

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 June 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: 001-40602

ERASCA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

10835 Road to the Cure, Suite 140

San Diego, CA

(Address of principal executive offices)

83-1217027

(I.R.S. Employer
Identification No.)

92121

(Zip Code)

Registrant's telephone number, including area code: (858) 465-6511

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, \$0.0001 par value per share	ERAS	Nasdaq Global Select Market

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

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

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

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

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

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

As of August 15, 2021, the registrant had 121,219,865 shares of common stock outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Erasca, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and par value amounts)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 156,396	\$ 65,376
Short-term investments	37,277	53,325
Prepaid expenses and other current assets	3,618	1,289
Total current assets	197,291	119,990
Long-term investments	5,000	—
Property and equipment, net	2,257	1,847
Operating lease assets	1,877	2,225
Restricted cash	408	312
Other assets	3,550	451
Total assets	\$ 210,383	\$ 124,825
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,507	\$ 878
Accrued expenses and other current liabilities	15,519	11,925
Operating lease liabilities	888	877
Total current liabilities	17,914	13,680
Operating lease liabilities, net of current portion	1,668	2,109
Preferred stock purchase right liability	—	1,615
Total liabilities	19,582	17,404
Commitments and contingencies (Note 12)		
Convertible preferred stock (Series A, B-1 and B-2), \$0.0001 par value; 97,622,409 shares authorized as of June 30, 2021 and December 31, 2020; 85,516,454 and 69,584,682 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively; aggregate liquidation preference of \$350,412 and \$230,924 as of June 30, 2021 and December 31, 2020, respectively	340,798	221,405
Stockholders' deficit:		
Common stock, \$0.0001 par value; 156,000,000 and 147,027,681 shares authorized as of June 30, 2021 and December 31, 2020, respectively, 27,300,123 and 25,189,673 shares issued at June 30, 2021 and December 31, 2020, respectively; 24,370,599 and 21,923,173 shares outstanding at June 30, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	11,634	1,413
Accumulated other comprehensive income (loss)	(1)	2
Accumulated deficit	(161,633)	(115,402)
Total stockholders' deficit	(149,997)	(113,984)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 210,383	\$ 124,825

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

Erasca, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 17,598	\$ 5,863	\$ 29,843	\$ 10,417
In-process research and development	5,488	—	9,168	17,670
General and administrative	5,098	1,421	8,780	3,032
Total operating expenses	28,184	7,284	47,791	31,119
Loss from operations	(28,184)	(7,284)	(47,791)	(31,119)
Other income (expense)				
Interest income	31	70	61	255
Other expense	(61)	(33)	(116)	(41)
Change in fair value of preferred stock purchase right liability	—	1,756	1,615	1,756
Total other income (expense), net	(30)	1,793	1,560	1,970
Net loss	\$ (28,214)	\$ (5,491)	\$ (46,231)	\$ (29,149)
Net loss per share, basic and diluted	\$ (1.20)	\$ (0.26)	\$ (2.02)	\$ (1.41)
Weighted-average shares of common stock used in computing net loss per share, basic and diluted	23,546,390	20,834,976	22,893,533	20,733,283
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net	(2)	8	(3)	(14)
Comprehensive loss	\$ (28,216)	\$ (5,483)	\$ (46,234)	\$ (29,163)

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

Erasca, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
Three months ended March 31, 2021 and June 30, 2021
(In thousands, except share data)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	69,584,682	\$ 221,405	25,189,673	\$ 3	\$ 1,413	\$ 2	\$ (115,402)	\$ (113,984)
Issuance of Series B-2 convertible preferred stock for cash, net of \$95 in issuance costs	15,931,772	119,393	—	—	—	—	—	—
Issuance of common stock in connection with asset acquisition	—	—	500,000	—	1,680	—	—	1,680
Exercise of stock options	—	—	439,610	—	94	—	—	94
Vesting of early exercised stock options	—	—	—	—	174	—	—	174
Stock-based compensation expense	—	—	—	—	795	—	—	795
Net loss	—	—	—	—	—	—	(18,017)	(18,017)
Unrealized loss on investments, net	—	—	—	—	—	(1)	—	(1)
Balance at March 31, 2021	85,516,454	\$ 340,798	26,129,283	\$ 3	\$ 4,156	\$ 1	\$ (133,419)	\$ (129,259)
Issuance of common stock in connection with license agreement	—	—	944,945	—	5,488	—	—	5,488
Exercise of stock options	—	—	225,895	—	180	—	—	180
Vesting of early exercised stock options	—	—	—	—	174	—	—	174
Stock-based compensation expense	—	—	—	—	1,636	—	—	1,636
Net loss	—	—	—	—	—	—	(28,214)	(28,214)
Unrealized loss on investments, net	—	—	—	—	—	(2)	—	(2)
Balance at June 30, 2021	85,516,454	\$ 340,798	27,300,123	\$ 3	\$ 11,634	\$ (1)	\$ (161,633)	\$ (149,997)

Erasca, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
Three months ended March 31, 2020 and June 30, 2020
(In thousands, except share data)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	38,103,681	\$ 63,403	22,629,158	\$ 3	\$ 124	\$ 11	\$ (13,742)	\$ (13,604)
Exercise of stock options	—	—	729,166	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	105	—	—	105
Net loss	—	—	—	—	—	—	(23,658)	(23,658)
Unrealized loss on investments, net	—	—	—	—	—	(22)	—	(22)
Balance at March 31, 2020	38,103,681	\$ 63,403	23,358,324	\$ 3	\$ 229	\$ (11)	\$ (37,400)	\$ (37,179)
Issuance of Series B-1 convertible preferred stock for cash, net of \$403 in issuance costs and preferred stock purchase right liability of \$7,355	25,081,001	117,647	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	109	—	—	109
Net loss	—	—	—	—	—	—	(5,491)	(5,491)
Unrealized gain on investments, net	—	—	—	—	—	8	—	8
Balance at June 30, 2020	63,184,682	\$ 181,050	23,358,324	\$ 3	\$ 338	\$ (3)	\$ (42,891)	\$ (42,553)

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

Erasca, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (46,231)	\$ (29,149)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	318	255
Stock-based compensation expense	2,431	214
In-process research and development expenses	9,168	17,670
(Accretion) amortization on investments, net	46	(20)
Change in fair value of preferred stock purchase right liability	(1,615)	(1,756)
Changes in operating assets and liabilities:		
Prepaid expenses and other current and long-term assets	(3,498)	(240)
Accounts payable	580	(521)
Accrued expenses and other current liabilities	4,984	1,458
Operating lease assets and liabilities, net	(82)	(26)
Net cash used in operating activities	(33,899)	(12,115)
Cash flows from investing activities:		
Purchases of investments	(31,911)	(39,970)
Maturities of investments	42,910	19,792
In-process research and development	(6,000)	(17,670)
Purchases of property and equipment	(701)	(773)
Net cash provided by (used in) investing activities	4,298	(38,621)
Cash flows from financing activities:		
Proceeds from the issuance of convertible preferred stock, net of issuance costs	119,393	125,002
Proceeds from the exercise of stock options, net of repurchases	1,324	490
Net cash provided by financing activities	120,717	125,492
Net increase in cash, cash equivalents and restricted cash	91,116	74,756
Cash, cash equivalents and restricted cash at beginning of the period	65,688	29,583
Cash, cash equivalents and restricted cash at end of the period	\$ 156,804	\$ 104,339
Supplemental disclosure of cash flow information:		
Cash paid for taxes	\$ 72	\$ 51
Supplemental disclosure of noncash investing and financing activity:		
Issuance of common stock in connection with asset acquisition	\$ 1,680	\$ —
Issuance of common stock in connection with license agreement	\$ 5,488	\$ —
Amounts accrued for purchases of property and equipment	\$ 101	\$ 4
Amounts accrued for deferred offering costs	\$ 1,930	\$ —
Vesting of early exercised options	\$ 348	\$ —
Preferred stock purchase right liability	\$ —	\$ 7,355

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

Erasca, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1. Organization and basis of presentation

Organization and nature of operations

Erasca, Inc. (Erasca or the Company) is a clinical-stage precision oncology company singularly focused on discovering, developing, and commercializing therapies for RAS/MAPK pathway-driven cancers. The Company has assembled a wholly-owned or controlled RAS/MAPK pathway-focused pipeline comprising 11 modality-agnostic programs aligned with its three therapeutic strategies of: (i) targeting key upstream and downstream signaling nodes in the RAS/MAPK pathway; (ii) targeting RAS directly; and (iii) targeting escape routes that emerge in response to treatment. The Company was incorporated under the laws of the State of Delaware on July 2, 2018, as Erasca, Inc., and is headquartered in San Diego, California. In September 2020, the Company established a wholly-owned Australian subsidiary, Erasca Australia Pty Ltd (Erasca Australia), in order to conduct clinical activities for its development candidates. In November 2020, the Company entered into an agreement and plan of merger with Asana BioSciences, LLC (Asana) and ASN Product Development, Inc. (the Asana Merger Agreement), pursuant to which Erasca—ASN Product Development, Inc. (ASN) became its wholly-owned subsidiary. In March 2021, the Company established a wholly-owned subsidiary, Erasca Ventures, LLC (Erasca Ventures), to potentially make equity investments in early-stage biotechnology companies that are aligned with the Company's mission and strategy.

Since inception, the Company has devoted substantially all of its efforts and resources to organizing and staffing the Company, business planning, raising capital, identifying, acquiring and in-licensing the Company's product candidates, establishing its intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of its product candidates and related raw materials, and providing general and administrative support for these operations. As of June 30, 2021, the Company had \$193.7 million in cash, cash equivalents, and short-term investments, respectively. As of June 30, 2021, the Company had an accumulated deficit of \$161.6 million. The Company has incurred significant operating losses and negative cash flows from operations. From its inception through June 30, 2021, the Company's financial support has primarily been provided from the sale of its convertible preferred stock.

As the Company continues its expansion, it expects to use its cash, cash equivalents, and short-term investments to fund research and development, working capital, and other general corporate purposes. The Company does not expect to generate any revenues from product sales unless and until the Company successfully completes development and obtains regulatory approval for any of its product candidates, which will not be for at least the next several years, if ever. Accordingly, until such time as the Company can generate significant revenue from sales of its product candidates, if ever, the Company expects to finance its cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses or other similar arrangements. However, the Company may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. The Company's failure to raise capital or enter into such other arrangements when needed would have a negative impact on the Company's financial condition and could force the Company to delay, limit, reduce or terminate its research and development programs or other operations, or grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market itself. The Company believes its cash, cash equivalents, and short-term investments as of June 30, 2021 and the net proceeds of \$317.7 million received from the Company's initial public offering (IPO), which closed on July 20, 2021, will be sufficient for the Company to fund operations for at least one year from the issuance date of these condensed consolidated financial statements.

Initial public offering

On July 20, 2021, the Company completed its initial public offering (IPO) in which the Company issued and sold 21,562,500 shares of common stock (including 2,812,500 shares of common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at an offering price of \$16.00 per share. Proceeds from the IPO, net of underwriting discounts, commissions and estimated offering costs, were \$317.7 million. In connection with the completion of the IPO, all outstanding shares of convertible preferred stock were converted into 71,263,685 shares of common stock.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with US generally accepted accounting principles (US GAAP). Any reference in these notes to applicable guidance is meant to refer to US GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) promulgated by the Financial Accounting Standards Board (FASB).

Principles of consolidation and foreign currency transactions

The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Erasca Australia, ASN and Erasca Ventures. Erasca Australia was registered under the laws of Australia on September 1, 2020, ASN was incorporated under the laws of the State of Delaware on November 23, 2020 and Erasca Ventures was formed under the laws of the State of Delaware on March 30, 2021. All intercompany balances and transactions have been eliminated. The functional currency of the Company and its wholly-owned subsidiaries is the US dollar. Assets and liabilities that are not denominated in the functional currency are remeasured into US dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), in the consolidated statements of operations and comprehensive loss and were not material for all periods presented.

Note 2. Summary of significant accounting policies

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with US GAAP requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities, expenses, and the disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Accounting estimates and management judgments reflected in the consolidated financial statements include, but are not limited to, the accrual of research and development expenses, fair value of common stock, preferred stock and freestanding instruments, stock-based compensation expense, and the incremental borrowing rate for determining the operating lease asset and liability. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Unaudited interim financial information

The accompanying condensed consolidated balance sheet as of June 30, 2021, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2021 and 2020, the condensed consolidated statements of convertible preferred stock and stockholders' deficit for the three and six months ended June 30, 2021 and 2020 and the condensed consolidated statements of cash flows for the six months ended June 30, 2021 and 2020 are unaudited. The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's condensed consolidated financial position as of June 30, 2021 and the condensed consolidated results of its operations and cash flows for the three and six months ended June 30, 2021 and 2020. The condensed consolidated financial data and other information disclosed in these notes related to the three and six months ended June 30, 2021 and 2020 are unaudited. The condensed consolidated results for the three and six months ended

June 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period.

Concentration of credit risk and off-balance sheet risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents and investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company's investment policy includes guidelines for the quality of the related institutions and financial instruments and defines allowable investments that the Company may invest in, which the Company believes minimizes the exposure to concentration of credit risk.

Cash, cash equivalents and restricted cash

Cash and cash equivalents include cash in readily available checking and savings accounts, money market funds, commercial paper, and corporate debt securities. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

The Company had deposited cash of \$408,000 and \$312,000 as of June 30, 2021 and December 31, 2020, respectively, to secure a letter of credit in connection with the lease of the Company's facilities (see Note 11). The Company has classified the restricted cash as a noncurrent asset on its condensed consolidated balance sheets.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows (in thousands):

	June 30,	
	2021	2020
Cash and cash equivalents	\$ 156,396	\$ 104,339
Restricted cash	408	—
Total cash, cash equivalents and restricted cash as shown on the condensed consolidated statements of cash flows	<u>\$ 156,804</u>	<u>\$ 104,339</u>

Investments

The Company classifies all marketable securities as available-for-sale, as the sale of such securities may be required prior to maturity. Management determines the appropriate classification of its investments in debt securities at the time of purchase. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than 12 months from, the balance sheet date are classified as short-term investments. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The Company regularly reviews all its investments for other-than-temporary declines in fair value. The review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its accounting basis and the decline is other-than-temporary, the Company reduces the carrying value of the security it holds and records a loss for the amount of such decline. Realized gains and losses and declines in value judged to be other than temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Fair value measurements

Certain assets and liabilities are carried at fair value under US GAAP. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Property and equipment, net

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the remaining lease term.

Impairment of long-lived assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company did not recognize any impairment losses for the three and six months ended June 30, 2021 and 2020.

Leases

The Company leases real estate facilities and equipment under non-cancelable and cancelable operating leases with various expiration dates through fiscal year 2032. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable.

Operating leases are included in operating lease assets and in operating lease liabilities in the accompanying condensed consolidated balance sheets. Operating lease assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term discounted based on the more readily determinable of (i) the rate implicit in the lease or (ii) the Company's incremental borrowing rate (which is the estimated rate the Company would be required to pay for a collateralized borrowing equal to the total lease payments over the term of the lease). Because the Company's operating leases generally do not provide an implicit rate, the Company estimates its incremental borrowing rate based on the information available at lease commencement date for borrowings with a similar term.

The Company's operating lease assets are measured based on the corresponding operating lease liability adjusted for (i) payments made to the lessor at or before the commencement date, (ii) initial direct costs incurred and (iii) tenant incentives under the lease. The Company does not assume renewals or early terminations unless it is reasonably certain to exercise these options at commencement. The Company elected the practical expedient which allows the Company to not allocate consideration between lease and non-lease components. Variable lease payments are recognized in the period in which the obligations for those payments are incurred. In addition, the Company elected the practical expedient such that it does not recognize lease assets or lease liabilities for leases with a term of 12 months or less of all asset classes. Operating lease expense is recognized on a straight-line basis over the lease term.

