

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

**FORM 10-Q**

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-38811



**TCR<sup>2</sup> Therapeutics Inc.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**47-4152751**

(IRS Employer Identification No.)

**100 Binney Street**

**Suite 710**

**Cambridge**

**MA**

**02142**

(Address of Principal Executive Offices)

(Zip Code)

**(617) 949-5200**

(Registrant's telephone number, including area code)

**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	TCRR	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or 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.:

<b>Large accelerated filer</b>	<input type="checkbox"/>	<b>Accelerated filer</b>	<input type="checkbox"/>
<b>Non-accelerated filer</b>	<input checked="" type="checkbox"/>	<b>Smaller reporting company</b>	<input checked="" type="checkbox"/>
<b>Emerging growth company</b>	<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 Act). Yes ☐ No ☒

As of November 2, 2021, there were 38,220,444 shares of the registrant's Common Stock, \$0.0001 par value per share, outstanding.

# TCR<sup>2</sup> Therapeutics Inc.

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## Summary of the Material Risks Associated with Our Business

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks are described more fully in “Item 1A—Risk Factors,” and include, but are not limited to, the following:

- Our approach to the discovery and development of product candidates based on our TRuC-T cell platform represents a novel approach to cancer treatment, which creates significant challenges for us. Further, we are very early in our development efforts. Most of our product candidates are still in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
  - Our business is highly dependent on our clinical trials for our lead product candidate, gavo-cel, and we must complete IND-enabling studies and clinical testing before we can seek regulatory approval and begin commercialization of any of our product candidates. We cannot be certain that we will be able to complete ongoing clinical trials, initiate future planned clinical trials, or advance our product candidates into additional trials, or to successfully develop, or obtain regulatory approval for, or successfully commercialize, any of our product candidates.
  - We have limited experience as a company in conducting clinical trials. Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.
  - Manufacturing and administering our product candidates are complex and we may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our TRuC-T cells for clinical trials or for commercial purposes could be delayed or stopped. We plan to establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on third parties for the manufacture of our product candidates and the use of third-party manufacturing suites, which will be costly, time-consuming, and which may not be successful.
  - The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.
  - We plan to rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.
  - Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
  - The current outbreak of novel coronavirus, or COVID-19, has caused, and could continue to cause, severe disruptions in the U.S., regional and global economies. COVID-19 has affected our on-going clinical trials and could seriously harm our development efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.
  - If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop, and our technology may be adversely affected.
  - The U.S. Food and Drug Administration (FDA) regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
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- Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
  - We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
  - Our stock price has been and will likely continue to be volatile. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.
  - We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are also a “smaller reporting company,” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.
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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q of TCR<sup>2</sup> Therapeutics Inc. ("we," "us" and "our") contains or incorporates statements that constitute forward-looking statements within the meaning of the federal securities laws. Any statements that do not relate to historical or current facts or matters are forward looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "continue" or the negative of these terms or other comparable terminology. Forward-looking statements appear in a number of places in this Quarterly Report on Form 10-Q and include, but are not limited to, statements about:

- ☐ the timing of preclinical studies and clinical trials of gavo-cel and any other product candidates;
- ☐ our need to raise additional funding before we can expect to generate any revenues from product sales;
- ☐ our ability to submit our planned INDs, conduct successful clinical trials and obtain regulatory approval for gavo-cel or any other product candidates that we may identify or develop;
- ☐ the ability of our TRuC-T cell platform to generate and advance additional product candidates;
- ☐ our ability to establish an adequate safety, potency and purity profile for gavo-cel or any other product candidates that we may identify or develop;
- ☐ our ability to manufacture gavo-cel, or any other product candidate in conformity with our specifications and with the FDA's requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- ☐ the implementation of our strategic plans for our business, any product candidates we may develop and our technology;
- ☐ our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- ☐ the rate and degree of market acceptance and clinical utility for any product candidates we may develop;
- ☐ our estimates regarding our expenses, future revenues, capital requirements and our needs for additional financing;
- ☐ our ability to maintain and establish collaborations;
- ☐ our ability to effectively manage our anticipated growth;
- ☐ developments relating to our competitors and our industry, including the impact of government regulation;
- ☐ our estimates regarding the market opportunities for our product candidates;
- ☐ our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- ☐ our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- ☐ our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act, or the JOBS Act;
- ☐ the current and future impact of the ongoing COVID-19 pandemic on our business;
- ☐ our financial performance; and
- ☐ other risks and uncertainties, including those listed under the section titled "Risk Factors."

Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors including, without limitation, risks, uncertainties and assumptions regarding the continuing impact of the COVID-19 pandemic on our business, operations, strategy, goals and anticipated timelines, our ongoing and planned preclinical activities, our ability to initiate, enroll, conduct or complete ongoing and planned clinical trials, our timelines for regulatory submissions and our financial position that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You are urged to carefully review the disclosures we make concerning these risks and other factors that may affect our business and operating results under "Item 1A. Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2020 and in this Quarterly Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. We do not intend, and undertake no obligation, to update any forward-looking

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information to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, unless required by law to do so.

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Part I

Item 1. Financial Statements

**TCR<sup>2</sup> THERAPEUTICS INC.**  
**UNAUDITED CONSOLIDATED BALANCE SHEETS**  
(amounts in thousands, except share data)

	September 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 262,497	\$ 94,155
Investments	33,244	133,831
Prepaid expenses and other current assets	7,478	7,552
Total current assets	303,219	235,538
Non-current assets		
Property and equipment, net	12,252	10,013
Right-of-use assets, operating leases	29,432	-
Restricted cash	1,155	583
Other assets, non-current	666	61
Total assets	\$ 346,724	\$ 246,195
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable	\$ 4,384	\$ 2,448
Accrued expenses and other current liabilities	8,654	6,392
Operating lease liabilities	3,482	-
Total current liabilities	16,520	8,840
Non-current liabilities		
Operating lease liabilities, non-current	23,635	-
Other liabilities	299	807
Total liabilities	40,454	9,647
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2021 and December 31, 2020, respectively.	-	-
Common stock, \$0.0001 par value; 150,000,000 shares authorized; 38,220,444 and 33,516,795 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively.	4	3
Additional paid-in capital	628,064	486,197
Accumulated other comprehensive income (loss)	(15)	63
Accumulated deficit	(321,783)	(249,715)
Total stockholders' equity	306,270	236,548
Total liabilities and stockholders' equity	\$ 346,724	\$ 246,195

