit such distributions. In addition, in the event that the board of directors and stockholders of ALX Oncology Holdings Inc. were to approve a sale of all of our equity in ALX Oncology Limited or any of our other indirect subsidiaries, your equity interest would be in a holding company with no material assets other than those assets and other consideration received in such transaction.

General Risks

If any of the third parties that we rely on for various operational and administrative aspects of our business fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third-party consultants and contractors to provide specific operational and administrative services, including research and clinical consultation and management. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on cloud-based platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our service providers and suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather

conditions, medical or public health crises, such as the COVID-19 pandemic, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

The majority of our operations including our corporate headquarters are located in the San Francisco Bay Area in California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches.

Despite the implementation of security measures, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Any system failure, accident or security breach that causes interruptions in our own or in third-party service providers' operations could result in a material disruption of our drug discovery and development programs. A system failure or security breach that causes the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. In addition, to the extent that any disruption or security breach results in a loss or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, including personal information related to the subjects in our clinical trial, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected and further development of our product candidates may be delayed. Any such disruption, failure or security breach could also cause us to incur additional costs to remedy the damages that arise from such disruption, failure or security breach.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and 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 facts 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 due to error or fraud may occur and not be detected.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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

Unregistered sales of equity securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

In July 2020, we closed the sale of 9,775,000 shares of common stock, which includes the additional overallotment of 1,275,000 shares exercised by the underwriters in the initial public offering, to the public at an initial public offering price of $19.00 per share. The aggregate offering price for shares sold in our initial public offering was $185.7 million. The offer and sale of the shares in the initial public offering was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333- 239490), which was filed with the SEC on June 26, 2020 and amended subsequently and declared effective on July 16, 2020, and Form S-1MEF, which was filed with the SEC on July 16, 2020 and became effective on July 16, 2020. The underwriters of the offering were Jefferies LLC, Credit Suisse Securities (USA) LLC, Piper Sandler & Co. and Cantor Fitzgerald & Co.

We received approximately $169.5 million in net proceeds after deducting underwriting discounts and commissions of approximately $13.0 million and offering-related expenses of $3.2 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We invested the funds received in accordance with our investment policy. None of such payments were direct or indirect payments to any of our directors or officers (or their associates), to persons owning ten percent or more of our common stock or to any other affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on July 17, 2020 pursuant to Rule 424(b)(4).

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	Filed herewith			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith			
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 has been formatted in Inline XBRL				

* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Date: November 12, 2021

ALX Oncology Holdings Inc.

By: /s/ Jaume Pons
Jaume Pons, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 12, 2021

By: /s/ Peter Garcia
Peter Garcia
Chief Financial Officer
(Principal Financial Officer)

Date: November 12, 2021

By: /s/ Shelly Pinto
Shelly Pinto
Vice President, Finance and Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

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

I, Jaume Pons, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ALX Oncology Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2021

By: /s/ Jaume Pons

Jaume Pons, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Peter Garcia, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ALX Oncology Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2021

By: /s/ Peter Garcia

Peter Garcia
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ALX Oncology Holdings Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2021

By: /s/ Jaume Pons

Jaume Pons, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ALX Oncology Holdings Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2021

By: /s/ Peter Garcia

Peter Garcia
Chief Financial Officer
(Principal Financial Officer)