Research and development expense

Research and development expenses consist of external and internal costs associated with the Company's research and development activities, including its discovery and research efforts and the preclinical and clinical development of its product candidates. Research and development costs are expensed as incurred. The Company's research and development expenses include external costs, consisting of expenses incurred under arrangements with third parties, such as contract research organizations, contract manufacturers, consultants and its scientific advisors; and internal costs, consisting of employee-related expenses, including salaries, benefits, and stock-based compensation for those individuals involved in research and development efforts, the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study materials, and facilities and depreciation, which include direct and allocated expenses for rent of facilities and depreciation of equipment.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

In-process research and development expense

The Company has acquired rights as part of asset acquisitions or in-licenses to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as in-process research and development (IPR&D) in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under US GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. The Company accounts for contingent consideration payable upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying contingency is resolved. Milestone payments made to third parties subsequent to regulatory approval will be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

Patent costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of proceeds generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. As of June 30, 2021, \$2.6 million of

deferred offering costs were recorded in other assets on the Company's condensed consolidated balance sheet. There were no deferred offering costs as of December 31, 2020.

Common stock valuation

Due to the absence of an active market for the Company's common stock prior to the IPO, the Company utilized methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: Valuation of Privately-Held Company Equity Securities Issued as Compensation to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the fair value of the common stock as of the grant date. The fair value of the common stock has been determined based upon a variety of factors, including valuations of the Company's common stock performed with the assistance of independent third-party valuation specialists; the Company's stage of development and business strategy, including the status of research and development efforts of its product candidates, and the material risks related to its business and industry; the Company's business conditions and projections; the Company's results of operations and financial position, including its levels of available capital resources; the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies; the lack of marketability of the Company's common stock as a private company; the prices of the Company's convertible preferred stock sold to investors in arm's length transactions and the rights, preferences and privileges of its convertible preferred stock relative to those of its common stock; the likelihood of achieving a liquidity event for the holders of the Company's common stock, such as an initial public offering or a sale of the Company given prevailing market conditions; trends and developments in its industry; the hiring of key personnel and the experience of management; and external market conditions affecting the life sciences and biotechnology industry sectors. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Stock-based compensation

The Company measures employee and nonemployee stock-based awards based on the fair value on the date of grant and records compensation expense on a straight-line basis over the requisite service period of the award. The Company records the expense for stock-based compensation awards subject to performance-based milestone vesting over the implied service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions at each reporting date. All stock-based compensation costs are recorded in the consolidated statements of operations and comprehensive loss based upon the underlying employees or nonemployee's roles within the Company. Forfeitures are accounted for as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes options-pricing model, which requires inputs based on certain subjective assumptions, including the:

- Fair value of common stock. As there was no active market for the Company's common stock prior to the IPO, the Company estimated the fair value of common stock on the date of grant based on the then current facts and circumstances.
- Risk-free interest rate. The risk-free interest rate is based on the US Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the options.
- Expected volatility. Given that the Company's common stock was privately held prior to the IPO, there was no active trading market for its common stock. The Company derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- Expected term. The expected term represents the period that the options granted are expected to be outstanding. The expected term of stock options issued is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

- Expected dividend yield. The Company has never paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. Therefore, the Company used an expected dividend yield of zero.

The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date.

Classification and accretion of convertible preferred stock

The Company's convertible preferred stock is classified outside of stockholders' deficit on the consolidated balance sheets because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock. The convertible preferred stock is not redeemable, except in the event of a deemed liquidation. Because the occurrence of a deemed liquidation event is not currently probable, the carrying values of the convertible preferred stock are not being accreted to their redemption values. Subsequent adjustments to the carrying values of the convertible preferred stock would be made only when a deemed liquidation event becomes probable.

Preferred stock purchase right liabilities

The Company has entered into convertible preferred stock financings where, in addition to the initial closing, investors agree to buy, and the Company agrees to sell, additional shares of that convertible preferred stock at a fixed price in the event that certain conditions are met or agreed upon milestones are achieved. The Company evaluates this purchase right and assesses whether it meets the definition of a freestanding instrument and, if so, determines the fair value of the purchase right liability and records it on the balance sheet with the remainder of the proceeds raised allocated to convertible preferred stock. The preferred stock purchase right liability is revalued at each reporting period with changes in the fair value of the liability recorded as change in fair value of preferred stock purchase right liability in the consolidated statements of operations and comprehensive loss. The preferred stock purchase right liability is revalued at settlement and the resultant fair value, if any, is then reclassified to convertible preferred stock at that time.

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts and the tax bases of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. As of June 30, 2021, the Company's tax years since inception are subject to examination by taxing authorities due to the Company's unutilized net operating losses and tax credits.

Comprehensive income (loss)

The Company reports all components of comprehensive income (loss), including net loss, in the consolidated financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on

investments. Other comprehensive income includes unrealized gains and losses on investments, which was the only difference between net loss and comprehensive loss for the applicable periods.

Net loss per share

The Company's net loss is equivalent to net loss attributable to common stockholders for all periods presented. Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, options to purchase common stock and common stock subject to repurchase related to unvested restricted stock and options early exercised are considered to be potentially dilutive securities. Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security because it participates in dividends with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Segments

The Company has determined that its chief executive officer is the chief operating decision maker (CODM). The Company operates and manages the business as one reporting and one operating segment, which is the business of discovering and developing precision medicines for the benefit of patients with cancer. The Company's CODM reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's assets are located in the United States.

Recently adopted accounting pronouncements

In August 2018, the FASB issued ASU 2018-13, Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. The primary focus of the standard is to improve the effectiveness of the disclosure requirements for fair value measurements. The Company adopted this guidance on January 1, 2020, with no material impact on its consolidated financial statements or related disclosures.

In August 2018, the FASB issued ASU 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (ASU 2018-15). The new standard will align the requirements for capitalizing implementation costs for hosting arrangements (services) with costs for internal-use software (assets). As a result, certain implementation costs incurred in hosting arrangements will be deferred and amortized. The Company adopted ASU 2018-15 on January 1, 2021, and the adoption had an immaterial impact on its consolidated financial statements and related disclosures.

Recently issued accounting pronouncements not yet adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company can adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU 2016-13) and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, ASU 2019-05, and ASU 2019-11. The standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and it establishes additional disclosure requirements related to credit risks. For available-for-sale debt securities with expected credit losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This guidance was originally effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption was permitted. In November 2019, the FASB subsequently issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates, whereby the effective date of this standard for smaller reporting companies was deferred to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and early adoption is still permitted. The Company is currently evaluating the potential impact ASU 2016-13, and related updates, will have on its consolidated financial statements and related disclosures upon adoption.

In August 2020, the FASB issued ASU 2020-06, Debt: Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40) (ASU 2020-06), which simplifies the accounting for convertible instruments and contracts in an entity’s own equity. This guidance is effective for the Company in its annual reporting period beginning after December 15, 2023, including interim periods within that reporting period, with early adoption permitted only as of annual reporting periods beginning after December 15, 2020. The Company is currently assessing the impact this standard will have on its consolidated financial statements and related disclosures upon adoption.

Note 3. Fair value measurements

The following tables summarize the Company’s financial assets and liabilities measured at fair value on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	June 30, 2021	Fair value measurements as of June 30, 2021 using		
		Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets:				
Money market funds ⁽¹⁾	\$ 150,184	\$ 150,184	\$ —	\$ —
US treasury securities ⁽²⁾	5,000	5,000	—	—
US government securities ⁽²⁾	5,053	—	5,053	—
Corporate debt securities ⁽²⁾	3,328	—	3,328	—
Commercial paper ⁽²⁾	22,380	—	22,380	—
Supranational debt securities ⁽²⁾	1,516	—	1,516	—
US government securities ⁽³⁾	5,000	—	5,000	—
Total fair value of assets	\$ 192,461	\$ 155,184	\$ 37,277	\$ —

(1) Included as cash and cash equivalents on the condensed consolidated balance sheets.

(2) Included as short-term investments on the condensed consolidated balance sheets.

(3) Included as long-term investments on the condensed consolidated balance sheets.

As of June 30, 2021, there were no financial liabilities measured at fair value on a recurring basis.

	December 31, 2020	Fair value measurements as of December 31, 2020 using		
		Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets:				
Money market funds ⁽¹⁾	\$ 57,238	\$ 57,238	\$ —	\$ —
Commercial paper ⁽¹⁾	900	—	900	—
US treasury securities ⁽²⁾	38,492	38,492	—	—
Corporate debt securities ⁽²⁾	3,793	—	3,793	—
Commercial paper ⁽²⁾	11,040	—	11,040	—
Total fair value of assets	<u>\$ 111,463</u>	<u>\$ 95,730</u>	<u>\$ 15,733</u>	<u>\$ —</u>
Liabilities:				
Preferred stock purchase right liability	1,615	—	—	1,615
Total fair value of liabilities	<u>\$ 1,615</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,615</u>

(1) Included as cash and cash equivalents on the consolidated balance sheets.

(2) Included as short-term investments on the consolidated balance sheets.

The carrying amounts of the Company's financial instruments, including cash, prepaid and other current assets, accounts payable, and accrued expenses and other current liabilities, approximate fair value due to their short maturities. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented. There are uncertainties on the fair value measurement of the instrument classified under Level 3 due to the use of unobservable inputs and interrelationships between these unobservable inputs, which could result in higher or lower fair value measurements.

Cash equivalents consist of money market funds, commercial paper and corporate debt securities, short-term investments consist of US treasury and government securities, corporate debt securities, commercial paper and supranational debt securities, and long-term investments consist of US government securities. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bid and/or offers.

Preferred stock purchase right liability

As of December 31, 2020, the quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock purchase right liability include the fair value per share of the underlying Series B-1 Preferred Stock, the expected term of the purchase right liability, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model impacting the fair value of the preferred stock purchase right liability was the fair value of the Company's convertible preferred stock as of each measurement date. The Company determined the fair value per share of the underlying preferred stock by taking into consideration its most recent sales of its convertible preferred stock as well as additional factors that the Company deemed relevant. The Company lacks company-specific historical and implied volatility information of its stock. Therefore, it estimated its expected preferred stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the expected term of the purchase right liability. The risk-free interest rate was determined by reference to the US Treasury yield curve for time periods approximately equal to the expected term of the purchase right liability. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company never paid or declared dividends. The change in fair value of the purchase right liability was a gain of \$1.8 million for the three and six months ended June 30, 2020, included in other income (expense) within the condensed consolidated statements of operations and comprehensive loss. Upon the issuance of the shares of the Company's Series B-2 convertible preferred stock in January 2021, the purchase right liability was revalued with the gain of \$1.6 million recorded in change in fair value of the purchase right liability for the six months ended June 30, 2021 within the condensed consolidated statements of operations and comprehensive loss. Significant changes in the assumptions could have a material impact on the value of the preferred stock purchase right liability. The assumptions used in the

Black-Scholes option pricing model to determine the fair value of the preferred stock purchase right liability at settlement date and December 31, 2020 were as follows:

	Settlement Date	December 31, 2020
Fair value of underlying preferred stock	\$ 6.11	\$ 6.11
Risk-free interest rate	0.07%	0.08%
Expected volatility	74.4%	71.8%
Expected term (in years)	0.00	0.08
Expected dividend yield	—%	—%

Note 4. Investments

The following tables summarize the Company's investments accounted for as available-for-sale securities (in thousands, except years):

	June 30, 2021				
	Maturity (in years)	Amortized cost	Unrealized losses	Unrealized gains	Estimated fair value
US treasury securities	1 or less	\$ 5,000	\$ —	\$ —	\$ 5,000
US government securities	1 or less	5,053	—	—	5,053
Corporate debt securities	1 or less	3,328	—	—	3,328
Commercial paper	1 or less	22,380	—	—	22,380
Supranational debt securities	1 or less	1,516	—	—	1,516
US government securities	1-2	5,001	(1)	—	5,000
Total		<u>\$ 42,278</u>	<u>\$ (1)</u>	<u>\$ —</u>	<u>\$ 42,277</u>

	December 31, 2020				
	Maturity (in years)	Amortized cost	Unrealized losses	Unrealized gains	Estimated fair value
US treasury securities	1 or less	\$ 38,489	\$ —	\$ 3	\$ 38,492
Corporate debt securities	1 or less	3,794	(1)	—	3,793
Commercial paper	1 or less	11,040	—	—	11,040
Total		<u>\$ 53,323</u>	<u>\$ (1)</u>	<u>\$ 3</u>	<u>\$ 53,325</u>

As of June 30, 2021, there were two available-for-sale securities with an estimated fair value of \$6.5 million in gross unrealized loss positions. None had been in such position for greater than 12 months. As of December 31, 2020, there were six available-for-sale securities with an estimated fair value of \$15.8 million in gross unrealized loss positions. Based on the Company's review of its investments, the Company believes that the unrealized losses were not other-than-temporary as of June 30, 2021 and December 31, 2020.

Note 5. Property and equipment, net

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

	June 30, 2021	December 31, 2020
Leasehold improvements	\$ 795	\$ 795
Laboratory equipment	2,083	1,380
Furniture and fixtures	168	165
Office equipment	61	61
Software	70	70
Computer equipment	299	278
Property and equipment	<u>3,476</u>	<u>2,749</u>
Less accumulated depreciation and amortization	(1,219)	(902)
Property and equipment, net	<u>\$ 2,257</u>	<u>\$ 1,847</u>

Depreciation and amortization expense related to property and equipment was \$169,000 and \$318,000 for the three and six months ended June 30, 2021, respectively, and \$134,000 and \$255,000 for the three and six months ended June 30, 2020, respectively.

Note 6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Accrued research and development expenses	\$ 6,307	\$ 6,649
Accrued compensation	3,069	2,416
Unvested early exercised stock option liability	3,230	2,526
Accrued offering costs	1,870	—
Accrued legal	468	194
Other accruals	575	140
Total	<u>\$ 15,519</u>	<u>\$ 11,925</u>

Note 7. Asset acquisitions

The following purchased assets were accounted for as asset acquisitions as substantially all of the fair value of the assets acquired were concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. Because the assets had not yet received regulatory approval, the fair value attributable to these assets was recorded as in-process research and development expenses in the Company's consolidated statements of operations and comprehensive loss.

Asana BioSciences, LLC

In November 2020, the Company entered into the Asana Merger Agreement, pursuant to which ASN became its wholly-owned subsidiary. Asana and ASN had previously entered into a license agreement, which was amended and restated prior to the closing of the merger transaction (the Asana License Agreement, and collectively with the Asana Merger Agreement, the Asana Agreements), pursuant to which ASN acquired an exclusive, worldwide license to certain intellectual property rights relating to inhibitors of ERK1 and ERK2 owned or controlled by Asana to develop and commercialize ERAS-007 and certain other related compounds for all applications. The Company has the right to sublicense (through multiple tiers) the licensed rights under the Asana Agreements, subject to certain conditions. The foregoing license is subject to Asana's non-exclusive right to practice the licensed rights to research and conduct preclinical pharmacology activities with a specified combination of compounds, subject to certain specified conditions. Pursuant to the Asana License Agreement, neither Asana nor ASN can directly or indirectly exploit certain classes of competing products, subject to specified exceptions. In addition, the Company is required to use commercially reasonable efforts to develop and obtain regulatory approval for ERAS-007 in the United States, at least one major market country in Europe, and either China or Japan.

Under the Asana Merger Agreement, the Company made an upfront payment of \$20.0 million and issued 4,000,000 shares of its Series B-2 convertible preferred stock to Asana at a value of \$7.50 per share or a total fair value of \$30.0 million. The Company is obligated to make future development and regulatory milestone cash payments for a licensed product in an amount of up to \$90.0 million. Additionally, upon achieving a development milestone related to demonstration of successful proof-of-concept in a specified clinical trial, the Company will also be required to issue 3,888,889 shares of its common stock to Asana. The Company is not obligated to pay royalties on the net sales of licensed products. The Company recorded IPR&D expense of \$50.0 million during the year ended December 31, 2020 in connection with the asset acquisition. No IPR&D expense was recorded during the three and six months ended June 30, 2021 and 2020. As of June 30, 2021 and December 31, 2020, no milestones had been accrued as the underlying contingencies had not yet been resolved.