See accompanying notes to unaudited consolidated financial statements

**TCR<sup>2</sup> THERAPEUTICS INC.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 20,277	\$ 12,820	\$ 54,828	\$ 37,682
General and administrative	5,963	4,371	17,297	12,451
Total operating expenses	26,240	17,191	72,125	50,133
Loss from operations	(26,240)	(17,191)	(72,125)	(50,133)
Interest income, net	38	300	186	1,546
Loss before income tax expense	(26,202)	(16,891)	(71,939)	(48,587)
Income tax expense	42	31	129	86
Net loss	<u>\$ (26,244)</u>	<u>\$ (16,922)</u>	<u>\$ (72,068)</u>	<u>\$ (48,673)</u>
Per share information				
Net loss per share of common stock, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.56)</u>	<u>\$ (1.91)</u>	<u>\$ (1.86)</u>
Weighted average shares outstanding, basic and diluted	38,197,929	30,340,355	37,816,345	26,158,040

See accompanying notes to unaudited consolidated financial statements



**TCR<sup>2</sup> THERAPEUTICS INC.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (26,244)	\$ (16,922)	\$ (72,068)	\$ (48,673)
Unrealized gain (loss) on investments, net	4	(211)	(78)	49
Comprehensive loss	<u>\$ (26,240)</u>	<u>\$ (17,133)</u>	<u>\$ (72,146)</u>	<u>\$ (48,624)</u>

See accompanying notes to unaudited consolidated financial statements

**TCR<sup>2</sup> THERAPEUTICS INC.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of December 31, 2020</b>	<b>33,516,795</b>	<b>\$ 3</b>	<b>\$ 486,197</b>	<b>\$ (249,715)</b>	<b>\$ 63</b>	<b>\$ 236,548</b>
Issuance of common stock, net of issuance costs	4,590,164	1	131,329	-	-	131,330
Exercise of stock options	52,243	-	376	-	-	376
Stock-based compensation expense	-	-	3,120	-	-	3,120
Unrealized loss on investments	-	-	-	-	(107)	(107)
Net loss	-	-	-	(21,512)	-	(21,512)
<b>Balance as of March 31, 2021</b>	<b>38,159,202</b>	<b>\$ 4</b>	<b>\$ 621,022</b>	<b>\$ (271,227)</b>	<b>\$ (44)</b>	<b>\$ 349,755</b>
Exercise of stock options	22,129	-	204	-	-	204
Stock-based compensation expense	-	-	3,219	-	-	3,219
Unrealized gain on investments	-	-	-	-	25	25
Net loss	-	-	-	(24,312)	-	(24,312)
<b>Balance as of June 30, 2021</b>	<b>38,181,331</b>	<b>\$ 4</b>	<b>\$ 624,445</b>	<b>\$ (295,539)</b>	<b>\$ (19)</b>	<b>\$ 328,891</b>
Exercise of stock options	39,113	-	433	-	-	433
Stock-based compensation expense	-	-	3,186	-	-	3,186
Unrealized gain on investments	-	-	-	-	4	4
Net loss	-	-	-	(26,244)	-	(26,244)
<b>Balance as of September 30, 2021</b>	<b>38,220,444</b>	<b>\$ 4</b>	<b>\$ 628,064</b>	<b>\$ (321,783)</b>	<b>\$ (15)</b>	<b>\$ 306,270</b>

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of December 31, 2019</b>	<b>23,981,109</b>	<b>\$ 2</b>	<b>\$ 342,896</b>	<b>\$ (182,591)</b>	<b>\$ 142</b>	<b>\$ 160,449</b>
Reclassification of shares issued and previously subject to repurchase	17,456	-	13	-	-	13
Exercise of stock options	57,904	-	185	-	-	185
Stock-based compensation expense	-	-	2,055	-	-	2,055
Unrealized loss on investments	-	-	-	-	(604)	(604)
Net loss	-	-	-	(15,506)	-	(15,506)
<b>Balance as of March 31, 2020</b>	<b>24,056,469</b>	<b>\$ 2</b>	<b>\$ 345,149</b>	<b>\$ (198,097)</b>	<b>\$ (462)</b>	<b>\$ 146,592</b>
Reclassification of shares issued and previously subject to repurchase	17,456	-	13	-	-	13
Exercise of stock options	30,670	-	125	-	-	125
Stock-based compensation expense	-	-	2,064	-	-	2,064
Unrealized gain on investments	-	-	-	-	864	864
Net loss	-	-	-	(16,245)	-	(16,245)
<b>Balance at June 30, 2020</b>	<b>24,104,595</b>	<b>\$ 2</b>	<b>\$ 347,351</b>	<b>\$ (214,342)</b>	<b>\$ 402</b>	<b>\$ 133,413</b>
Issuance of common stock, net of issuance costs	9,200,000	1	133,570	-	-	133,571
Reclassification of shares issued and previously subject to repurchase	17,457	-	13	-	-	13
Exercise of stock options	58,159	-	432	-	-	432
Stock-based compensation expense	-	-	2,067	-	-	2,067
Unrealized loss on investments	-	-	-	-	(211)	(211)
Net loss	-	-	-	(16,922)	-	(16,922)
<b>Balance at September 30, 2020</b>	<b>33,380,211</b>	<b>\$ 3</b>	<b>\$ 483,433</b>	<b>\$ (231,264)</b>	<b>\$ 191</b>	<b>\$ 252,363</b>

See accompanying notes to unaudited consolidated financial statements

**TCR<sup>2</sup> THERAPEUTICS INC.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(amounts in thousands)

	Nine Months Ended September 30,	
	2021	2020
<b>Operating activities</b>		
Net loss	\$ (72,068 )	\$ (48,673 )
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,976	1,114
Stock-based compensation expense	9,525	6,186
Amortization (accretion) on investments	626	(574 )
Deferred tax liabilities	105	86
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(41 )	(1,875 )
Operating leases, net	(2,811 )	-
Accounts payable	2,066	610
Accrued expenses and other liabilities	2,299	(114 )
Cash used in operating activities	(58,323 )	(43,240 )
<b>Investing activities</b>		
Purchases of equipment	(4,352 )	(2,523 )
Software development costs	(308 )	-
Purchases of investments	(40,732 )	(162,147 )
Proceeds from sale or maturity of investments	140,622	109,916
Cash provided by (used in) investing activities	95,230	(54,754 )
<b>Financing activities</b>		
Proceeds from public offering of common stock, net of issuance costs	131,330	133,570
Proceeds from the exercise of stock options	1,013	742
Payment of deferred offering costs	(336 )	-
Cash provided by financing activities	132,007	134,312
<b>Net change in cash, cash equivalents, and restricted cash</b>	168,914	36,318
Cash, cash equivalents, and restricted cash at beginning of year	94,738	65,713
<b>Cash, cash equivalents, and restricted cash at end of period</b>	<u>\$ 263,652</u>	<u>\$ 102,031</u>
<b>Supplemental disclosure of noncash activities</b>		
Property and equipment additions in accounts payable	\$ 481	\$ 125
Right-of-use assets obtained in exchange for operating lease liabilities	21,315	-
Operating cash flows used in operating leases	9,171	-

See accompanying notes to unaudited consolidated financial statements

**TCR<sup>2</sup> Therapeutics Inc.**  
**Notes to Unaudited Consolidated Financial Statements**  
**(Amounts in thousands, excluding share and per share items or noted otherwise)**

**1. Organization and Description of Business**

TCR<sup>2</sup> Therapeutics Inc. (the Company) is a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer. The Company was incorporated under the laws of the State of Delaware on May 29, 2015 under the name TCR<sup>2</sup>, Inc. In November 2016, the Company changed its name to TCR<sup>2</sup> Therapeutics Inc. The Company's principal operations are located in Cambridge, Massachusetts.