Upon the Company's payment to Asana of all merger consideration, including upfront cash and equity payments, the equity payment related to the proof-of-concept development milestone, and all other development milestone payments, with the exception of a specific milestone that does not need to be achieved at such time and will remain subject to payment in the event that such milestone is achieved at a later time, all licensed rights will become fully paid-up, perpetual, and irrevocable. The Asana License Agreement may be terminated by either Asana or the Company in the event of an uncured material breach by the other party. Asana also has the right to terminate the Asana License Agreement if the Company fails to engage in material activities in support of clinical development and commercialization of ERAS-007 for a period of 12 consecutive months, excluding reasons outside of its reasonable control and subject to certain limitations. However, Asana's right to terminate the Asana License Agreement for any reason ends once the Company has paid to Asana all merger consideration, or if Asana's equity interest in the Company becomes publicly traded and exceeds a certain threshold value. The Company may terminate the Asana License Agreement at any time upon the provision of prior written notice to Asana.

Emerge Life Sciences, Pte. Ltd.

In March 2021, the Company entered into an asset purchase agreement (ELS Purchase Agreement) with Emerge Life Sciences, Pte. Ltd. (ELS) wherein it purchased all rights, title, and interest (including all patent and other intellectual property rights) to EGFR antibodies directed against the EGFR domain II (EGFR-D2) and domain III (EGFR-D3) as well as a bispecific antibody where one arm is directed against EGFR-D2 and the other is directed against EGFR-D3 (the Antibodies). Under the terms of the ELS Purchase Agreement, the Company made an upfront payment of \$2.0 million and issued to ELS 500,000 shares of the Company's common stock at a value of \$3.36 per share or a total fair value of \$1.7 million. Under the ELS Purchase Agreement, ELS is committed to performing certain studies on the applicable antibodies to assist in development activities, the costs of which shall be mutually agreed upon and for which the Company will be responsible. The Company recorded IPR&D expense of \$0 and \$3.7 million during the three and six months ended June 30, 2021 in connection with the asset acquisition.

Pursuant to the ELS Purchase Agreement, at any time between 12 months and 36 months after the effective date of the ELS Purchase Agreement, if the Company reasonably determines that none of the Antibodies should be taken into human clinical trials due to safety, efficacy or CMC issues, then the Company has the option to select another antibody developed and solely owned by ELS that is not the subject of a license, collaboration, or option to a third party (the Option). If the Company elects to exercise the Option, then ELS will provide to the Company a list of all available antibodies that meet the aforementioned requirements, and the Company has the right to select one antibody from the list. Upon the Company's selection of an antibody, ELS will assign it all rights, title and interest to such antibody (including patent and other intellectual property rights) subject to any pre-existing obligations or restrictions. In the event that the Company wishes to have ELS conduct any studies on such optioned antibody, then after mutual agreement as to the scope of the studies, the Company will be responsible for the cost for such studies.

Note 8. License agreements

NiKang Therapeutics, Inc.

In February 2020, the Company entered into a license agreement (the NiKang Agreement) with NiKang Therapeutics, Inc. (NiKang) under which the Company was granted an exclusive, worldwide license to certain intellectual property rights owned or controlled by NiKang related to certain SHP2 inhibitors to develop and commercialize ERAS-601 and certain other related compounds for all applications. The Company has the right to sublicense (through multiple tiers) its rights under the NiKang Agreement, subject to certain conditions, and is required to use commercially reasonable efforts to develop and commercialize licensed products. The parties are obligated to negotiate in good faith for a certain period of time to grant NiKang the exclusive commercial distribution rights in greater China once a licensed product reaches a certain development stage.

Under the NiKang Agreement, the Company made an upfront payment of \$5.0 million to NiKang and reimbursed NiKang \$0.4 million for certain initial manufacturing costs. In addition, the Company paid \$7.0 million in April 2020 related to the publication of a US patent application that covered the composition of matter of ERAS-601. The Company is also obligated to pay (i) development and regulatory milestone payments in an aggregate amount of up to \$16.0 million for the first licensed product and \$12.0 million for a second licensed product, and (ii) commercial milestone payments in an aggregate amount of up to \$157.0 million for the first licensed product and \$151.0 million for a second licensed product. The Company is also obligated to: (i) pay tiered royalties on net sales of all licensed products in the mid-single digit percentages, subject to certain reductions; and (ii) equally split all net sublicensing revenues earned under sublicense agreements that the Company enters into with any third party

before commencement of the first Phase I clinical trial for a licensed product. As of June 30, 2021 and December 31, 2020, the Company had accrued \$0 and \$4.0 million related to a development milestone, respectively. The Company recorded IPR&D expense of \$0 during the three and six months ended June 30, 2021 and \$0 and \$12.0 million during the three and six months ended June 30, 2020, respectively, related to the upfront and milestone payments.

The NiKang Agreement will expire upon the last to expire royalty term, which is determined on a licensed product-by-licensed product and country-by-country basis, and is the later of (i) ten years from the date of first commercial sale, (ii) the last to expire valid claim within the licensed patent rights covering such licensed product, or (iii) the expiration of all regulatory exclusivity for the licensed product in such country. Upon expiration of the NiKang Agreement, on a licensed product-by-licensed product and country-by-country basis, the Company will have a fully paid-up, non-exclusive license to conduct research and to develop and commercialize the licensed products.

The NiKang Agreement may be terminated in its entirety by NiKang in the event of the Company's uncured material breach, which includes its failure to use commercially reasonable efforts to satisfy certain specified clinical development diligence milestones. In addition, NiKang may terminate if the Company, directly or indirectly, commences a legal action challenging the validity or enforceability of any licensed patents. Further, if the Company acquires more than 50% of the equity or assets of a company that owns a competing small molecule that is designed to prevent the same target as set forth in the NiKang Agreement from switching to an enzymatically active state, then the Company must either divest such competing product or terminate the NiKang Agreement. The Company may terminate the NiKang Agreement at any time upon the provision of prior written notice to NiKang. Upon termination of the NiKang Agreement for any reason, all rights and licenses granted to the Company, as well as any sublicenses that the Company granted thereunder, will terminate. In addition, upon any termination (but not expiration) of the NiKang Agreement and upon NiKang's request, the parties are obligated to meet and negotiate in good faith the terms of a license from the Company to NiKang to allow NiKang's continued development, manufacture, and commercialization of the licensed products.

Katmai Pharmaceuticals, Inc.

In March 2020, the Company entered into a license agreement (the Katmai Agreement) with Katmai Pharmaceuticals, Inc. (Katmai) under which the Company was granted an exclusive, worldwide, royalty-bearing license to certain patent rights and know-how controlled by Katmai related to the development of small molecule therapeutic and diagnostic products that modulate EGFR and enable the identification, diagnosis, selection, treatment, and/or monitoring of patients for neuro-oncological applications to develop, manufacture, use, and commercialize ERAS-801 and certain other related compounds in all fields of use. The Company has the right to sublicense (through multiple tiers) its rights under the Katmai Agreement, subject to certain limitations and conditions, and is required to use commercially reasonable efforts to develop, manufacture, and commercialize licensed products and to meet certain specified development and launch milestones by certain dates. The Company is obligated to use commercially reasonable efforts to develop the licensed products first for use within the neuro-oncology field before expanding its development efforts to include other indications in the oncology field. Following the first achievement of a clinical proof-of-concept for any indication, the Company has the right to submit a non-binding offer to Katmai for (i) the purchase of all licensed patent rights, know-how, and other assets owned by Katmai that are necessary or useful for the exploitation of the licensed products or (ii) for the purchase of Katmai. Pursuant to the Katmai Agreement, neither Katmai nor the Company can directly or indirectly exploit certain specified classes of competing products.

The license granted under the Katmai Agreement is subject to The Regents of the University of California's reserved right to (i) use the licensed patent rights and know-how for educational and non-commercial research purposes, and to publish results arising therefrom, and (ii) grant licenses to the licensed know-how to third parties without notice because the licensed know-how is non-exclusively licensed to Katmai by The Regents of the University of California. Further, the license granted under the Katmai Agreement is subject to the rights of the United States government under the Bayh-Dole Act, including (i) a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced the invention claimed by the licensed patent rights throughout the world and (ii) the obligation that any licensed products used or sold in the United States be manufactured substantially in the United States.

Under the Katmai Agreement, the Company made an upfront payment of \$5.7 million and Katmai agreed to purchase shares of the Company's Series B-1 convertible preferred stock and Series B-2 convertible preferred stock having an aggregate value of \$2.7 million. In April 2020, Katmai purchased 356,000 shares of the Company's Series B-1 convertible preferred stock for \$1.8 million, and in January 2021, Katmai purchased 118,666 shares of the Company's Series B-2 convertible preferred stock for \$0.9 million. The Company is obligated to make future development and regulatory milestone payments of up to \$26.0 million and commercial milestone payments of up to \$101.0 million. The Company is also obligated to pay tiered royalties on net sales of each licensed product, at rates ranging from the mid- to high-single digit percentages, subject to a minimum annual royalty

payment in the low six figures and certain permitted deductions. No IPR&D expense was recorded for the three and six months ended June 30, 2021. The Company recorded IPR&D expense of \$0 and \$5.7 million in connection with the upfront payment during the three and six months ended June 30, 2020, respectively.

The Company's royalty obligations and the Katmai Agreement will expire, on a licensed product-by-licensed product and country-by-country basis, on the earlier of (i) the ten-year anniversary of the expiration of all valid claims included in the licensed patents covering the composition of matter or method of use of such licensed product in such country or (ii) the twentieth anniversary of the first commercial sale of such licensed product in such country. Upon the expiration of the Katmai Agreement, the Company will have a fully paid-up and irrevocable license.

The Katmai Agreement may be terminated in its entirety by either party (i) in the event of an uncured material breach by the other party or (ii) in the event the other party becomes subject to specified bankruptcy, insolvency, or similar circumstances. Provided that the Company is in full compliance with the Katmai Agreement, the Company may terminate the Katmai Agreement upon written notice to Katmai. Upon termination of the Katmai Agreement for any reason, all rights and licenses granted to the Company thereunder will terminate. Upon termination of the Katmai Agreement, the Company is obligated, among other things, to (i) grant an exclusive license to Katmai under all of the Company's right, title and interest in all inventions and know-how developed under the Katmai Agreement existing at the time of termination that are specific to the licensed compounds or products, including without limitation all data and results related to Katmai's exploitation and (ii) transfer to Katmai ownership and possession of all regulatory filings related to the licensed compounds and products. Unless the Katmai Agreement is terminated for the Company's material breach, the parties will negotiate in good faith the financial terms pursuant to which the foregoing actions will be conducted, provided that the Company's performance of such actions may not be conditioned upon the conduct or completion of such negotiations. If the parties are unable to agree upon such terms within the specified time period, then the parties will submit all unresolved matters for resolution by arbitration.

LifeArc

In April 2020, the Company entered into a license agreement with LifeArc (the LifeArc Agreement) under which the Company was granted an exclusive, worldwide license to certain materials, know-how, and intellectual property rights owned or controlled by LifeArc to develop, manufacture, use, and commercialize certain ULK inhibitors for all applications. The Company also has the right to sublicense (through multiple tiers) its rights under the LifeArc Agreement, subject to certain conditions. The foregoing license is subject to LifeArc's retained non-exclusive, irrevocable, worldwide, sublicensable (to its academic collaborators), royalty-free right to use the licensed intellectual property rights within all fields of use for LifeArc's own non-commercial, non-clinical academic research. Notwithstanding its retained rights, LifeArc will not seek to develop or undertake any other ULK1/2 therapeutic development programs either in-house or via third parties until April 2025. The Company is required to use diligent efforts to achieve certain development and regulatory milestones with respect to submission of an IND, initiation of clinical trials, submission of an NDA, and commencement of commercial sales.

Under the LifeArc Agreement, the Company was granted the license at no upfront cost and a period of three months after the effective date to conduct experiments on LifeArc's compounds. Upon completion of this initial testing period, the Company had the option to continue the license and make a one-time license payment of \$75,000 to LifeArc, which payment was subsequently made. The Company is obligated to make future development milestone payments for a licensed product of up to \$11.0 million and sales milestone payments of up to \$50.0 million. The Company is also obligated to pay royalties on net sales of all licensed products, in the low-single digit percentages, subject to certain reductions. No IPR&D expense was recorded during the three and six months ended June 30, 2021 and 2020.

The Company's royalty obligations and the LifeArc Agreement will expire, on a licensed product-by-licensed product and country-by-country basis, on the later of (i) ten years from the date of first commercial sale, (ii) when there is no longer a valid patent claim covering such licensed product, or (iii) expiration of regulatory exclusivity for the licensed product in such country. Upon expiration of the LifeArc Agreement, all rights and licenses granted to the Company and under the LifeArc Agreement will continue on a fully paid-up basis.

The LifeArc Agreement may be terminated in its entirety by either LifeArc or the Company in (i) the event of an uncured material breach by the other party or (ii) in the event the other party becomes subject to an order by a court of competent jurisdiction for winding-up or dissolution or similar circumstances. Further, LifeArc may terminate the LifeArc Agreement by giving written notice to the Company if (i) the Company fails to comply with its diligence obligations and fails to take remedial actions, (ii) the Company fails to agree on a mechanism to cure a persistent breach, or (iii) the Company fails to provide proof of the insurance coverage as required under the LifeArc Agreement. The Company may terminate the agreement at any time upon the provision of written notice to LifeArc.

Upon termination of the LifeArc Agreement for any reason, all rights and licenses granted to the Company, as well as any sublicenses the Company granted thereunder, will terminate. In addition, upon termination of the LifeArc Agreement for any reason other than its natural expiration or termination by the Company for LifeArc's material breach, LifeArc has an option to negotiate an exclusive, worldwide, sublicensable license to commercialize any patent rights, technical and clinical data, and any development results relating to the licensed products that are owned or controlled by the Company for the purpose of developing, manufacturing and commercializing the licensed products on terms to be negotiated between the parties.

University of California, San Francisco

In December 2018, the Company entered into a license agreement, as amended (the UCSF Agreement), with The Regents of the University of California, San Francisco (the Regents), under which the Company was granted an exclusive, worldwide, royalty-bearing license under certain patent rights claiming novel covalent inhibitors of GTP- and GDP-bound RAS for the development and commercialization of products covered by such patent rights for the prevention, treatment and amelioration of human cancers and other diseases and conditions. The UCSF Agreement was amended in May 2021. The Company has the right to sublicense (through multiple tiers) its rights under the UCSF Agreement, subject to certain conditions. The foregoing license is subject to various retained rights and restrictions, including (i) the Regents' reserved right to make, use and practice the licensed patent rights and any technology relating thereto for educational and research purposes, (ii) Howard Hughes Medical Institute's non-exclusive, fully paid-up, irrevocable worldwide license to use the licensed patent rights for research purposes, (iii) Howard Hughes Medical Institute's statement of policy on research tools, and (iv) the obligations to the US government under the Bayh-Dole Act, including the obligation to report on the utilization of the invention covered by the licensed patent rights and a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced such invention throughout the world. The Company is required to use diligent efforts to proceed with the development and commercialization of licensed products including by achieving certain milestone events within the specified time periods.

Under the UCSF Agreement, the Company made upfront payments of \$50,000 to the Regents and pays the Regents an annual license maintenance fee during the term of the license, but such fee will not be due on any anniversary if, on that date, the Company is making royalty payments to the Regents. The Company is obligated to make future development and regulatory milestone payments of up to \$6.4 million and a sales milestone payment of \$2.0 million for either of the first two licensed products. The Company is also obligated to pay royalties on net sales of all licensed products in the low-single digit percentages, subject to a minimum annual royalty payment in the low six figures, commencing on the year of the first sale of a licensed product and continuing, on a licensed product-by-licensed product and country-by-country basis, until there are no valid claims of the licensed patent rights covering the licensed product in such country.