***Shelf registration statement***

On March 16, 2021, the Company filed an automatic shelf registration statement on Form S-3 (the Shelf), with the Securities and Exchange Commission (SEC), which covers the offering, issuance and sale of an indeterminate amount of the Company's common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. The Shelf was automatically effective when filed. As of September 30, 2021, no sales have been made under the Shelf.

***Equity offerings***

On July 31, 2020, the Company closed a public offering of its common stock pursuant to which it issued and sold 9,200,000 shares of its common stock at a price to the public of \$15.50 per share. The aggregate net proceeds received by the Company from the offering were approximately \$133.6 million after deducting \$9.0 million relating to underwriting discounts and commissions and offering expenses.

On January 22, 2021, the Company closed a public offering of its common stock pursuant to which it issued and sold 4,590,164 shares of its common stock at a price to the public of \$30.50 per share. The aggregate net proceeds received by the Company from the offering were approximately \$131.3 million after deducting \$8.7 million relating to underwriting discounts and commissions and offering expenses.

**2. Liquidity**

The Company's operations to date have focused on organization and staffing, business planning, raising capital, acquiring technology and assets, manufacturing, conducting preclinical studies and clinical activities. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company's product candidates are subject to long development cycles and the Company may be unsuccessful in its efforts to develop, obtain regulatory approval for or market its product candidates.

The Company is subject to a number of risks including, but not limited to, the need to obtain adequate additional funding for the ongoing and planned clinical development of its product candidates. Because of the numerous risks and uncertainties associated with pharmaceutical products and development, the Company is unable to accurately predict the timing or amount of funds required to complete development of its product candidates, and costs could exceed the Company's expectations for a number of reasons, including reasons beyond the Company's control. The Company is also subject to a number of other risks including possible failure of preclinical studies or clinical trials, the need to obtain marketing approval for its product candidates, the development of new technological innovations by competitors, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved and uncertainty around intellectual property matters. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability.

The Company expects to continue to generate losses for the foreseeable future. The Company expects that its cash, cash equivalents and investments as of September 30, 2021 of \$295.7 million will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the date of issuance of these unaudited consolidated financial statements.

**TCR<sup>2</sup> Therapeutics Inc.**  
**Notes to Unaudited Consolidated Financial Statements**  
**(Amounts in thousands, excluding share and per share items or noted otherwise)**

**3. Summary of Significant Accounting Policies**

***Principles of consolidation and basis of presentation***

The unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and in accordance with Article 10 of Regulation S-X of the SEC, and reflect the financial position, results of operations and cash flows of the Company's business. Accordingly, they do not include all of the disclosures required by U.S. GAAP for a complete set of annual audited financial statements. All significant intercompany accounts and transactions are eliminated in consolidation.

The unaudited consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The accompanying financial information should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2021 for the year ended December 31, 2020 (the 2020 Form 10-K). In the opinion of the Company's management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement of the results for the interim periods presented have been included.

***Use of estimates***

The preparation of the accompanying unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited consolidated financial statements and reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these unaudited consolidated financial statements include, but are not limited to, the fair value of the royalty transfer agreement obligations, and the fair value of stock-based compensation awards granted under the Company's equity-based compensation plans. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

***Concentrations of credit risk and of manufacturing risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and investments. The Company's cash, cash equivalents and investments are held by financial institutions in the United States. Amounts on deposit may at times exceed federally insured limits. Management believes that the financial institutions are financially sound, and accordingly, minimal credit risk exists with respect to the financial institutions.

As of September 30, 2021, the Company has manufacturing arrangements with vendors for the supply of materials for use in preclinical and clinical studies. If the Company were to experience any disruptions in the party's ability or willingness to continue to provide manufacturing services, the Company may experience significant delays in its product development timelines and may incur substantial costs to secure alternative sources of manufacturing.

***Fair value of financial instruments***

As of September 30, 2021 and December 31, 2020, the Company's financial instruments consist of money market funds, U.S. Treasury securities, and corporate bonds and are included in investments. The carrying value of investments is the estimated fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

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***Cash equivalents***

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of September 30, 2021 and December 31, 2020, cash equivalents consisted of U.S treasuries, corporate bonds, and government-backed money market funds.

***Investments***

As of September 30, 2021, all investments were classified as available-for-sale and were carried at their estimated fair value. Unrealized gains and losses are recorded as a component of accumulated other comprehensive income (loss) until realized. The Company determines the appropriate classification of its investments in debt securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in debt securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings. The Company classifies its available-for-sale marketable securities as current or non-current based on each instrument's underlying effective maturity date and for which the Company has the intent and ability to hold the investment for a period of greater than 12 months. Marketable securities with maturities of less than 12 months are classified as current and are included in investments in the consolidated balance sheets. Marketable securities with maturities greater than 12 months for which the Company has the intent and ability to hold the investment for greater than 12 months are classified as non-current and are included in investments, non-current in the consolidated balance sheets.

***Restricted cash***

Cash accounts that are restricted as to withdrawal or usage are presented as restricted cash. Restricted cash includes amounts held as a security deposit in the form of a letter of credit for the Company's leased facilities.

***Assets not placed in service***

Assets not placed in service includes direct costs related to the acquisition of property including leasehold improvements. Such costs are not depreciated until the asset is completed and placed into service.

***Stock-based compensation***

The Company measures stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues awards with only service-based vesting conditions. The Company accounts for forfeitures as they occur. For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed.

Stock-options exercised prior to vesting are subject to repurchase by the Company until vested at the lesser of the initial exercise price and the fair market value of the Company's common stock at the time of repurchase. The proceeds from the shares subject to repurchase are classified as a liability and reclassified to equity as the shares vest.

Estimating the fair value of stock options and warrants requires the input of subjective assumptions, including the expected life of the instrument and stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards and warrants. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

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The Company classifies stock-based compensation expense in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

***Leases***

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 in the arrangement. Leases are classified at their commencement date, which is defined as the date on which the lessor makes the underlying asset available for use by the lessee, as either operating or finance leases based on the economic substance of the agreement. The Company recognizes lease right-of-use assets and related liabilities in its consolidated balance sheets for both operating and finance leases. Lease liabilities are measured at the lease commencement date as the present value of the future lease payments using the interest rate implicit in the lease, or the incremental borrowing rate if the rate implicit in the lease is not readily determinable. Lease right-of-use assets are measured as the lease liability plus initial direct costs and prepaid lease payments less lease incentives. The lease term is the non-cancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised. The Company recognizes operating lease costs in operating expenses in its consolidated statements of operations, inclusive of rent escalation provisions and rent holidays, on a straight-line basis over the respective lease term.

***Research and development expenses***

Research and development costs are expensed as incurred and consist primarily of funds paid for employee wages and funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, and regulatory compliance costs. At the end of the reporting period, the Company compares payments made to third party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs.

Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered.

***Income taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A reduction in the carrying value of the deferred tax assets is required when it is not more likely than not that such deferred tax assets are realizable.

***Net loss per share***

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average shares of common stock outstanding during the period. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive shares of common stock are not assumed to have been issued if their effect is

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anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities, on an as converted basis, have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2021 and 2020, as they would be antidilutive:

	As of September 30,	
	2021	2020
Stock options outstanding	5,495,365	4,131,932
Common stock warrants	203,676	203,676
Employee stock purchase plan	4,011	1,557
Total	5,703,052	4,337,165

***Comprehensive loss***

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources (which excludes investments from owners). The Company's only element of other comprehensive loss is unrealized gains and losses on investments.

***Common stock***

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

***Preferred stock***

The Board of Directors or any authorized committee thereof is expressly authorized, to the fullest extent permitted by law, to provide by resolution or resolutions for, out of the unissued shares of Undesignated Preferred Stock, the issuance of the shares of Undesignated Preferred Stock in one or more series of such stock, and by filing a certificate of designations pursuant to applicable law of the State of Delaware, to establish or change from time to time the number of shares of each such series, and to fix the designations, powers, including voting powers, full or limited, or no voting powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof. As of September 30, 2021, there are no preferred shares issued.

***Reconciliation of cash, cash equivalents and restricted cash as presented in the statements of cash flows***

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the unaudited consolidated balance sheets to the total of the same such amounts shown in the unaudited consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020.

	As of September 30,	
	2021	2020
Cash and cash equivalents	\$ 262,497	\$ 101,614
Restricted cash	1,155	417
Cash, cash equivalents and restricted cash shown in the statements of cash flows	\$ 263,652	\$ 102,031

***JOBS Act accounting election***

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for



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public and private companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

**Recently adopted accounting pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASC 842"), which amends a number of aspects of lease accounting and requires entities to recognize right-of-use assets and liabilities on the balance sheet. The Company adopted ASC 842 during the second quarter of 2021 effective on January 1, 2021. The Company has finalized its review of its portfolio of existing leases and current accounting policies and has concluded that the amended guidance results in the recognition of additional assets and corresponding liabilities on its balance sheets.

In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), which offered a transition option to entities adopting ASC 842. Under ASU 2018-11, entities could elect to apply ASC 842 using a modified-retrospective adoption approach resulting in a cumulative effect adjustment to accumulated deficit at the beginning of the year in which the new lease standard is adopted, rather than adjustments to the earliest comparative period presented in their financial statements.

The Company adopted ASC 842, Leases effective January 1, 2021 on a modified retrospective basis under which requires the recognition of lease liabilities and right-of-use assets at the adoption date but does not require retrospective adjustments of prior periods. The Company elected the optional transition approach of not adjusting its comparative period financial statements for the impacts of adoption. The Company elected the package of transition practical expedients for leases that commenced prior to January 1, 2021, allowing it not to reassess (i) whether any expired or existing contracts contain leases, (ii) the lease classification for any expired or existing leases and (iii) the initial indirect costs for any existing leases.

The Company recorded, upon adoption of ASC 842 effective January 1, 2021, operating lease assets and liabilities of \$11.3 million and \$11.8 million, respectively, related to its real estate leases under ASC 842.

The cumulative effect of applying ASC 842 on the Company's consolidated balance sheet as of January 1, 2021 was as follows:

Assets	Balance as of December 31, 2020	Adjustments	Balance as of January 1, 2021
Prepaid expenses and other current assets	\$ 7,552	\$ (154)	\$ 7,398
Right-of-use assets, operating leases	-	11,300	11,300
Total assets		<u>\$ 11,146</u>	
<b>Liabilities and Shareholders' Equity</b>			
Accrued expenses and other current liabilities	\$ 6,392	\$ (168)	\$ 6,224
Operating lease liabilities	-	2,630	2,630
Other liabilities	807	(482)	325
Operating lease liabilities, non-current	-	9,166	9,166
Total liabilities and shareholders' equity		<u>\$ 11,146</u>	

Adopting ASC 842 did not result in a material impact to our statements of operations or cash flows.

Please refer to Note 8, "Leases," for further information regarding the Company's leases as well as certain disclosures required by ASC 842.

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**4. Investments and Fair Value Measurements**

As of September 30, 2021, investments were comprised of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate bonds	\$ 33,259	\$ -	\$ (15)	\$ 33,244
Total	<u>\$ 33,259</u>	<u>\$ -</u>	<u>\$ (15)</u>	<u>\$ 33,244</u>

As of December 31, 2020, investments were comprised of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate bonds	\$ 34,801	\$ 60	\$ -	\$ 34,861
U.S. Treasury securities	98,967	3	-	98,970
Total	<u>\$ 133,768</u>	<u>\$ 63</u>	<u>\$ -</u>	<u>\$ 133,831</u>

The amortized cost and estimated fair value of marketable securities, by contractual maturity:

September 30, 2021			
	Amortized Cost	Fair Value	
Due within one year or less	\$ 33,259	\$ 33,244	

  

December 31, 2020			
	Amortized Cost	Fair Value	
Due within one year or less	\$ 133,768	\$ 133,831	

The Company follows FASB's accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. Fair value is defined as the price at which an asset could be exchanged in a current transaction between knowledgeable, willing parties. Where available, fair value is based on observable market prices, or parameters derived from such prices. Where observable prices or inputs are not available, valuation models are applied. This hierarchy requires the use of observable market data when available and to minimize the use of unobservable inputs when determining fair value. These valuation techniques involve some level of management estimation and judgment. The degree of management estimation and judgment is dependent on the price transparency for the instruments, or market, and the instruments' complexity.