Additionally, the Company is obligated to pay tiered sublicensing fees, with the first two tiers in the low-to-mid teen percentages and the third tier at 30%, on certain fees the Company receives from any sublicense that the Company grants, depending on the stage of development of a licensed product when such sublicense is granted. Prior to the execution of the amendment, the Company was obligated to make a cash payment to the Regents in the event of the Company's initial public offering, a change of control transaction or a reverse merger (the Corporate Milestone). In the amendment, the amount of the cash payment payable upon the Company's achievement of a Corporate Milestone was reduced and the Company agreed to issue the Regents 944,945 shares of the Company's common stock, which issuance is not contingent upon the achievement of a Corporate Milestone and occurred in May 2021. The Company recorded IPR&D expense of \$5.5 million during the three and six months ended June 30, 2021 related to the issuance of these 944,945 common stock shares. No IPR&D expense was recorded during the three and six months ended June 30, 2020.

The UCSF Agreement will expire upon the expiration of the last of the licensed patent rights. The UCSF Agreement may be terminated in its entirety by the Regents (i) for the Company's uncured breach; (ii) for the Company's bankruptcy; or (iii) if the Company challenges, directly or indirectly, the validity or enforceability of any licensed patents. Further, if the Company fails to satisfy any diligence milestones, the Regents has the right and option to either terminate the UCSF Agreement or modify the exclusive license granted thereunder to a non-exclusive license. The Company may terminate the UCSF Agreement in its entirety or on a country-by-country basis at any time upon the provision of written notice to the Regents. Upon termination of the UCSF Agreement for any reason, all rights and licenses granted to the Company thereunder will terminate.

Note 9. Stockholders' deficit

Under its Amended and Restated Certificate of Incorporation dated April 15, 2020, the Company was authorized to issue 147,027,681 shares of its common stock, par value of \$0.0001 per share. In February 2021, the Company's Board of Directors increased the authorized number of shares of its common stock to 156,000,000 shares. As of June 30, 2021, the Company was authorized to issue 97,622,409 shares of its convertible preferred stock, par value of \$0.0001 per share, of which 38,103,681 shares are designated as Series A convertible preferred stock, 28,741,400 shares are designated as Series B-1 convertible preferred stock and 30,777,328 shares are designated as Series B-2 convertible preferred stock.

Convertible preferred stock

In 2018, the Company issued 27,953,681 shares of its Series A convertible preferred stock at \$1.667 per share. The Company received proceeds of approximately \$46.5 million, net of issuance costs.

In 2019, the Company issued 10,150,000 shares of its Series A convertible preferred stock at \$1.667 per share. The Company received proceeds of approximately \$16.9 million, net of issuance costs.

In April 2020, the Company entered into a Series B convertible preferred stock purchase agreement (the Series B Agreement) under which it issued 27,481,001 shares of its Series B-1 convertible preferred stock at various closing dates in 2020, for cash, at a price of \$5.00 per share, for net proceeds of \$137.0 million (the Series B-1 Closing). The Series B Agreement contained provisions that potentially obligates the Company to issue 13,175,191 shares of Series B-2 convertible preferred stock at \$7.50 per share in an additional closing to certain Series B-1 Closing purchasers, upon the achievement of certain milestones as defined in the Series B Agreement, which purchase right terminates on September 30, 2022 or at certain specified events, including an initial public offering of the Company, if any (the Series B-2 Closing). In the event that a Series B-1 Closing purchaser fails to purchase all of its required shares in the subsequent Series B-2 Closing, each of the Series B-1 convertible preferred shares held by such purchaser will automatically be converted into one-tenth of a share of the Company's common stock.

The Company determined its obligation to issue additional shares of its Series B-2 convertible preferred stock in the Series B-1 Closing represented a freestanding financial instrument that required liability accounting. This freestanding preferred stock purchase right liability for the Series B-2 Closing was recorded at fair value and is remeasured at each reporting period. As of the Series B-1 Closing, the estimated fair value of the preferred stock purchase right liability was \$9.0 million. The Company records any changes in the fair value of the Series B-2 convertible preferred stock purchase right liability as changes in the fair value of convertible preferred stock purchase right liability in the accompanying consolidated statements of operations and comprehensive loss, and recorded a gain of \$7.4 million for the year ended December 31, 2020. To satisfy its obligation, in January 2021, the Company sold 13,175,191 shares of its Series B-2 convertible preferred stock and an additional 2,756,581 shares of its Series B-2 convertible preferred stock at a price of \$7.50 per share and received aggregate net proceeds of \$119.4 million.

Also in 2020, the Company issued 4,000,000 shares of its Series B-2 convertible preferred stock at \$7.50 per share in connection with an asset acquisition (see Note 7).

Convertible preferred stock consisted of the following (in thousands, except share data):

	June 30, 2021				
	Preferred shares authorized	Preferred shares issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A preferred stock	38,103,681	38,103,681	\$ 63,403	\$ 63,519	31,753,064
Series B-1 preferred stock	28,741,400	27,481,001	128,002	137,405	22,900,819
Series B-2 preferred stock	30,777,328	19,931,772	149,393	149,488	16,609,802
Total	<u>97,622,409</u>	<u>85,516,454</u>	<u>\$ 340,798</u>	<u>\$ 350,412</u>	<u>71,263,685</u>

December 31, 2020

	Preferred shares authorized	Preferred shares issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A preferred stock	38,103,681	38,103,681	\$ 63,403	\$ 63,519	31,753,064
Series B-1 preferred stock	28,741,400	27,481,001	128,002	137,405	22,900,819
Series B-2 preferred stock	30,777,328	4,000,000	30,000	30,000	3,333,333
Total	<u>97,622,409</u>	<u>69,584,682</u>	<u>\$ 221,405</u>	<u>\$ 230,924</u>	<u>57,987,216</u>

Convertible preferred stock rights and preferences

The rights and preferences for convertible preferred stock are detailed in the Company's final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on July 16, 2021.

Common stock

The Company had 156,000,000 and 147,027,681 shares of its common stock authorized as of June 30, 2021 and December 31, 2020, respectively. The Company had 27,300,123 and 25,189,673 shares of its common stock issued and 24,370,599 and 21,923,173 shares of common stock outstanding as of June 30, 2021 and December 31, 2020, respectively. As of June 30, 2021 and December 31, 2020, the fair value of common stock was \$9.28 and \$3.36, respectively.

Shares of common stock subject to repurchase

During 2018, the Company issued 1,458,332 shares of restricted stock for cash at a price of \$0.0001 per share. The restricted stock vests 25% one year from the vesting commencement date and monthly thereafter over a three-year period and is subject to repurchase by the Company in the event of any voluntary or involuntary termination of services to the Company prior to vesting. Any shares subject to repurchase by the Company are not deemed, for accounting purposes, to be outstanding until those shares vest. As of June 30, 2021 and December 31, 2020, 394,966 shares and 577,259 shares of common stock, respectively, were subject to repurchase by the Company. The unvested stock liability related to these awards is immaterial for all periods presented. For the three and six months ended June 30, 2021, 91,146 and 182,293 shares vested, respectively. For the three and six months ended June 30, 2020, 91,146 and 182,292 shares vested, respectively.

Note 10. Stock-based compensation

In July 2018, the Company adopted the 2018 Equity Incentive Plan (the Plan), which expires ten years from its effective date. The Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, and other stock awards to employees, consultants and directors of the Company. As of June 30, 2021 and December 31, 2020, a total of 21,545,845 and 13,212,511 shares of common stock, respectively, were authorized for issuance under the Plan.

Options granted under the Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. Stock options generally vest over a four-year term. The exercise price of each option shall be determined by the Company's Board of Directors based on the estimated fair value of the Company's stock on the date of the option grant. The exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. For holders of more than 10% of the Company's total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair market value of the Company's common stock on the date of grant and for a term that exceeds five years. Early exercise is permitted for certain grants.

Stock options

A summary of the Company's stock option activity under the Plan is as follows (in thousands, except share and per share data and years):

	Shares	Weighted- average exercise price	Weighted- average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at December 31, 2020	6,541,422	\$ 0.98	9.23	\$ 15,571
Granted	7,658,023	4.92		
Exercised	(665,505)	1.99		1,984
Canceled	(8,333)	5.81		
Outstanding at June 30, 2021	13,525,607	\$ 3.16	9.24	\$ 82,735
Options exercisable at June 30, 2021	1,902,188	\$ 1.97	8.87	\$ 13,903

The weighted-average grant date fair value of options granted for the three and six months ended June 30, 2021 was \$4.59 and \$3.45, respectively, and for the three and six months ended June 30, 2020 was \$0 and \$0.45, respectively. As of June 30, 2021, the unrecognized compensation cost related to unvested stock option grants was \$29.3 million and is expected to be recognized as expense over approximately 3.68 years. The aggregate fair value of stock options that vested for the three and six months ended June 30, 2021 was \$0.5 million and \$0.8 million, respectively, and for the three and six months ended June 30, 2020 was \$0.1 million.

Certain individuals were granted the ability to early exercise their stock options. The shares of common stock issued from the early exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees and non-employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. The cash received in exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock options on the accompanying consolidated balance sheets and will be transferred into common stock and additional paid-in capital as the shares vest. As of June 30, 2021 and December 31, 2020, there were 2,149,221 shares and 2,131,510 shares subject to repurchase by the Company, respectively. As of June 30, 2021 and December 31, 2020, the Company recorded \$3.2 million and \$2.5 million of liabilities associated with shares issued with repurchase rights, respectively, which is recorded in accrued expenses and other current liabilities.

In January 2019, the Company granted 250,000 options that vest based on a performance milestone. For the three and six months ended June 30, 2021, the Company recognized \$22,000 and \$115,000 of stock-based compensation associated with the performance-based options as the performance milestone was determined to be probable as of March 31, 2021. As of December 31, 2020, the milestone for the performance-based options was not probable of achievement, and therefore, no compensation expense for performance-based options had been recognized.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020 ⁽¹⁾	2021	2020
Risk-free interest rate	1.02%-1.09%	--%	0.59%-1.09%	1.22%
Expected volatility	82.08%-82.54%	--%	82.08%-83.88%	74.72%
Expected term (in years)	6.08	0.00	6.08	6.25
Expected dividend yield	--%	--%	--%	--%

(1) No stock options were granted during the three months ended June 30, 2020.

Restricted stock

The Company granted 1,795,827 shares of its restricted stock in 2018, which vest 25% one year from the vesting commencement date and monthly thereafter over a three-year period. The weighted-average grant date fair value of restricted stock granted in 2018 was \$0. No shares of restricted stock were granted during the three and six months ended June 30, 2021 and 2020. The restricted stock shares are subject to forfeiture upon the stockholders' termination of employment or service to the Company. Any shares subject to forfeiture are not deemed, for accounting purposes, to be outstanding until those shares vest. As such, the Company recognizes the measurement date fair value of the restricted stock over the vesting period as compensation expense. As of June 30, 2021 and December 31, 2020, 385,337 shares and 557,731 shares of common stock, respectively, were subject to forfeiture.

The summary of the Company's restricted stock activity during the six months ended June 30, 2021 is as follows:

	Number of restricted stock shares outstanding	Weighted-average grant date fair Value
Nonvested at December 31, 2020	557,731	\$ 0.001
Vested	(172,394)	0.001
Nonvested at June 30, 2021	385,337	\$ 0.001

At June 30, 2021, the total unrecognized compensation related to unvested restricted stock awards granted was \$0.

Stock-based compensation expense

The allocation of stock-based compensation for all stock awards was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Research and development	\$ 925	\$ 52	\$ 1,416	\$ 101
General and administrative	711	57	1,015	113
Total	\$ 1,636	\$ 109	\$ 2,431	\$ 214

Common stock reserved for future issuance

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

	June 30, 2021	December 31, 2020
Conversion of preferred stock outstanding	71,263,685	57,987,216
Conversion of preferred stock in future issuance (B-2)	—	10,979,319
Stock options issued and outstanding	13,525,607	6,541,422
Awards available for future grant	2,998,389	2,314,746
Total	87,787,681	77,822,703

Note 11. Leases

Operating leases

The Company has facility leases for office space under non-cancellable and cancelable operating leases with various expiration dates through 2032 and equipment under a non-cancellable operating lease with a term expiring in 2022. Operating lease cost was approximately \$380,000 and \$742,000, including variable lease costs of \$123,000 and \$228,000, and short-term lease costs of \$30,000 and \$59,000 during the three and six months ended June 30, 2021, respectively. Operating lease cost was approximately \$321,000 and \$661,000, including variable lease costs of \$78,000 and \$175,000, and short-term lease costs of \$22,000 and \$41,000 during the three and six months ended June 30, 2020, respectively. The Company paid \$535,000 and \$470,000 in cash for operating leases that were included in the operating activities section of the consolidated statements of cash flows for the six months ended June 30, 2021 and 2020, respectively.

The weighted-average remaining lease term and the weighted-average discount rate of the Company's operating leases was 2.71 years and 7.8% at June 30, 2021, respectively. The weighted-average remaining lease term and the weighted-average discount rate of the Company's operating leases was 3.16 years and 7.8% at December 31, 2020, respectively. The weighted-average remaining lease term does not include any renewal options at the election of the Company.

The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Facility leases

In 2018, the Company entered into a lease agreement for approximately 11,000 square feet of office space in San Diego, California which was subsequently amended resulting in a total of approximately 16,153 square feet of office space leased. The amended space is accounted for as a separate lease. The non-cancellable operating leases expire in May 2024. The Company's lease payments consist primarily of fixed rental payments for the right to use the underlying leased assets over the lease terms. The Company is responsible for operating expenses over base operating expenses as defined in the original lease agreement.

In September 2020, the Company entered into a lease agreement for 59,407 square feet of laboratory and office space in San Diego, California (2020 Lease), which represented a portion of a new facility that is under construction. The construction and design of the asset is the primary responsibility of the lessor. The Company is involved in certain aspects of construction and design for certain interior features and leasehold improvements that will be beneficial to the Company to better suit its business needs and intended purpose of the space. The lease will be accounted for as an operating lease and has a target commencement date of August 2021. The lease has an initial term of 10.5 years and includes aggregate monthly payments to the lessor of approximately \$39.5 million beginning in January 2023 with a rent escalation clause, and a tenant improvement allowance of approximately \$13.4 million. The lease is cancellable at the Company's request after the 84th month with 12 months written notice and a lump-sum cancellation payment of \$1.9 million. As discussed in Note 2, the Company provided a letter of credit to the lessor for \$312,000, which expires October 31, 2031.

In March 2021, the Company entered into the first amendment to the 2020 Lease to expand the rented premises by 18,421 square feet for additional consideration of \$96,000 per month starting in January 2023 with a rent escalation clause and to receive an additional \$3.4 million tenant improvement allowance. The payment associated with the option to cancel the lease after the 84th month was increased to \$2.5 million, and the letter of credit provided to the lessor was increased to \$408,000.

Future minimum lease payments under non-cancelable operating leases with initial lease terms in excess of one year as of June 30, 2021 are as follows (in thousands):

Year ending December 31,	
2021 (6 months remaining)	\$ 538
2022	969
2023	937
2024	<u>401</u>
Total lease payments	\$ 2,845
Less: Amount representing interest	<u>(288)</u>
Operating lease liabilities	<u>\$ 2,557</u>

As of June 30, 2021, the Company had commitments of \$51.6 million for a cancelable operating lease of a new real estate facility that has not yet commenced, and therefore are not included in the operating lease assets or liabilities. This operating lease commenced in August 2021 with a lease term of 10.5 years.