The guidance requires fair value measurements to be classified and disclosed in one of the following three categories:

Level 1—Quoted prices (unadjusted in active markets for identical assets or liabilities)

Level 2—Inputs other than quoted prices in active markets that are observable either directly or indirectly

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

As of September 30, 2021, the Company has classified assets measured at fair value on a recurring basis as follows:

	Amortized Cost	Fair Value	Fair Value Measurement Based on		
			Quoted Prices in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents <sup>(1)</sup>	\$ 256,956	\$ 256,956	\$ 256,956	\$ -	\$ -
Corporate bonds	33,259	33,244	-	33,244	-
Total	<u>\$ 290,215</u>	<u>\$ 290,200</u>	<u>\$ 256,956</u>	<u>\$ 33,244</u>	<u>\$ -</u>

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As of December 31, 2020, the Company has classified assets measured at fair value on a recurring basis as follows:

	Amortized Cost	Fair Value	Fair Value Measurement Based on		
			Quoted Prices in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents <sup>(1)</sup>	\$ 89,319	\$ 89,319	\$ 89,319	\$ -	\$ -
Corporate bonds	34,801	34,861	-	34,861	-
U.S. Treasury securities	98,967	98,970	-	98,970	-
Total	<u>\$ 223,087</u>	<u>\$ 223,150</u>	<u>\$ 89,319</u>	<u>\$ 133,831</u>	<u>\$ -</u>

<sup>(1)</sup> Includes cash sweep accounts, U.S. Treasury money market mutual fund, bank certificates of deposit, U.S. Treasury bills and corporate bonds that have a maturity of three months or less from the original acquisition date.

## 5. Property and Equipment

Property and equipment, net, consisted of:

	As of	
	September 30, 2021	December 31, 2020
Laboratory equipment	\$ 13,417	\$ 8,566
Computer hardware and equipment	97	109
Furniture and fixtures	432	432
Leasehold improvements	551	320
Assets not placed in service	1,810	3,320
	16,307	12,747
Less: accumulated depreciation	(4,055)	(2,734)
	<u>\$ 12,252</u>	<u>\$ 10,013</u>

Depreciation expense was \$1,938 and \$1,114 for the nine months ended September 30, 2021 and 2020, respectively.

## 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	As of	
	September 30, 2021	December 31, 2020
Employee compensation and related benefits	\$ 3,890	\$ 3,808
Professional fees	535	224
Contract manufacturing organization fees	1,044	582
Contract research organization fees	2,134	487
Property received not yet invoiced	797	385
Other	254	906
	<u>\$ 8,654</u>	<u>\$ 6,392</u>

## 7. Commitments and Contingencies

### *Litigation*

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

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***Royalty transfer agreement***

In connection with the sale of Series A redeemable convertible preferred stock, certain investors are entitled to receive, in the aggregate, a royalty from the Company equal to one percent of (i) all global net sales of any Company products and (ii) any license income on intellectual property that was in existence at the time of the Series A preferred stock financing. The Company has elected to account for this liability at fair value with changes recognized in the statements of operations. Given the early-stage nature of the underlying technology and inherent risks associated with obtaining regulatory approval and achieving commercialization, the Company ascribed no value to the royalty agreement at inception and as of September 30, 2021 and December 31, 2020. The Company currently does not have any net sales or license income and as a result has paid no royalties under this obligation for the three and nine months ended September 30, 2021 and 2020 nor has the Company accrued any liability as of September 30, 2021 or December 31, 2020.

## **8. Leases**

The Company leases all of its offices and facilities, including its corporate headquarters, under operating leases. The Company has entered into various non-cancellable lease arrangements for facilities expiring at various times through 2036. Certain of these arrangements have free rent periods or escalating rent payment provisions. None of our leases include residual value guarantees.

Fixed fees for use of property or equipment and other services are included in the right-of-use assets and lease liabilities. Rent expense is recognized on a straight-line basis for total rent over the lease period. Variable service costs are included in the lease expense as incurred. The Company is generally obligated for the cost of property taxes, insurance, common area maintenance, and other administrative fees relating to its leases, which are considered variable lease costs and are expensed as incurred. In addition, the Company enters into contracts that have different service obligations. These contracts are considered multiple-element service contracts. When leases are embedded in multiple-element service contracts, all contract services are included in lease costs.

### ***Operating Leases***

#### ***Office space and lab facility, Cambridge, Massachusetts***

In March 2018, the Company entered into a lease for office and laboratory facilities that expires in July 2025. Under the terms of the lease, the Company placed a \$290 letter of credit into a restricted cash account as security for the facility.

#### ***Catapult manufacturing facility, Stevenage, United Kingdom***

In December 2018, the Company signed a collaboration agreement (the Collaboration Agreement) with Cell Therapy Catapult Limited (Catapult) to establish the Company's manufacturing process in Catapult's good manufacturing practice (GMP) manufacturing facility in the United Kingdom. The initial term of the Collaboration Agreement is three years which began March 1, 2019. The Company can terminate the Collaboration Agreement earlier with 12 months' notice and continued payment for contributions during the 12-month termination period.

The Collaboration Agreement provides for Catapult to provide identified space, called a module. The Company has concluded that the Collaboration Agreement contains an embedded lease as the Company has the right to operate the module in a manner it determines.

#### ***Office space, Cambridge, Massachusetts***

In September 2019, the Company entered into a lease for office facilities that expires in August 2024. Under the terms of the lease, the Company placed a \$127 letter of credit into a restricted cash account as security for the facility.

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**Lab facility, Cambridge Massachusetts**

In November 2020, the Company entered into a lease for office and laboratory facilities that expires in January 2024. Under the terms of the lease, the Company placed \$166 letter of credit into a restricted cash account as security for the facility.

**Manufacturing facility, Waltham, Massachusetts**

In November 2020, the Company entered into a manufacturing agreement with ElevateBio LLC (ElevateBio) which includes identified space dedicated to the Company. The Company has determined the agreement contains an embedded lease. The lease began in February 2021 when the Company obtained control of the dedicated manufacturing space and ends July 2022.

**Manufacturing facility, Rockville, Maryland**

In March 2021, the Company entered into a lease for a new manufacturing facility for an initial term of 15 years through June 2036. The Company also has an option to extend the term of the lease for two consecutive terms of five years each. The Company placed a \$557 letter of credit into a restricted cash account as security for the facility.

Right-of-use assets and lease liabilities as of September 30, 2021 and January 1, 2021, the date of adoption of ASC 842, were as follows:

	September 30, 2021	January 1, 2021
<b>Assets:</b>		
Right-of-use assets, operating	\$ 29,432	\$ 11,300
<b>Liabilities</b>		
Operating lease liabilities	\$ 3,482	\$ 2,630
Operating lease liabilities, non-current	23,635	9,166
Total lease liabilities	\$ 27,117	\$ 11,796

The components of the lease costs for the nine months ended September 30, 2021 were as follows:

	September 30, 2021
Operating lease costs	\$ 5,579
Short-term lease costs	395
Variable lease costs	3,130
Total lease costs	\$ 9,104

Weighted average remaining lease term and discount rate as of September 30, 2021 were as follows:

	September 30, 2021
Weighted-average remaining lease term (in years)	
Operating leases	9.9
Weighted-average discount rate:	
Operating leases	12.6 %

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The following table presents future minimum lease payments under for operating leases as of September 30, 2021:

	September 30, 2021
2021	\$ 2,139
2022	7,529
2023	7,144
2024	6,351
2025	5,255
Thereafter	40,674
Total minimum payments required	69,092
Less amounts representing imputed interest	(41,975)
Present value of lease liabilities	\$ 27,117

Prior to adoption of ASC 842, future minimum lease payments under non-cancelable operating lease agreements as of December 31, 2020, were as follows:

	December 31, 2020
	Minimum Lease Payments
2021	\$ 4,966
2022	3,985
2023	3,690
2024	2,537
2025	1,054
Thereafter	-
Total	\$ 16,232

Rent expense for the nine months ended September 30, 2020 was \$2.6 million.

## 9. Stock-based Compensation

In February 2019, the Company's Board of Directors and stockholders approved the 2018 Stock Option and Incentive Plan (the 2018 Plan), which replaced the 2015 Stock Option and Grant Plan (the 2015 Plan). The shares under the 2015 Plan which were not issued were rolled into the 2018 Plan. The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company's officers, employees, directors, and other key persons (including consultants) are eligible to receive awards under the 2018 Plan. The maximum number of authorized shares to be issued under the 2018 Plan is 7,394,606 shares of common stock. The number of shares of common stock reserved for issuance under the 2018 Plan shall be cumulatively increased on January 1, 2020 and each January 1 thereafter by 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by the Company's Board of Directors. The amount, terms of grants, and exercisability provisions are determined and set by the Compensation Committee of the Company's Board of Directors. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the Board of Directors.

As of September 30, 2021, there were 1,469,370 shares of common stock available for future issuance under the 2018 Plan. Generally, options and restricted stock awards vest over a four-year period.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying unaudited consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 1,336	\$ 798	\$ 4,147	\$ 2,414
General and administrative	1,850	1,269	5,378	3,772
	\$ 3,186	\$ 2,067	\$ 9,525	\$ 6,186

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**Stock options**

During the nine months ended September 30, 2020, there were 207,148 grants of stock options, 141,639 options forfeited, and 122,869 options exercised, respectively.

The following table summarizes the activity related to stock option grants to employees and non-employees for the nine months ended September 30, 2021:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Balance as of December 31, 2020	5,011,349	\$ 14.99	8.4
Granted	803,103	15.84	
Exercised	(95,596)	7.78	
Forfeited	(223,491)	20.84	
Balance as of September 30, 2021	<u>5,495,365</u>	<u>\$ 15.00</u>	<u>7.8</u>
Exercisable as of September 30, 2021	<u>2,592,536</u>	<u>\$ 9.42</u>	<u>6.7</u>
Vested and expected to vest as of September 30, 2021	<u>5,495,365</u>	-	

As of September 30, 2021, there was \$32.6 million in unrecognized compensation cost that is expected to be recognized over an estimated weighted-average amortization period of 2.7 years.

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying common stock at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options for the nine months ended September 30, 2021 and 2020 was determined using the methods and assumptions discussed below:

- The expected term of employee options is determined using the "simplified" method, as prescribed in the SEC Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data. The expected term of non-employee options is equal to the contractual term.
- The expected volatility was based on the historical stock volatility of several comparable publicly traded companies over a period of time equal to the expected term of the options, as we do not have sufficient trading history to use the volatility of our own common stock.
- The estimated annual dividend yield is 0% because the Company has not historically paid and does not expect for the foreseeable future to pay, a dividend on its common stock.
- The Company is traded on the Nasdaq Select Market. Fair value is determined by the stock price quoted on Nasdaq.

The grant date fair value of all option grants was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	For the Nine Months Ended September 30, 2021	2020
Risk-free interest rate	0.9 %	0.5 %
Expected term (in years)	6.1	6.1
Expected volatility	72.6 %	72.9 %
Annual dividend yield	0 %	0 %
Fair value of common stock	\$ 11.61	\$ 7.86

**Warrants**

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As of September 30, 2021 and December 31, 2020, there were 203,676 warrants outstanding. During the nine months ended September 30, 2021 and 2020, the Company granted no warrants, and there were no forfeitures or exercises.

***Employee stock purchase plan (ESPP)***

In February 2019, the Company's Board of Directors adopted and the Company's stockholders approved the 2018 Employee Stock Purchase Plan (2018 ESPP). The 2018 ESPP enables eligible employees to purchase shares of the Company's common stock at the end of each six-month offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Eligible employees generally included all employees. Offering periods begin on the first trading day of September and March of each year and end on the last trading day in February and August of each year. Share purchases are funded through payroll deductions of up to 15% of an employee's eligible compensation for each payroll period, or \$25 each calendar year.

During the nine months ended September 30, 2021 and 2020, there were 17,889 shares and 23,864 shares issued under the 2018 ESPP, respectively.

**10. Related party transactions**

***Manufacturing agreement***

During November 2020, the Company entered into a manufacturing partnership with ElevateBio. Dr. Ansbert Gadick is a member of the board of directors at the Company and ElevateBio. The agreement is to establish a manufacturing partnership with ElevateBio for production of the Company's clinical trial products. During the nine months ended September 30, 2021, the Company has incurred \$883 in expenses and has incurred additional costs of \$252 for equipment owned by the Company for use by ElevateBio.

***Consulting arrangement***

On October 1, 2015, the Company entered into a consulting agreement with Dr. Patrick Baeuerle. Pursuant to the consulting agreement, Dr. Baeuerle agreed to perform such consulting, advisory and related services to and for the Company as may be reasonably requested. In exchange, the Company agreed to pay Dr. Baeuerle a consulting fee of €15 per month. On November 1, 2016, the Company amended the consulting agreement to revise Dr. Baeuerle's consulting fee to be €3 per month. Dr. Baeuerle is also eligible for an annual bonus equal to 33% of the annual fees paid under the consulting agreement, subject to the discretion of the Company's Board of Directors based on Dr. Baeuerle's performance and the Company's performance. The term of the agreement is one year, and automatically extends for additional one-year periods unless terminated. During the nine months ended September 30, 2021 and 2020, the Company incurred fees to Dr. Baeuerle in the amount of \$39 and \$54, respectively, under the consulting agreement. Dr. Baeuerle was a member of the Company's Board of Directors and is a managing director at MPM Capital, the beneficial owner of more than 5% of the Company's voting securities. As of August 24, 2021, Dr. Baeuerle resigned from the Board of Directors and is no longer considered a related party.

**11. Subsequent Event**

**UK Operations**

On November 1, 2021, the Company announced a proposal to consolidate its manufacturing operations in the United States. Under the proposal, manufacturing operations at the Company's facility in Stevenage, United Kingdom ("UK"), would cease by the end of 2021. The Company estimates that this could affect an estimated 34 employees in the UK. In accordance with UK law, the UK-based employees will enter into a consultation period in respect of the proposed plan to close the Stevenage, UK, facility



prior to any final decision being made. The Company anticipates that the consultation period will be concluded on or about December 10, 2021.