Note 12. Commitments and contingencies

As of June 30, 2021 and December 31, 2020, there was no litigation against the Company.

Note 13. Income taxes

No provision for federal, state or foreign income taxes has been recorded for the three and six months ended June 30, 2021 and 2020. The Company has incurred net operating losses for all the periods presented and has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements due to uncertainty around utilizing these tax attributes within their respective carryforward periods. The Company has recorded a full valuation allowance against all of its deferred tax assets as it is not more likely than not that such assets will be realized in the near future. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. For the three and six months ended June 30, 2021 and 2020, the Company has not recognized any interest or penalties related to income taxes.

Note 14. Net loss per share

The following table summarizes the computation of basic and diluted net loss per share of the Company (in thousands, except share and per share data):

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net loss	\$ (28,214)	\$ (5,491)	\$ (46,231)	\$ (29,149)
Weighted-average shares of common stock used in computing net loss per share, basic and diluted	23,546,390	20,834,976	22,893,533	20,733,283
Net loss per share, basic and diluted	<u>\$ (1.20)</u>	<u>\$ (0.26)</u>	<u>\$ (2.02)</u>	<u>\$ (1.41)</u>

The Company's potentially dilutive securities, which include its convertible preferred stock, options to purchase common stock and common stock subject to repurchase related to unvested restricted stock and options early exercised, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Convertible preferred stock issued	71,263,685	52,653,884	71,263,685	52,653,884
Conversion of convertible preferred stock in future issuance (B-2)	—	8,312,653	—	8,312,653
Options to purchase common stock	13,525,607	3,390,918	13,525,607	3,390,918
Restricted stock subject to future vesting	780,303	1,706,689	780,303	1,706,689
Options early exercised subject to future vesting	2,149,221	729,166	2,149,221	729,166
Total potentially dilutive shares	<u>87,718,816</u>	<u>66,793,310</u>	<u>87,718,816</u>	<u>66,793,310</u>

Note 15. Retirement plan

The Company sponsors an employee savings plan that qualifies as a deferred salary arrangement under Section 401(k) of the IRC. Participating employees may defer up to the Internal Revenue Service annual contribution limit. Beginning in 2021, the Company provides a safe harbor contribution of 3.0% of the employee's compensation, not to exceed eligible limits. For the three and six months ended June 30, 2021, the Company incurred \$105,000 and \$232,000 in expenses related to the safe harbor contribution, respectively. No expenses were incurred for the three and six months ended June 30, 2020 related to the safe harbor contribution.

Note 16. COVID-19 pandemic

The current COVID-19 pandemic, which is impacting worldwide economic activity, poses the risk that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. During the three and six months ended June 30, 2021 and 2020, the Company has not experienced significant impact from the pandemic. The extent to which the COVID-19 pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Note 17. Subsequent events

Reverse stock split

On July 9, 2021, the Company effected a one-for-1.2 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's Preferred Stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios. The par value and the number of authorized shares of the convertible preferred stock and common stock were not adjusted in connection with the reverse stock split.

Initial public offering

On July 20, 2021, the Company completed its IPO in which the Company issued and sold 21,562,500 shares of common stock (including 2,812,500 shares of common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at an offering price of \$16.00 per share. Proceeds from the IPO, net of underwriting discounts, commissions and estimated offering costs, were \$317.7 million. In connection with the completion of the IPO, all outstanding shares of convertible preferred stock were converted into 71,263,685 shares of common stock.

Erasca Foundation

In May 2021, the Company established the Erasca Foundation to provide support such as direct research grants, hardship grants, patient advocacy, patient education in underserved populations, and funding for other initiatives to positively impact society. In July 2021, the Company issued 1,093,557 shares of its common stock to the Erasca Foundation.

Amendment of certificate of incorporation

In connection with the IPO, on July 20, 2021, the Company amended and restated its certificate of incorporation to, among other things, (i) increase the number of authorized shares of common stock from 156,000,000 to 800,000,000 and (ii) authorize 80,000,000 shares of undesignated preferred stock with a par value of \$0.0001.

2021 Incentive award plan

In July 2021, the Company's board of directors adopted and the Company's stockholders approved the Company's 2021 Incentive Award Plan (the 2021 Plan), which became effective in connection with the IPO. Under the 2021 Plan, the Company may grant stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock or cash-based awards to individuals who are then employees, officers, directors or non-entity consultants of the Company. A total of 15,150,000 shares of common stock were initially reserved for issuance under the 2021 Plan. In addition, the number of shares of common stock available for issuance under the 2021 Plan will be increased annually on the first day of each fiscal year during the term of the 2021 Plan, beginning with the 2022 fiscal year, by an amount equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year or (b) such smaller number of shares as determined by the Company's board of directors.

Employee stock purchase plan

In July 2021, the Company's board of directors adopted and the Company's stockholders approved the Company's 2021 Employee Stock Purchase Plan (the ESPP), which became effective in connection with the IPO. The ESPP permits participants to contribute up to a specified percentage of their eligible compensation during defined rolling six-month periods to purchase the Company's common stock. The purchase price of the shares will be 85% of the lower of the fair market value of the Company's common stock on the first day of trading of the offering period or on the applicable purchase date. A total of 1,260,000 shares of common stock was initially reserved for issuance under the ESPP.

UCSF Agreement amendment

In connection with the UCSF Agreement amendment, in August 2021, following the achievement of the Corporate Milestone, the Company made a cash payment to the Regents in the amount of \$1.7 million.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2020, included in our Prospectus dated July 15, 2021 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities Exchange Commission (SEC) on July 16, 2021 (the Prospectus).

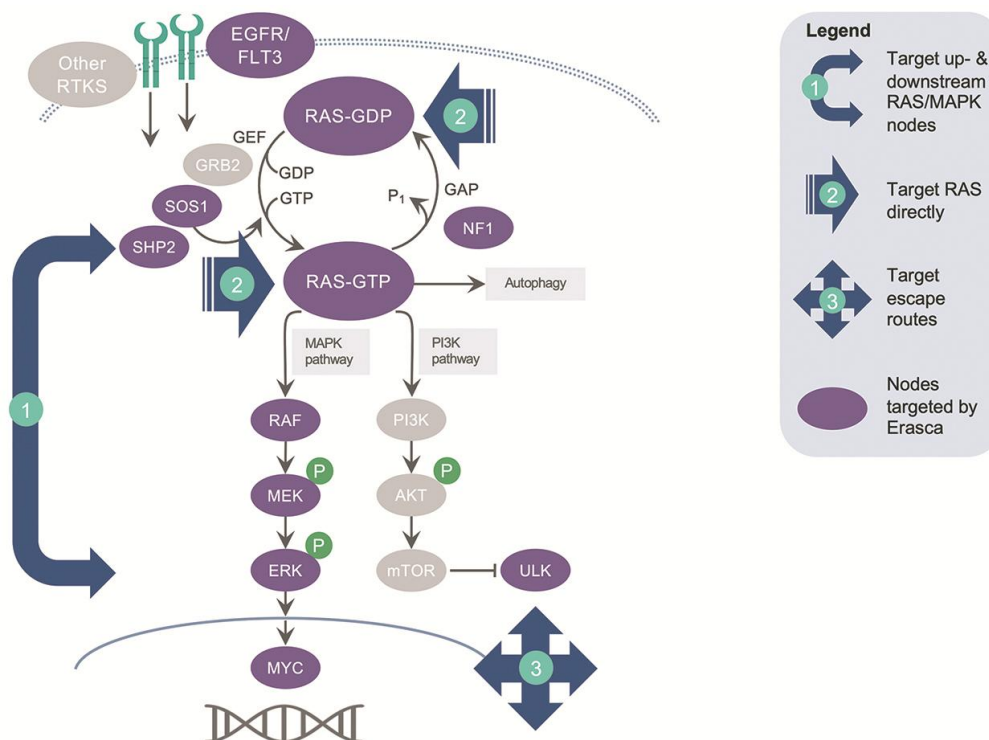
Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned preclinical studies and planned clinical trials for our product candidates, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, the impact of the COVID-19 pandemic on our business, the pricing and reimbursement of our product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "expect," "intend," "target," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue," or the negative of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors." 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, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

We are a clinical-stage precision oncology company singularly focused on discovering, developing, and commercializing therapies for patients with RAS/MAPK pathway-driven cancers. Molecular alterations in RAS, the most frequently mutated oncogene, and the MAPK pathway, one of the most frequently altered signaling pathways in cancer, account for approximately 5.5 million new patients diagnosed globally each year. Our company was co-founded by leading pioneers in precision oncology and RAS targeting to create novel therapies and combination regimens designed to comprehensively shut down the RAS/MAPK pathway for the treatment of cancer. We have assembled what we believe to be the deepest, wholly-owned or controlled RAS/MAPK pathway-focused pipeline in the industry, comprising 11 modality-agnostic programs aligned with our three therapeutic strategies of: (1) targeting key upstream and downstream signaling nodes in the RAS/MAPK pathway; (2) targeting RAS directly; and (3) targeting escape routes that emerge in response to treatment.

The following figure shows the RAS/MAPK pathway and the manner in which the three therapeutic strategies listed above seek to comprehensively, and perhaps synergistically, shut down the RAS/MAPK pathway.



The target breadth and molecular diversity represented in our pipeline enable us to pursue a systematic, data-driven clinical development effort to identify single agent and combination approaches with the goal of prolonging survival in a wide range of patient populations with high unmet needs. Our modality-agnostic approach aims to allow us to selectively and potently inhibit or degrade critical signaling nodes with small molecule therapeutics, large molecule therapeutics, and protein degraders. Our purpose-built pipeline includes two clinical-stage programs (ERK and SHP2 inhibitors), two preclinical-stage programs (CNS-penetrant KRAS G12C and EGFR inhibitors), and seven discovery-stage programs targeting other key oncogenic drivers. We believe our world-class team's capabilities and experience, further guided by our scientific advisory board, which includes the world's leading experts in the RAS/MAPK pathway, uniquely position us to achieve our bold mission of erasing cancer.

Our lead product candidates are ERAS-007 (our oral ERK1/2 inhibitor) and ERAS-601 (our oral SHP2 inhibitor), which together comprise our first MAPKlamp to target upstream and downstream nodes of the RAS/MAPK pathway. ERAS-007 is the first prong of our first MAPKlamp. We are pursuing a broad clinical development plan for ERAS-007, which we refer to as our HERKULES series of clinical trials, across multiple tumor types that includes both monotherapy and combinations with approved and investigational agents, such as RTK, SHP2, RAS, RAF, and/or cell cycle inhibitors. The first four HERKULES Phase 1b/2 proof-of-concept (POC) clinical trials will explore both tissue agnostic and tissue specific indications in patients with solid tumors and hematologic malignancies, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC), and acute myeloid leukemia. In May 2021, we dosed the first patient in HERKULES-1, a Phase 1b/2 clinical trial evaluating ERAS-007 as a single agent and in combination with ERAS-601 (our first MAPKlamp) in advanced solid tumors. We are planning to dose the first patient in HERKULES-2, a Phase 1b/2 clinical trial for ERAS-007/MAPKlamp in combination with various agents in patients with NSCLC, in the third quarter of 2021. We are planning to dose the first patient in HERKULES-3, a Phase 1b/2 clinical trial for ERAS-007/MAPKlamp in combination with various agents in patients with CRC, in the second half of 2021. Finally, in the first quarter of 2022, we plan to dose the first patient in HERKULES-4, a Phase 1b/2 clinical trial for ERAS-007/MAPKlamp in combination with various agents in patients with hematologic malignancies. While providing POC data, these trials may be expanded to enable potential accelerated approvals in their respective indications.

The second prong of our first MAPKlamp, ERAS-601, is designed to be a potent and selective oral inhibitor of SHP2, a convergent node for upstream RTK signaling and a critical “on/off switch” that activates RAS-GTP signaling. SHP2 also drives tumor cell proliferation and development of resistance. ERAS-601 is designed to block oncogenic signal transduction and delay the onset of therapeutic resistance, and thereby serve as a backbone of combination therapy. In the fourth quarter of 2020, we initiated FLAGSHP-1, a Phase 1 clinical trial for ERAS-601 in patients with advanced solid tumors. We expect to file an investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for ERAS-3490, the development candidate nominated from our CNS-penetrant ERAS-1 KRAS G12C inhibitor program, in the second half of 2022. We are conducting IND-enabling studies for ERAS-801, our CNS-penetrant EGFR inhibitor, and expect to file an IND for development in refractory glioblastoma multiforme in the first quarter of 2022. We are also advancing seven other programs targeting key oncogenic drivers in the RAS/MAPK pathway, which we will need to successfully progress through discovery and IND-enabling activities prior to advancing these programs into clinical development, if at all.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates obtain marketing approval. We are working with our current manufacturers to ensure that we will be able to scale up our manufacturing capabilities to support our clinical plans. We are also in the process of locating and qualifying additional manufacturers to build redundancies into our supply chain. In addition, we rely on third parties to package, label, store, and distribute our product candidates, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the design and development of our product candidates.

Since our inception in 2018, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, identifying, acquiring, and in-licensing our product candidates, establishing our intellectual property portfolio, conducting research, preclinical studies and clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and related raw materials, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue. As of June 30, 2021, we have raised a total of \$320.4 million to fund our operations, comprised primarily of gross proceeds from the sale and issuance of convertible preferred stock. As of June 30, 2021, we had cash, cash equivalents and investments of \$198.7 million. In July 2021, we completed our initial public offering (IPO) of 21,562,500 shares of our common stock at a price to the public of \$16.00 per share, including the exercise in full by the underwriters of their option to purchase 2,812,500 additional shares of our common stock. Including the option exercise, our aggregate net proceeds from the offering were \$317.7 million, net of underwriting discounts, commissions and estimated offering costs.

We have incurred significant operating losses since inception. Our net losses were \$28.2 million and \$5.5 million for the three months ended June 30, 2021 and 2020, respectively, and \$46.2 million and \$29.1 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$161.6 million. We expect our expenses and operating losses will increase substantially for the foreseeable future, particularly if and as we conduct our ongoing and planned clinical trials and preclinical studies; continue our research and development activities; utilize third parties to manufacture our product candidates and related raw materials; hire additional personnel; acquire, in-license, or develop additional product candidates; expand and protect our intellectual property; and incur additional costs associated with being a public company. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed or acquired our product candidates. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and preclinical studies and our expenditures on other research and development activities.

Based upon our current operating plans, we believe that our existing cash, cash equivalents and investments, together with the net proceeds received from our IPO, will be sufficient to fund our operations for at least the next 24 months. We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and may never occur. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce, or terminate our research and development programs

or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the US and global economies and financial markets. To date, we have not experienced material disruptions in our business operations. However, while it is not possible at this time to estimate the impact that COVID-19 could have on our business in the future, particularly as we advance our product candidates through clinical development, the continued spread of COVID-19 and the measures taken by the governmental authorities, and any future epidemic disease outbreaks, could: disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research, preclinical studies and clinical trials; delay, limit or prevent our employees and CROs from continuing research and development activities; impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including the risk that participants enrolled in our clinical trials will contract COVID-19 or other epidemic disease while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; impede testing, monitoring, data collection and analysis and other related activities; any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Our acquisition and license agreements

In November 2020, we entered into an Agreement and Plan of Merger and an Amended and Restated License Agreement (the Asana Agreements), pursuant to which we acquired an exclusive, worldwide license to certain intellectual property rights relating to inhibitors of ERK1 and ERK2 owned or controlled by Asana to develop and commercialize ERAS-007 and certain other related compounds for all applications.

Under the Asana Agreements, we made an upfront payment of \$20 million and issued 4,000,000 shares of our Series B-2 convertible preferred stock at a price of \$7.50 per share to Asana. We are obligated to make future milestone payments of up to \$90 million upon the achievement of various development and regulatory milestones and to issue 3,888,889 shares of common stock upon the achievement of a development milestone. We are not obligated to pay royalties on the net sales of ERAS-007.