Should the Company proceed with the proposal, the Company expects to reduce annual operating expenses in 2022 by approximately \$16 million and incur pre-tax restructuring charges in the fourth quarter of 2021, which could include one-time employee severance and termination benefits, facility closure costs, costs to relocate certain equipment and other disposal and restructuring charges of approximately \$4.0 million to \$4.5 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 consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report") and our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 16, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. Actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those set forth in Item 1A, "Risk Factors" and elsewhere in our Annual Report and this Quarterly Report.*

### Overview

We are a clinical-stage cell therapy company developing a pipeline of novel T cell therapies for patients suffering from cancer by powering the T cell receptor (TCR) with our proprietary, first-in-class TCR Fusion Construct T cells (TRuC-T cells). Designed to overcome the limitations of current cell therapy modalities, our TRuC-T cells specifically recognize and kill cancer cells by harnessing the entire TCR signaling complex, which we believe is essential for T cell therapies to be effective in patients with solid tumors.

Since our inception in May 2015, we have focused significant efforts and financial resources on developing our TRuC platform, establishing and protecting our intellectual property portfolio, conducting research and development of our product candidates, manufacturing drug product material for use in preclinical studies, staffing our company and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales.

To date, we have funded our operations with proceeds from the sale of our preferred and common stock. Through September 30, 2021, we have received gross proceeds of \$541.1 million from the sale of our preferred and common stock.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. As of September 30, 2021, we had an accumulated deficit of \$321.8 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- ☐ conduct additional preclinical studies for our product candidates;
- ☐ initiate and conduct clinical trials for our product candidates;
- ☐ continue to discover and develop additional product candidates;
- ☐ acquire or in-license other product candidates and technologies;
- ☐ maintain, expand and protect our intellectual property portfolio;
- ☐ hire additional clinical and scientific personnel;
- ☐ expand our manufacturing capabilities with third parties and establish manufacturing capabilities in-house;
- ☐ seek regulatory approvals for any product candidates that successfully complete clinical trials; and
- ☐ add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval

for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. Additionally, we expect to incur significant expenses if we acquire and establish our own commercial manufacturing facility, which will be a costly and time-consuming process, and in our operations as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

## **Recent Developments**

### **Impact of the COVID-19 Pandemic**

On March 11, 2020, the World Health Organization declared COVID-19 a global pandemic and on March 13, 2020, the U.S. declared a national emergency with respect to COVID-19. Efforts to contain the spread of COVID-19 have intensified and the United States, including the Commonwealth of Massachusetts where a majority of our operations are located, Europe and Asia, all of which to varying degrees have implemented severe travel restrictions, social distancing requirements, and stay-at-home orders, and such restrictions have had the effect of delaying the commencement of non-COVID-19-related clinical trials, among other restrictions. As a result, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets. Safety measures in response to the pandemic continue to evolve and vary by jurisdiction.

We have been carefully monitoring the COVID-19 pandemic, new variants of COVID-19, vaccination rates of our employees, and vaccine availability. We continue to analyze the pandemic's potential impact on our business and have taken important steps to help ensure the safety of employees and their families and to reduce the spread of COVID-19 in our communities while balancing our commitment to conduct our clinical trials. We have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. We have also maintained efficient communication with our partners and clinical sites as the COVID-19 situation has progressed. We have taken these precautionary steps while maintaining business continuity so that we can continue to progress our programs. COVID-19 has significantly impacted the global healthcare system, including the conduct of clinical trials as medical institutions prioritize the treatment of those afflicted with COVID-19. We continue to closely monitor the adverse impact of the COVID-19 pandemic, including new variants of COVID-19 and vaccine efficacy, on our operations and ongoing clinical and preclinical development.

The effect of the COVID-19 pandemic on our development timelines for gavo-cel and our other product candidates and its effect on our ability to manufacture for our clinical trials is uncertain. We believe that we have been able, as of the date of this Quarterly Report, to mitigate some of the impact from the COVID-19 pandemic on our ongoing clinical programs, however, we have been affected.

The future impact of the COVID-19 pandemic on our industry, the healthcare system, clinical trials and our current and future operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact, as well as the prevalence of vaccination efforts, the effect of any relaxation of current restrictions within the Cambridge community or regions in which our partners and clinical sites are located, and the direct and indirect economic effects of the pandemic and containment measures, among others. See "Item 1A. Risk Factors" for a discussion

of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

### **TC-110 Program**

In alignment with its pipeline prioritization on solid tumors, we have deprioritized the development of TC-110 for the treatment of patients with CD19+ non-Hodgkin lymphoma or adult acute lymphoblastic leukemia and plan instead to evaluate business development options.

## **Components of Our Results of Operations**

### ***Operating Expenses***

#### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants, contractors and contract research organizations (CROs);
- the cost of acquiring and manufacturing preclinical and clinical trial materials, including under agreements with third parties, such as consultants, contractors and contract manufacturing organizations (CMOs);
- consultant fees and expenses associated with outsourced professional scientific development services;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Any nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

We typically use our employee, consultant and infrastructure resources across our development programs. We track certain outsourced development costs by product candidate, but we do not allocate personnel costs or other internal costs to specific product candidates.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development and manufacturing activities in the near term and in the future. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- the number and scope of preclinical and clinical programs we decide to pursue;

- ☐ the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- ☐ our ability to maintain our current research and development programs and to establish new ones;
- ☐ our ability to establish licensing or collaboration arrangements;
- ☐ our ability to complete investigational new drug application (IND)-enabling studies and successfully submit IND or comparable applications;
- ☐ whether we are required by the U.S. Food and Drug Administration (FDA) or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- ☐ the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- ☐ our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMP);
- ☐ our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, potency, purity and acceptable risk to benefit profile of our product candidates or any future product candidates;
- ☐ the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- ☐ our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- ☐ our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- ☐ the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates to treat solid and hematologic cancers;
- ☐ patient demand for our product candidates and any future product candidates, if licensed;
- ☐ competition with other products; and
- ☐ continued acceptable safety profile of our product candidates following approval.

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

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services associated with operating as a public company.

### ***Interest Income, net***

Interest income, net consists of interest earned on our cash equivalents and investment balances, net of investment charges.

### Three Month Consolidated Statements of Operations

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

	For the Three Months Ended September 30,		
	2021	2020	Change
Operating expenses			
Research and development	\$ 20,277	\$ 12,820	\$ 7,457
General and administrative	5,963	4,371	1,592
Total operating expenses	26,240	17,191	9,049
Loss from operations	(26,240)	(17,191)	(9,049)
Interest income, net	38	300	(262)
Loss before income taxes	\$ (26,202)	\$ (16,891)	\$ (9,311)

#### Research and Development Expenses

Research and development expenses were \$20.3 million for the three months ended September 30, 2021 compared to \$12.8 million for the three months ended September 30, 2020. The following table summarizes our research and development expenses for the three months ended September 30, 2021 and 2020 (in thousands).