We have entered into additional in-license and acquisition agreements pursuant to which we in-licensed or acquired certain intellectual property rights related to our product candidates and development programs, including license agreements with NiKang Therapeutics, Inc. (NiKang), Katmai Pharmaceuticals, Inc. (Katmai) and University of California, San Francisco (the Regents), under which we were granted certain intellectual property rights related to ERAS-601, ERAS-801 and ERAS-2/3, respectively, and an asset purchase agreement with Emerge Life Sciences, Pte. Ltd. (ELS) under which we acquired certain intellectual property rights related to ERAS-12.

For additional information regarding the Asana Agreements as well as these and other additional agreements, see the section titled “Business—Our acquisition and license agreements” in our Prospectus.

Components of results of operations

Revenue

We do not expect to generate any revenue from the sale of products unless and until such time that our product candidates have advanced through clinical development and regulatory approval, if ever. If we fail to complete preclinical and clinical development of product candidates or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Operating expenses

Research and development

Research and development expenses consist of external and internal costs associated with our research and development activities, including our discovery and research efforts and the preclinical and clinical development of our product candidates. Research and development costs are expensed as incurred. Our research and development expenses include:

- external costs, including expenses incurred under arrangements with third parties, such as CROs, contract manufacturers, consultants and our scientific advisors; and
- internal costs, including:
 - employee-related expenses, including salaries, benefits, and stock-based compensation for those individuals involved in research and development efforts;
 - the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study materials; and
 - facilities and depreciation, which include direct and allocated expenses for rent of facilities and depreciation of equipment.

The following table summarizes our research and development expenses incurred for the following periods (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
ERAS-007 ⁽¹⁾	\$ 6,511	\$ —	\$ 8,855	\$ —
ERAS-601	3,203	1,420	6,354	2,138
Other discovery and preclinical programs	7,884	4,443	14,634	8,279
Total research and development	<u>\$ 17,598</u>	<u>\$ 5,863</u>	<u>\$ 29,843</u>	<u>\$ 10,417</u>

(1) ERAS-007 was acquired in November 2020.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to conduct our ongoing research and development activities, conduct clinical trials and advance our preclinical research programs toward clinical development, particularly as more of our product candidates move into later stages of development which typically cost more. The process of conducting clinical trials and preclinical studies necessary to obtain regulatory approval is costly and time-consuming. We may never succeed in achieving marketing approval for any of our product candidates.

The timelines and costs with research and development activities are uncertain, can vary significantly for each product candidate and program and are difficult to predict. We anticipate we will make determinations as to which product candidates and programs to pursue and how much funding to direct to each product candidate and program on an ongoing basis in response to preclinical and clinical results, regulatory developments, ongoing assessments as to each product candidate's and program's commercial potential, and our ability to enter into collaborations, to the extent we determine the resources or expertise of a collaborator would be beneficial for a given product candidate or program. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates and programs may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our development costs may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies and clinical trials;
- per patient trial costs;
- the number of trials required for approval;

- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the timing, receipt and terms of any approvals from applicable regulatory authorities;
- maintaining a continued acceptable safety profile of our products candidates following approval, if any;
- significant and changing government regulation and regulatory guidance;
- the impact of any interruptions to our operations or to those of the third parties with whom we work due to the ongoing COVID-19 pandemic; and
- the extent to which we establish additional collaboration, license or other arrangements.

In-process research and development

In-process research and development expenses include rights acquired as part of asset acquisitions or in-licenses to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a “business” as defined under US generally accepted accounting principles (US GAAP), the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use.

In-process research and development expenses consist primarily of our upfront payment and issuance of our Series B-2 convertible preferred stock to Asana in connection with ERAS-007, our upfront and milestone payments to NiKang in connection with ERAS-601, our upfront payment to Katmai in connection with ERAS-801, our upfront payment and issuance of our common stock to ELS in connection with ERAS-12 and issuance of our common stock to the Regents in connection with ERAS-2/3.

General and administrative

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and stock-based compensation, for employees in our finance, accounting, legal, information technology, business development and support functions. Other general and administrative expenses include allocated facility and depreciation related costs not otherwise included in research and development expenses and professional fees for auditing, tax, intellectual property and legal services. Costs related to filing and pursuing patent applications are recognized as general and administrative expenses as incurred since recoverability of such expenditures is uncertain.

We expect our general and administrative expenses will increase substantially for the foreseeable future as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally. We also expect to incur increased costs associated with operating as a public company. These increased costs will likely include increased expenses related to audit, legal, regulatory and tax services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Other income (expense), net

Interest income

Interest income consists primarily of interest earned on our cash, cash equivalents and investments.

Change in fair value of preferred stock purchase right liability

Our issuance of shares of our Series B-1 convertible preferred stock in April and August 2020 potentially obligated us to issue 13,175,191 shares of our Series B-2 convertible preferred stock at a price of \$7.50 per share in an additional closing to certain purchasers of our Series B-1 convertible preferred stock, upon the achievement of certain milestones set forth in the Series B financing purchase agreement. We determined our obligation to issue these shares of Series B-2 convertible preferred stock represented a freestanding financial instrument that required liability accounting. This freestanding preferred stock purchase right liability for the Series B-2 convertible preferred stock was recorded at fair value upon issuance and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the preferred stock purchase right liability were recognized in the consolidated statements of operations and comprehensive loss until the obligation for the Series B-2 shares was fulfilled upon the Series B-2 issuance in January 2021.

Results of operations

Comparison of the three months ended June 30, 2021 and 2020

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

	Three months ended June 30,		Change
	2021	2020	
Operating expenses:			
Research and development	\$ 17,598	\$ 5,863	\$ 11,735
In-process research and development	5,488	—	5,488
General and administrative	5,098	1,421	3,677
Total operating expenses	<u>28,184</u>	<u>7,284</u>	<u>20,900</u>
Loss from operations	(28,184)	(7,284)	(20,900)
Total other income (expense), net	(30)	1,793	(1,823)
Net loss	<u>\$ (28,214)</u>	<u>\$ (5,491)</u>	<u>\$ (22,723)</u>

Research and development expenses

Research and development expenses were \$17.6 million for the three months ended June 30, 2021 compared to \$5.9 million for the three months ended June 30, 2020. The increase of \$11.7 million was primarily driven by a \$4.7 million increase in expenses incurred in connection with clinical trials and preclinical studies, a \$4.0 million increase in personnel costs due to increased headcount to support increased development activities, and a \$2.8 million increase in outsourced services and consulting.

In-process research and development expenses

In-process research and development expenses were \$5.5 million for the three months ended June 30, 2021 related to the issuance of 944,945 shares of our common stock at a price of \$5.81 per share or a total fair value of \$5.5 million in connection with the amendment to our in-license agreement with the Regents. There were no in-process research and development expenses for the three months ended June 30, 2020.

General and administrative expenses

General and administrative expenses were \$5.1 million for the three months ended June 30, 2021 compared to \$1.4 million for the three months ended June 30, 2020. The increase of \$3.7 million was primarily driven by increases of \$2.3 million in personnel costs, \$0.6 million in legal fees and \$0.3 million in audit fees.

Other income (expense), net

Other income (expense), net was \$(30,000) for the three months ended June 30, 2021 compared to \$1.8 million for the three months ended June 30, 2020. The decrease of \$1.8 million was primarily related to the change in fair value of the preferred stock purchase right liability of \$1.8 million as a result of the obligation of the Series B-2 shares being fulfilled upon the Series B-2 issuance in January 2021.

Comparison of the six months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020 (in thousands):

	Six months ended June 30,		Change
	2021	2020	
Operating expenses:			
Research and development	\$ 29,843	\$ 10,417	\$ 19,426
In-process research and development	9,168	17,670	(8,502)
General and administrative	8,780	3,032	5,748
Total operating expenses	47,791	31,119	16,672
Loss from operations	(47,791)	(31,119)	(16,672)
Total other income (expense), net	1,560	1,970	(410)
Net loss	\$ (46,231)	\$ (29,149)	\$ (17,082)

Research and development expenses

Research and development expenses were \$29.8 million for the six months ended June 30, 2021 compared to \$10.4 million for the six months ended June 30, 2020. The increase of \$19.4 million was primarily driven by a \$6.7 million increase in personnel costs due to increased headcount to support increased development activities, a \$6.5 million increase in expenses incurred in connection with clinical trials and preclinical studies and a \$5.8 million increase in outsourced services and consulting.

In-process research and development expenses

In-process research and development expenses were \$9.2 million for the six months ended June 30, 2021 compared to \$17.7 million for the six months ended June 30, 2020. In-process research and development expenses for the six months ended June 30, 2021 related to the issuance of 944,945 shares of our common stock at a price of \$5.81 per share or a total fair value of \$5.5 million in connection with the amendment to our in-license agreement with the Regents and a \$2.0 million upfront payment and issuance of 500,000 shares of our common stock at a price of \$3.36 per share or a total fair value of \$1.7 million in connection with the ELS asset acquisition. In-process research and development expenses for the six months ended June 30, 2020 related to a \$5.0 million upfront payment and a \$7.0 million milestone payment in connection with the in-license agreement with NiKang and a \$5.7 million upfront payment in connection with the in-license agreement with Katmai.

General and administrative expenses

General and administrative expenses were \$8.8 million for the six months ended June 30, 2021 compared to \$3.0 million for the six months ended June 30, 2020. The increase of \$5.7 million was primarily driven by increases of \$3.6 million in personnel costs, \$0.9 million in legal fees and \$0.4 million in audit fees.

Other income (expense), net

Other income (expense), net was \$1.6 million for the six months ended June 30, 2021 compared to \$2.0 million for the six months ended June 30, 2020. The decrease of \$0.4 million was primarily related to the decrease of \$0.2 million in interest and accretion income earned on our cash, cash equivalents and investments and a decrease of \$0.1 million in the change in fair value of the preferred stock purchase right liability.

Liquidity and capital resources

Sources of liquidity

From our inception through June 30, 2021, we have received aggregate gross proceeds of \$320.4 million from the sale of shares of our convertible preferred stock. In July 2021, we completed our IPO of 21,562,500 shares of our common stock at a price to the public of \$16.00 per share, including the exercise in full by the underwriters of their option to purchase 2,812,500 additional shares of our common stock. Including the option exercise, our aggregate net proceeds from the offering were \$317.7 million, net of underwriting discounts, commissions and estimated offering costs.

Future capital requirements

As of June 30, 2021, we had cash, cash equivalents and investments of \$198.7 million, which did not include net proceeds of \$317.7 million received in July 2021 from the sale of shares in our IPO. Based upon our current operating plans, we believe that our existing cash, cash equivalents and investments, together with the net proceeds from our IPO, will be sufficient to fund our operations for at least the next 24 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain.

Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of discovery, preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future, including the costs of any third-party products used in our combination clinical trials that are not covered by such third party or other sources;

- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed or acquired our product candidates or technologies;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- any delays and cost increases that result from the COVID-19 pandemic;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

We have no other committed sources of capital. Until we can generate a sufficient amount of product revenue to finance our cash requirements, if ever, we expect to finance our future cash needs primarily through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve 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 other collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Cash flows

The following table shows a summary of our cash flows for the periods presented (in thousands):

	Six months ended June 30,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	\$ (33,899)	\$ (12,115)
Investing activities	4,298	(38,621)
Financing activities	120,717	125,492
Net increase in cash, cash equivalents and restricted cash	\$ 91,116	\$ 74,756

Operating activities

Cash used in operating activities was \$33.9 million during the six months ended June 30, 2021, primarily resulting from a net loss of \$46.2 million, partially reduced by in-process research and development expenses of \$9.2 million, which is reflected in noncash and investing activities, stock-based compensation of \$2.4 million, changes in operating assets and liabilities of \$2.0 million and depreciation expense of \$0.3 million, partially offset by a \$1.6 million change in fair value of the preferred stock purchase right liability. Net cash provided by changes in operating assets and liabilities consisted primarily of increases in accounts payable, accrued expenses and other current liabilities of \$5.6 million, partially offset by an increase in prepaid expenses and other current and long-term assets of \$3.5 million.

Cash used in operating activities was \$12.1 million during the six months ended June 30, 2020, primarily resulting from a net loss of \$29.1 million, partially reduced by in-process research and development expenses of \$17.7 million, which is reflected in investing activities, changes in operating assets and liabilities of \$0.7 million, depreciation expense of \$0.3 million and stock-based compensation expense of \$0.2 million, partially offset by a \$1.8 million change in fair value of the preferred stock purchase right liability. Net cash provided by changes in operating assets and liabilities consisted primarily of increases in accrued expenses and other current liabilities of \$1.5 million, partially offset by a decrease in accounts payable of \$0.5 million and an increase in prepaid expenses and other current and long-term assets of \$0.2 million.

Investing activities

Net cash provided by investing activities was \$4.3 million during the six months ended June 30, 2021 as compared to cash used in investing activities of \$38.6 million during the six months ended June 30, 2020. The increase in cash provided by investing activities of \$42.9 million was primarily the result of additional maturities of investments of \$23.1 million, a decrease in in-process research and development of \$11.7 million and a decrease in purchases of investments of \$8.1 million.

Financing activities

Net cash provided by financing activities was \$120.7 million during the six months ended June 30, 2021 as compared to \$125.5 million during the six months ended June 30, 2020. During the six months ended June 30, 2021, we received \$119.4 million from the sale of shares of our Series B-2 convertible preferred stock, net of issuance costs and \$1.3 million from the exercise of stock options. During the six months ended June 30, 2020, we received \$125.0 million from the sale of shares of our Series B-1 convertible preferred stock, net of issuance costs, and \$0.5 million from the exercise of stock options.

Contractual obligations and commitments

As of June 30, 2021, there have been no material changes outside the ordinary course of our business to the contractual obligations we reported in "Management's discussion and analysis of financial condition and results of operations – Contractual obligations and commitments," included in the Prospectus.

Off-balance sheet arrangements

During the periods 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 estimates

This management discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with US GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. As of June 30, 2021, there have been no material changes to our critical accounting policies and estimates from those disclosed in “Management’s discussion and analysis of financial condition and results of operations – Critical accounting policies and estimates,” included in the Prospectus.

Recently issued and adopted accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Emerging growth company and smaller reporting company status

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion; (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than \$1.0 billion in nonconvertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of June 30, 2021, there have been no material changes surrounding our market risk, including interest rate risk, foreign currency exchange risk, and inflation risk, from the discussion provided in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Quantitative and Qualitative Disclosures About Market Risk" in the Prospectus.

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 our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2021 that have 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 proceedings. From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before making investment decisions regarding our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. The risks described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risk Factor Summary

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in this Item 1A.

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We are early in our development efforts and are only beginning to test our product candidates in clinical trials. If we are unable to successfully develop and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.
- Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing approaches will limit the commercial value of our product candidates.
- Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our product candidates may not have favorable results in clinical trials, if any, or receive regulatory approval on a timely basis, or at all.
- Any difficulties or delays in the commencement or completion, or termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.
- We rely on third parties to conduct many of our preclinical studies and clinical trials and to manufacture our product candidates, and these third parties may not perform satisfactorily.

- We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our business and ability to develop and successfully commercialize products may be adversely affected.
- Our business is subject to risks arising from COVID-19 and other epidemic diseases.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Risks related to our limited operating history, financial position and need for additional capital

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying, acquiring and in-licensing our product candidates, establishing our intellectual property portfolio, conducting research, preclinical studies and clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and related raw materials, and providing general and administrative support for these operations. Our approach to the discovery and development of product candidates based on our scientific approach is unproven, and we do not know whether we will be able to develop or obtain regulatory approval for any products of commercial value. In addition, we only have two product candidates, ERAS-007 and ERAS-601, in early clinical development, and our other product candidates remain in the preclinical or discovery stage. We have not yet completed any later-stage, large-scale or pivotal clinical trials, obtained regulatory approvals, manufactured a commercial-scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We do not have any products approved for sale and have not generated any revenue since our inception. If we are unable to successfully develop and obtain requisite approval for our product candidates, we may never generate any revenue. Our net losses were \$28.2 million and \$5.5 million for the three months ended June 30, 2021 and 2020, respectively, and \$46.2 million and \$29.1 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$161.6 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize any of our product candidates and seek to identify, assess, acquire, in-license or develop additional product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of our product candidates, discovering, acquiring or in-licensing additional product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even 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 may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials and preclinical studies, and seek regulatory approval for our current product candidates and any future product candidates we may develop or otherwise acquire. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed or acquired our product candidates, including ERAS-007 and ERAS-601. If we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based on our current operating plan, we believe that our existing cash, cash equivalents and investments, together with the net proceeds from our IPO, will be sufficient to fund our operations for at least the next 24 months. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. 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. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future capital requirements will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of discovery, preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future, including the costs of any third-party products used in our combination clinical trials that are not covered by such third party or other sources;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed our acquired our product candidates;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;

- any delays and cost increases that result from the COVID-19 pandemic;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies and identifying potential product candidates is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize our product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. We do not have any committed external source of funds. 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 capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks related to the discovery, development and regulatory approval of our product candidates

We are early in our development efforts and have only two product candidates in clinical development. All of our other development programs are still in the preclinical or discovery stage. If we are unable to successfully develop, obtain regulatory approval and ultimately commercialize any of our current or future product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and have only two product candidates, ERAS-007 and ERAS-601, in early clinical development. All of our other programs are still in the preclinical or discovery stage. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- initiation and successful enrollment of clinical trials and timely completion of clinical trials and preclinical studies with favorable results;
- acceptance of INDs by the FDA, or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- the frequency and severity of adverse events in clinical trials;

- maintaining and establishing relationships with contract research organizations (CROs) and clinical sites for the clinical development of our product candidates both in the United States and internationally;
- demonstrating the safety, purity, potency and efficacy of our product candidates to the satisfaction of applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including new drug applications (NDAs) and biologics license applications (BLAs) from the FDA and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our products following approval, if any; and
- maintaining and growing an organization of people who can develop and commercialize our products and technology.

If we are unable to develop, obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing approaches will limit the commercial value of our product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our scientific approach, which is singularly focused on shutting down the RAS/MAPK pathway, a novel and unproven approach. While we have had favorable preclinical study results for certain of our development programs, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approvals from the FDA or other regulatory authorities or in commercializing such product candidates. Our lead product candidates, ERAS-007 and ERAS-601, are in early clinical development and, as an organization, we have not completed any clinical trials for any of our product candidates. In addition, while we believe our pipeline will yield multiple additional INDs for our development programs in the future, we may not be successful in our discovery efforts, and even if successful, we may not be able to submit INDs and have such INDs accepted to enable us to commence clinical trials on the timelines we expect, if at all. Our research methodology and scientific approach may be unsuccessful in identifying additional product candidates, and any product candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In particular, using multiple agents to shut down multiple nodes of the RAS/MAPK pathway simultaneously is a novel approach that may have unexpected consequences, including adverse events that preclude successful development and approval of our product candidates. Further, because all of our current product candidates and development programs are based on the RAS/MAPK pathway, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our scientific approach. If we fail to stay at the forefront of technological change in utilizing our approach to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete, or limit the commercial value of our products or product candidates by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our approach. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our product candidates.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Any of our product candidates may not have favorable results in clinical trials, if any, or receive regulatory approval on a timely basis, if at all.

Clinical and preclinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process, including due to factors that are beyond our control. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of a product candidate or a competitor's product candidate in the same class may not predict the results of later clinical trials of our product candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. For example, while a Phase 1 clinical trial of ERAS-007 was completed prior to our acquisition of this product candidate and while we have conducted preclinical studies of ERAS-601, we do not know whether they or our other potential product candidates will perform in future clinical trials as they have performed in these prior trials and studies. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. We are currently conducting IND-enabling preclinical studies for ERAS-801. If unexpected observations or toxicities are observed in these studies, or in future IND-enabling studies for any of our other development programs, such results may delay or prevent the initiation of clinical trials for such development programs. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety, purity, potency and efficacy of the product candidates in humans. Before we can initiate clinical trials for our preclinical product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND application or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any delays in the commencement or completion of our ongoing and planned clinical trials for our current and any future product candidate could significantly affect our product development timelines and product development costs.

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trial;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;

- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards (IRBs) at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by us or our CROs to perform in accordance with good clinical practice (GCP) requirements or applicable regulatory guidelines in other countries;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from the COVID-19 pandemic;
- patients choosing alternative treatments for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials or costs being greater than we anticipate;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO), delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current good manufacturing (cGMP) regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, our conduct of clinical trials in foreign countries presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

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

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timeline of clinical trials, is affected by many factors including the size and characteristics of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Potential subjects for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. In particular, because certain of our product candidates are focused on patients with specific molecular alterations within the RAS/MAPK pathway, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. Additionally, other pharmaceutical companies targeting these same types of cancer are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing patients may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. If patients are unwilling to participate in our trials for any reason, including the existence of concurrent clinical trials for similar patient populations, the availability of approved therapies or as a result of the COVID-19 pandemic, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Additionally, because our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment. Our inability to enroll a sufficient number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we have entered into agreements governing their services, we have limited influence over their actual performance. We cannot assure you that our assumptions used in determining expected clinical trial timelines are

correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with oncology drugs generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates when used alone or in combination with other approved or investigational drugs or biologics could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their 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, which may limit the commercial expectations for the product candidate if approved. For example, ophthalmic toxicities have been observed during treatment with MEK-targeted agents and also occur with ERK inhibitors, and reversible retinopathy is a well-known MEK/ERK class effect. Skin toxicities have also been noted as a class effect of inhibitors of RAF, MEK, and ERK. Both skin and ophthalmic treatment-related adverse events were observed in the completed Phase 1 trial of ERAS-007, consistent with these class effects. Gastrointestinal toxicities are associated with the use of MEK/ERK inhibitors and SHP2 inhibitors, whereas hematological toxicities are more commonly associated with SHP2 inhibitors. Furthermore, skin and gastrointestinal side effects represent overlapping toxicities of ERK inhibitors and SHP2 inhibitors with EGFR inhibitors and BRAF inhibitors. In our FLAGSHIP-1 trial, as of June 1, 2021, ERAS-601 had one dose-limiting toxicity of grade 3 thrombocytopenia observed at the highest once-daily dose tested to date, and a total of four serious adverse events were observed, three of which were attributed to ERAS-601 (two grade 3 hypertension and one grade 3 diarrhea) and one of which was unrelated to study drug (grade 3 bladder infection). Therefore, unacceptable enhancement of certain toxicities may be seen when our product candidates are combined with standard of care therapies, or when they are used as single agents. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

In addition, we plan to study our product candidates in combination with other therapies, including those that are also known to act on the RAS/MAPK pathway, which may exacerbate adverse events associated with such product candidates. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials, which has occurred in the past.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

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

As an organization, we have never completed any clinical trials and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates, have never completed any clinical trials and we will need to successfully complete our Phase 1 clinical trials and later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market our product candidates. Carrying out later-stage clinical trials and the submission of a successful NDA or BLA is a complicated process. A Phase 1 clinical trial for ERAS-007 was completed prior to our acquisition of this product candidate, and we are currently conducting our first Phase 1 clinical trial for ERAS-601 and we plan to conduct multiple Phase 1b/2 trials for ERAS-007. We are only beginning to conduct clinical trials for our product candidates, and we have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an NDA, BLA or other comparable foreign regulatory submission for any product candidate. We are also conducting and plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years, which may be a difficult process to manage with our limited resources and which may divert the attention of management. In addition, we have had limited interactions with the FDA and cannot be certain how many additional clinical trials of our product candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials could prevent us from or delay us in submitting NDAs and BLAs for and commercializing our product candidates.

We intend to develop our product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop our current and any future product candidates for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or biologics or for indications other than cancer. Developing combination therapies using approved

therapeutics, as we plan to do for our product candidates, also exposes us to additional clinical risks, such as the requirement that we demonstrate the safety and efficacy of each active component of any combination regimen we may develop.

In addition, we are also evaluating the combination of ERAS-007 and ERAS-601 with each other, and may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We may not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other combination agents or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with the drugs or biologics we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates for combination therapy regimens.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Because we have a number of product candidates and development programs in our pipeline, we may expend our limited resources to pursue a particular product candidate 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 specific product candidates, development programs and indications. We are also conducting and plan to conduct several clinical trials for multiple product candidates in parallel over the next several years, which may make our decision as to which product candidates to focus on more difficult. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. 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 collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

We may not be able to obtain or maintain orphan designations for any of our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We may seek orphan designation for some of our product candidates; however, we may never receive such designations. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product candidate if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. Orphan drug designation must be requested before submitting an NDA or BLA.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA or BLA, to market the

same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even if we obtain orphan drug exclusivity for a product, such exclusivity may not effectively protect the product from competition because different drugs and biologics can be approved for the same condition. Even after an orphan drug or biologic is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug or biologic for the same condition if such regulatory authority concludes that the later drug or biologic is clinically superior because it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective, or if the sponsor seeks approval for an indication broader than the designated indication. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs or biologics for the same or similar indication containing a different active ingredient. In addition, if a subsequent drug or biologic is approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity. Orphan designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We are currently conducting and may in the future conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are currently conducting and may in the future conduct one or more of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the US population and US medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. For studies that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-US clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Interim, topline and preliminary data from our clinical trials and preclinical studies that we announce or publish from time to time may change as more patient 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 interim, top-line, or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, or preliminary 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. Top-line 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. As a result, top-line data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. 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 patient enrollment continues and more patient data become available. Adverse differences between interim, top-line, or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and 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 drug, product candidate or our business. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug or biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug or biologic's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug or biologic.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA for accelerated approval or any other form of expedited development, review or approval.

Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval program, even if we initially decide to do so.

Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the US government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If safe and effective use of any of our product candidates depends on an *in vitro* diagnostic that is not otherwise commercially available, then the FDA generally may require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to develop or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostics is time-consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If the FDA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after such candidate obtains marketing approval, if ever, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such companion diagnostic. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidate, if approved, on a timely or profitable basis, if at all.

Risks related to our reliance on third parties

We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.

We are dependent on third parties to conduct our clinical trials and preclinical studies. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our preclinical studies and clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials are expected to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA or BLA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for clinical and preclinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA or any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, 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 third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable 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 our ability to develop, obtain regulatory approval for or market our product candidates, if approved. 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, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

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

- an inability to initiate clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- additional inspections by regulatory authorities of third-party manufacturing facilities or our manufacturing facilities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product candidates or any other future product candidates.

In addition, we do not have any long-term commitments or supply agreements with our third-party manufacturers. We may be unable to establish any supply agreements with our third-party manufacturers or to do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of our product candidates or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and products 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, in particular due to the high potency of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. For example, we are collaborating with Emerge Life Sciences PTE, LTD. (ELS) on large molecule capabilities. Such collaborative discovery efforts may not yield additional development or product candidates for our pipeline. We may not be successful in our efforts to establish or maintain such collaborations for our product candidates because our research and development pipeline may be insufficient, 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. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. We may have to relinquish valuable rights to our future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. We cannot be certain that, following a collaboration, license or strategic transaction, 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, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned or the sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Risks related to commercialization of our product candidates

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our 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 continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of approved 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. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also 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. For example, the results of the 2020 US Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of a new administration are unknown and could materially impact the regulations governing our product candidates. 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 be subject to enforcement action and we may not achieve or sustain profitability.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The US federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated.

The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.

Our product candidates may not be commercially successful. Even if any of our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;

- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our current or potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of 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 prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if 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. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. 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 biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. 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 products and may not be able to obtain a satisfactory financial return on products that we may develop. In addition, in the event that we develop companion diagnostic tests for use with our products, once approved, such companion diagnostic tests will require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement applicable to pharmaceutical or biological products will apply to companion diagnostics tests.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers

who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, 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.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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 products. We expect to experience pricing pressures in connection with the sale of any of our products 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 and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We face significant competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.

Although the biotechnology and pharmaceutical industries, and the oncology sector, are characterized by rapid evolution of technologies, fierce competition, and strong defense of intellectual property rights, we believe the most fearsome competitor of all is cancer itself. As such, we view other companies in this sector more as potential allies and collaborators than as competitors, as we all have a common cause: to defeat cancer. Many of the companies that are developing or marketing treatments for cancer, including major pharmaceutical and biotechnology companies that are working on therapies targeting the RAS/MAPK pathway, are companies with whom we endeavor to collaborate in our mission to erase cancer. That being said, our commercial potential could be reduced or eliminated if other companies develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of indications for which we may attempt to develop product candidates. In particular, there is intense competition in the oncology field. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in oncology research and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

If any of our product candidates are approved, they will compete with small molecule therapies, biologics, cell-based therapies and traditional chemotherapy, either approved or under development, which are intended to treat the same indications that we are targeting or may target, including through approaches that may prove to be more effective, have fewer side effects, be less costly to manufacture, be more convenient to administer or have other advantages over our product candidates. In addition to competing with other therapies targeting similar indications, there are numerous other companies and academic institutions focused on similar targets as our product candidates and/or different scientific approaches to treating the same indications. We face competition from such companies in seeking any future potential collaborations to partner our product candidates, as well as potentially competing commercially for any approved products.

Specifically, there are also a number of pharmaceutical companies with product candidates in development that target the nodes involving the RAS/MAPK pathway. These include, among others, Amgen, AstraZeneca, Black Diamond Therapeutics, BioMed Valley Discoveries, Boehringer Ingelheim, Deciphera Pharmaceuticals, Eli Lilly, Jacobio Pharmaceuticals (in collaboration with AbbVie), Janssen, Merck, Mirati Therapeutics, Navire Pharma (a subsidiary of BridgeBio), Novartis, Pfizer, Relay Therapeutics (in collaboration with Genentech), Revolution Medicines, Roche/Genentech, Sanofi, and Schrödinger (in collaboration with Bristol Myers Squibb).

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products approaches may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

The market opportunities for our product candidates may be limited to patients who are ineligible for or have failed prior treatments and may be small or different from our estimates.

Cancer therapies are defined by lines of therapy as well as by treatment-naïve or previously-treated status. Often the initial approval for a new therapy is in later lines and subsequent approval in an earlier line may not be feasible. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, including targeted therapy, immunotherapy, chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, there is no guarantee that our product candidates, even if approved, would be approved for second line or first line therapy. This could limit our potential market opportunity. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, publicly available clinical molecular reports, patient foundations or market research, and may prove to be incorrect. Further, new trials or information may change the estimated incidence or prevalence of these cancers. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

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

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time-consuming, or 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 have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may 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.

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

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks related to our business operations and industry

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 any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we will or may incur to acquire, develop or commercialize additional product candidates and technologies or other assets;
- the level of demand for any approved products, which may vary significantly and be difficult to predict; and
- future accounting pronouncements or changes in our accounting policies;

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. 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 revenue or earnings guidance we may provide.

Our success is dependent on our ability to attract and retain highly qualified management and other clinical and scientific personnel.

Our success depends in part on our continued ability to attract, retain, manage, and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation, or completion of our clinical trials and preclinical studies or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology, and other businesses, particularly in the San Diego area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain, and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy.

We may encounter difficulties in managing our growth and expanding our operations successfully.

We have substantially increased our organization from 30 employees as of December 31, 2019 to 102 employees as of June 30, 2021. As we continue development and pursue the potential commercialization of our product candidates, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We are subject to various US federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which 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 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;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such healthcare professionals and their

immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require certain biotechnology companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration of pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare program.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the US federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. Among the provisions of the ACA of importance to our potential product candidates, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expands eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; creates a new Medicare Part D coverage gap discount program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the US Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the

healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended these Medicare sequester reductions from May 1, 2020 through December 31, 2021. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent 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 products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that the ACA, these new laws and 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, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

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

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

We currently hold approximately \$10 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile, workers' compensation, products liability, malicious invasion of our electronic systems, clinical trials, and directors' and officers' employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we or any of our potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and such collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or current or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development programs, harm our reputation, significant fines, penalties and liability and loss of customers or sales.

In the ordinary course of business, we collect, store, transmit and otherwise process large amounts of data including, without limitation, proprietary business information and personal information. Despite the implementation of security measures, our information technology systems (including infrastructure) and those of our current and any future CROs and other contractors, consultants, third-party service providers and collaborators are vulnerable to damage from computer viruses, cybersecurity threats (such as denial-of-service attacks, ransomware, supply chain attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks), unauthorized access or use, natural disasters, terrorism, war and telecommunication and electrical failures. Our systems are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper or accidental actions by employees, vendors and other third parties with otherwise legitimate access to our systems. Third parties may also attempt to fraudulently induce our employees and contractors into disclosing sensitive information such as usernames, passwords or other information, or otherwise compromise the security of our electronic systems, networks, and/or physical facilities in order to gain access to our data. Additionally, due to the COVID-19 pandemic, our employees are temporarily working remotely, which may pose additional data security risks.

Given the unpredictability of the timing, nature and scope of information technology disruptions, there can be no assurance that any security procedures and controls that we or our third-party partners and service providers have implemented will be sufficient to prevent cyber-attacks from occurring. The latency of a compromise is often measured in months, but could be years, and we may not be able to detect a compromise in a timely manner. New techniques may not be identified until they are launched against a target, and we may be unable to anticipate these techniques or detect an incident, assess its severity or impact, react or appropriately respond in a timely manner or implement adequate preventative measures, resulting in potential data loss or other damage to our information technology systems.

If a security breach were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information (potentially violating certain privacy laws), it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships.

Any security breach or other incident, whether actual or perceived, could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance with certain privacy and security laws. For further discussion on the potential liability related to the violation of these laws, see “—Risks related to our intellectual property—We and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties, harm our reputation and otherwise harm our business.”

Our business is subject to risks arising from COVID-19 and other epidemic diseases.

The COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the US and global economies and financial markets. International and US governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one's home. In response, our administrative employees have worked remotely and we have limited the number of staff in our research and development laboratories. To date we have not experienced material disruptions in our

business operations. However, while it is not possible at this time to estimate the impact that COVID-19 could have on our business in the future, particularly as we advance our product candidates through clinical development, the continued spread of COVID-19 and the measures taken by the governmental authorities, and any future epidemic disease outbreaks, could: disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research, preclinical studies and clinical trials; delay, limit or prevent our employees and CROs from continuing research and development activities; impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including the risk that participants enrolled in our clinical trials will contract COVID-19 or other epidemic disease while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; impede testing, monitoring, data collection and analysis and other related activities; any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic and any future epidemic disease outbreak could also potentially further affect the business of the FDA, EMA or other regulatory authorities, which could result in delays in meetings related to planned clinical trials. The COVID-19 pandemic and mitigation measures have had and may continue to have, and any future epidemic disease outbreak may have, an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceeding, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

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

earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies, similar to our approach in which we in-licensed and acquired certain of our current product candidates and development programs. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). As of December 31, 2020, we had federal, California and other state net operating loss (NOL) carryforwards of \$49.1 million, \$13.0 million and \$2.4 million, respectively.

Under the legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (Tax Act), federal NOL carryforwards arising in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in tax year in tax years beginning after December 31, 2020, is limited. Under the Coronavirus Aid, Relief and Economic Security Act (CARES Act), federal NOL carryforwards arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, our NOL carryforwards are subject to review and possible adjustment by the IRS and state tax authorities. Under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), our federal NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership of our company. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not yet formally determined the amount of the cumulative change in our ownership resulting from our IPO or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities is likely to be limited as a result of ownership changes, including potential changes in connection with our IPO. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance factors. Some investors may use these factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies relating to corporate responsibility are inadequate, including if they believe our policies relating to the Erasca Foundation are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for

measurement of corporate responsibility performance. The criteria by which companies' corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate certain initiatives and goals regarding environmental, social and governance matters, including with respect to the initiatives and goals we established as part of the Erasca Foundation, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors, employees and other stakeholders or our initiatives are not executed as planned, our reputation and financial results could be materially and adversely affected.

Risks related to our intellectual property

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

Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection with respect to our therapeutic programs, proprietary technologies, and their uses. We seek to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to our product candidates. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. If we are unable to obtain or maintain patent protection with respect to our product candidates, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection against competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to invent the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our owned and in-licensed patent applications may not result in patents being issued which protect our therapeutic programs and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the claim coverage in a patent application can be significantly reduced before the patent is granted. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our owned and in-licensed patent applications may be challenged, narrowed,

circumvented or invalidated by third parties. Consequently, we do not know whether our therapeutic programs and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our therapeutic programs and eventual product candidates, patents protecting the product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the US Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our therapeutic programs and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Moreover, some of our owned and in-licensed patent rights are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, our owned and in-licensed patent rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our patent rights and technology was funded in part by the US government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to US industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of 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 intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our owned and in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of 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 owned and in-licensed patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent

protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our owned and in-licensed patents at risk of being invalidated or interpreted narrowly, could put our owned and in-licensed 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

The USPTO and various non-US government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we are dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to US and non-US patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The USPTO and various non-US government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the US, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some cases, a foreign filing license may be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We are also dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property. The Indian patent application covering ERAS-007 as composition of matter was filed without obtaining a foreign filing license from the Indian Patent Office. As such, any patent issuing from the pending patent application in India may be vulnerable to revocation by the Indian Patent Office or invalidity or unenforceability attacks by third parties.

The COVID-19 pandemic may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our products and product candidates.

Changes in US patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

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

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

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent US Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the US Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement lack of sufficient written description or obviousness-type double patenting. 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. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our owned and in-licensed patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose

at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on products and 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 US non-provisional or international patent application 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 has expired, we may be vulnerable to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one or more of our owned and in-licensed issued US patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent term extension (PTE) of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC). However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed).

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our therapeutic programs and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our therapeutic programs and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to seeking patent protection for our product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or

misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our therapeutic programs and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators may prevent or delay the development and commercialization of our product candidates.

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in US law referred to as patent reform, new procedures including inter partes review and post-grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our owned and in-licensed patents in the future.

Numerous US and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our therapeutic and diagnostic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk that our therapeutic and diagnostic programs and commercializing activities may give rise to claims of infringement of the patent rights of others increases. We cannot assure you that our therapeutic programs and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, including a competitor in the fields in which we are developing our therapeutic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our products or product candidates. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such legal proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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

Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question. In addition, our patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our licensors or collaborators might not have been the first to file patent applications covering our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending and future patent applications we own or in-license will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;
- the patents of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

We partially depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are dependent, in part, on patents, know-how and proprietary technology licensed from others. We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property

rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on reasonable terms, we may be unable to successfully develop and commercialize the affected technology or product candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our product candidates, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner, or jointly between us and the third party. If we determine that rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing our product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the chance to access technology that is important to our business. We also may need the cooperation of any co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owner's interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same

technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

We and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties, harm our reputation and otherwise harm our business.

We maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical studies, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal information. Guidance on implementation and compliance practices are often updated or otherwise revised.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, HIPAA imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates and subcontractors, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. HIPAA mandates the reporting of certain breaches of health information to the US Department of Health and Human Services (HHS), affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the US Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA has been amended from time to time, and it is possible that

further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. The CCPA may increase our compliance costs and potential liability. Further, California voters recently approved the California Privacy Rights Act of 2020 (CPRA) that goes into effect on January 1, 2023. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their sensitive personal information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. Some observers have noted that the CCPA and the CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

In Europe, Regulation 2016/676, known as the General Data Protection Regulation (GDPR), went into effect in May 2018. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area (EEA). Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, imposes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. In addition, the European Commission recently proposed updates to the standard contractual clauses. Such developments may cause us to have to make further expenditures, limit our ability to process personal data, change internal business processes or otherwise affect or restrict sales and operations.

Further, the exit of the United Kingdom (UK) from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, the UK exited the EU on January 1, 2020, subject to a transition period that ended December 31, 2020. Under the post-Brexit Trade and Cooperation Agreement between the EU and the UK, the UK and EU have agreed that transfers of personal data to the UK from EEA Member States will not be treated as 'restricted transfers' to a non-EEA country for a period of up to four months from January 1, 2021, plus a potential further two months extension (the Extended Adequacy Assessment Period). Although the current maximum duration of the Extended Adequacy Assessment Period is six months, it may end sooner, for example, in the event that the European Commission adopts an adequacy decision in respect of the UK, or the UK amends the UK GDPR and/or makes certain changes regarding data transfers under the UK GDPR/Data Protection Act 2018 without the consent of the EU (unless those amendments or decisions are made simply to keep relevant UK laws aligned with the EU's data protection regime). If the European Commission does not adopt an 'adequacy decision' in respect of the UK prior to the expiry of the Extended Adequacy Assessment Period, from that point onwards the UK will be an 'inadequate third country' under the GDPR and transfers of personal data from the EEA to the UK will require a 'transfer mechanism' such as the Standard Contractual Clauses.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no personal information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 US states and the District of Columbia require businesses to provide notice to affected consumers whose unencrypted personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be required to notify regulators, credit reporting agencies or other

counterparties of a security breach. Such notifications are costly, and the disclosures or the failure to comply such requirements, could lead to material adverse effects, including without limitation, negative publicity, a loss of consumer confidence or security measures or breach of contract claims.

Compliance with US and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and service providers to comply with US and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Risks related to ownership of our common stock

An active, liquid trading market for our common stock may not develop or be sustained, which may make it difficult for you to sell your shares.

Prior to our IPO, there had been no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Select Market, and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active trading market is developed, it may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at the time you wish to sell them or at a price that is attractive to you, or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by those factors discussed in this "Risk factors" section and many others, including:

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll subjects in our future clinical trials;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;

- the success or failure of our efforts to develop, acquire or license additional product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us, or fluctuations in the valuation of such other companies;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by us, our insiders and our other stockholders;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- expiration of market stand-off or lock-up agreements;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

Following completion of our IPO and based on our shares of common stock outstanding as of August 15, 2021, our executive officers, directors and greater than 5% stockholders, in the aggregate, owned approximately 51% of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other

business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders 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 or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Based on shares of common stock outstanding as of June 30, 2021, upon the closing of our IPO and the exercise of the underwriter's option to purchase additional shares, we had outstanding a total of 120,126,308 shares of common stock, assuming no exercise of outstanding options. Of these shares, only the 21,562,500 shares of common stock sold in the IPO are freely tradable, without restriction, in the public market, unless they are purchased by one of our affiliates.

Our directors and executive officers and holders of substantially all of our outstanding securities prior to the IPO have entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of the final prospectus for our IPO, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC and BofA Securities, Inc. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. After the lock-up agreements expire, up to an additional 98,563,808 shares of common stock will be eligible for sale in the public market, of which 43,601,238 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of June 30, 2021, 13,525,607 shares of common stock that are subject to outstanding options under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After our IPO, the holders of 71,263,685 shares of our outstanding common stock, or approximately 59.3% of our total outstanding common stock based on shares outstanding as of June 30, 2021, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS ACT), and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, as defined under the Exchange Act, our annual gross revenue exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain

disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. 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. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine, provided that this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. These choice of 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 such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General risk factors

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

We are subject to US and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the US Export Administration Regulations, US Customs regulations, and various economic and trade sanctions regulations administered by the US Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the US Foreign Corrupt Practices Act of 1977, as amended, the US domestic bribery statute contained in 18 U.S.C. § 201, the US Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities.

We are also subject to other US laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time-consuming or costly.

We and any of our third-party manufacturers or suppliers and current or potential future collaborators will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that future deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Changes in US tax law may materially adversely affect our financial condition, results of operations and cash flows.

Changes in laws and policy relating to taxes may have an adverse effect on our financial condition, results of operations and cash flows. For example, the Tax Act significantly changed the US federal income taxation of US corporations. The Tax Act remains unclear in various respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (IRS), which have lessened or increased certain adverse impacts of the Tax Act and may continue to do so in the future. In addition, it is unclear how these US federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. On March 27, 2020, the CARES Act was signed into law to address the COVID-19 crisis. The CARES Act is an approximately \$2 trillion emergency economic stimulus package that includes numerous US federal income tax provisions, including the modification of: (i) NOL rules (as discussed above), (ii) the alternative minimum tax refund, and (iii) business interest deduction limitations under Section 163(j) of the Code. We continue to work with our tax advisors and auditors to determine the full impact the Tax Act and the CARES Act will have on us. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an “emerging growth company” and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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 could be subject to securities class action litigation.

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

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

Unregistered Sales of Equity Securities

During the three months ended June 30, 2021, we granted options to purchase an aggregate of 3,729,154 shares of our common stock at a weighted-average exercise price of \$6.57 per share. The stock options were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder as a transaction not involving any public offering.

In May 2021, we issued an aggregate of 944,945 shares of common stock to The Regents of the University of California, San Francisco in connection with a license agreement amendment. Such shares were issued in reliance on the exemption set forth in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder as a transaction not involving any public offering.

Use of Proceeds

On July 15, 2021, the SEC declared effective our registration statement on Form S-1 (File No. 333-257436), as amended, filed in connection with our IPO. Our IPO closed on July 20, 2021, and we issued and sold 21,562,500 shares of our common stock at a price to the public of \$16.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds from our IPO of \$345.0 million, before deducting underwriting discounts, commissions and estimated offering costs of \$27.3 million. The managing underwriters of the offering were J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, BofA Securities, Inc., Evercore Group L.L.C. and Guggenheim Securities, LLC. No offering costs were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the planned use of such proceeds from that described in the Prospectus.

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	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of Erasca, Inc.	8-K	7/20/2021	3.1	
3.2	Amended and Restated Bylaws of Erasca, Inc.	8-K	7/20/2021	3.2	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1	6/25/2021	4.1	
4.2	Amended and Restated Stockholders Agreement, dated April 15, 2020, by and among the Registrant and certain of its stockholders	S-1	6/25/2021	4.2	
31.1	Certification of Chief Executive Officer of Erasca, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Chief Financial Officer of Erasca, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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.

Erasca, Inc.

Date: August 26, 2021

By: /s/ Jonathan E. Lim M.D.
Jonathan E. Lim, M.D.
Chairman, Chief Executive Officer and Co-Founder
(Principal Executive Officer)

Date: August 26, 2021

By: /s/ David M. Chacko, M.D.
David M. Chacko, M.D.
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

I, Jonathan E. Lim, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Erasca, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) [omitted];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 26, 2021

By: _____ /s/ Jonathan E. Lim, M.D.

Jonathan E. Lim, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, David M. Chacko, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Erasca, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) [omitted];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 26, 2021

By:

/s/ David M. Chacko, M.D.

David M. Chacko, M.D.

Chief Financial Officer
(Principal Financial and Accounting Officer)

**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 on Form 10-Q of Erasca, Inc. (the "Company") for the period ended June 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 § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (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 results of operations of the Company.

Date: August 26, 2021

By: _____ /s/ Jonathan E. Lim, M.D.

Jonathan E. Lim, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

**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 on Form 10-Q of Erasca, Inc. (the "Company") for the period ended June 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 § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (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 results of operations of the Company.

Date: August 26, 2021

By: _____
 /s/ David M. Chacko, M.D.
 David M. Chacko, M.D.
 Chief Financial Officer
 (Principal Financial and Accounting Officer)