	For the Three Months Ended September 30,		
	2021	2020	Change
Clinical program expenses	\$ 3,404	\$ 3,154	\$ 250
Platform development expenses	2,348	1,321	1,027
Personnel expenses	9,212	5,742	3,470
Allocated facility expenses	4,137	1,469	2,668
Other expenses	1,176	1,134	42
	\$ 20,277	\$ 12,820	\$ 7,457

The \$7.5 million increase in research and development expense for three months ended September 30, 2021 as compared to the three months ended September 30, 2020 is primarily attributable to an increase of \$3.5 million in additional personnel expenses as we have increased our headcount and related personnel expenses. Facility costs increased \$2.7 million for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 primarily due to additional lab and manufacturing space.

#### General and Administrative Expenses

General and administrative expenses were \$6.0 million for the three months ended September 30, 2021, compared to \$4.4 million for the three months ended September 30, 2020. The increase in general and administrative expenses was primarily due to an increase in personnel costs of \$1.1 million, and an increase in legal and other expenses of \$0.5 million.

#### Interest Income, net

Interest income, net was nil for the three months ended September 30, 2021, compared to \$0.3 million for the three months ended September 30, 2020. The decrease was due to lower interest rates in our commercial and investment accounts for the three months ended September 30, 2021.

## Nine Month Consolidated Statements of Operations

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

	For the Nine Months Ended September 30,		
	2021	2020	Change
Operating expenses			
Research and development	\$ 54,828	\$ 37,682	\$ 17,146
General and administrative	17,297	12,451	4,846
Total operating expenses	72,125	50,133	21,992
Loss from operations	(72,125)	(50,133)	(21,992)
Interest income, net	186	1,546	(1,360)
Loss before income taxes	(71,939)	(48,587)	(23,352)

### Research and Development Expenses

Research and development expenses were \$54.8 million for the nine months ended September 30, 2021 compared to \$37.7 million for the nine months ended September 30, 2020. The following table summarizes our research and development expenses for the nine months ended September 30, 2021 and 2020 (in thousands).

	For the Nine Months Ended September 30,		
	2021	2020	Change
Clinical program expenses	\$ 9,475	\$ 9,751	\$ (276)
Platform development expenses	5,671	3,462	2,209
Personnel expenses	25,127	17,064	8,063
Allocated facility expenses	10,483	4,083	6,400
Other expenses	4,072	3,322	750
	<u>\$ 54,828</u>	<u>\$ 37,682</u>	<u>\$ 17,146</u>

The \$17.1 million increase in research and development expense for nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 is primarily attributable to an increase of \$8.1 million in additional personnel expenses as we have increased our headcount and related personnel expenses. Facility costs increased \$6.4 million for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 primarily due to additional lab and manufacturing space.

### General and Administrative Expenses

General and administrative expenses were \$17.3 million for the nine months ended September 30, 2021, compared to \$12.5 million for the nine months ended September 30, 2020. The increase in general and administrative expenses was primarily due to an increase in personnel costs of \$2.6 million, an increase in legal and other professional fees of \$1.2 million, and an increase in other expenses of \$1.0 million.

### Interest Income, net

Interest income, net was \$0.2 million for the nine months ended September 30, 2021, compared to \$1.5 million for the nine months ended September 30, 2020. The decrease was due to lower interest rates in our commercial and investment accounts for the nine months ended September 30, 2021.

### Liquidity and Capital Resources

Since our inception, we have incurred net losses and generated negative cash flows from operations. Since inception, we have funded our operations with proceeds from the sale of preferred and common stock.

In July 2020, we completed a common stock offering, pursuant to which we issued and sold 9,200,000 shares of our common stock at a price to the public of \$15.50 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-236965), filed with the SEC on March 6, 2020 (the Prior Shelf) and declared effective on April 28, 2020, as supplemented by a prospectus supplement dated July 28, 2020 that was filed with the SEC on July 29, 2020. We received aggregate net proceeds from the offering of approximately \$133.6 million, after deducting underwriting discounts and commissions and other offering expenses paid.

In January 19, 2021, we completed a common stock offering, pursuant to which we issued and sold 4,590,164 shares of our common stock at a price to the public of \$30.50 per share. The offering was made pursuant to the Prior Shelf, as supplemented by a prospectus supplement dated January 19, 2021 that was filed with the SEC on January 21, 2021. The Company received net proceeds from the offering, after deducting the underwriting discounts and commissions and other estimated offering expenses payable by the Company, of approximately \$131.3 million.

As of September 30, 2021, we had cash, cash equivalents, and investments of \$295.7 million.

### ***Funding Requirements***

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical studies and clinical trials of our product candidates in development and we will incur additional costs associated with operating as a public reporting company. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to establishing sales, marketing, distribution and other commercial infrastructure to commercialize such products.

In addition, our expenses will increase as we:

- ☐ conduct clinical trials for our product candidates;
- ☐ seek regulatory approval for any product candidates that successfully complete preclinical and clinical trials;
- ☐ establish manufacturing capabilities in-house for the production of preclinical and clinical supply;
- ☐ hire additional clinical, medical, research and operational personnel; and
- ☐ maintain, expand and protect our intellectual property portfolio.

We believe that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements through [2023]. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research,



product development, or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

## Cash Flows

The following table summarizes our sources and uses of cash for the nine months ended September 30, 2021 and 2020 (in thousands):

	For the Nine Months Ended September 30,	
	2021	2020
Operating activities	\$ (58,323 )	\$ (43,240 )
Investing activities	95,230	(54,754 )
Financing activities	132,007	134,312

### *Operating Activities*

During the nine months ended September 30, 2021, we used \$58.3 million of cash in operating activities, resulting primarily from our net loss of \$72.1 million and a net increase in operating assets and liabilities of \$1.5 million partially offset by non-cash charges of \$12.2 million, which primarily related to depreciation and amortization and stock-based compensation. The increase of non-cash charges for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 is due to an increase in the number of employees which drives the amount of share-based compensation as well as a higher level of investment in property and equipment which increases the amount of depreciation. The net increase in operating assets and liabilities cash flows were primarily attributable to reduced payments to vendors as compared to our expenses as well increased compensation accruals, which are generally paid in the fourth quarter of the current year and first quarter of the subsequent year, offset by operating lease payments.

During the nine months ended September 30, 2020, we used \$43.2 million of cash in operating activities, resulting primarily from our net loss of \$48.7 million partially offset by non-cash charges of \$7.4 million, which related to depreciation and amortization and stock-based compensation, and a net decrease in operating assets and liabilities of \$2.0 million. The increase of non-cash charges for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 is due to an increase in the number of employees, which drives the amount of share-based compensation as well as a higher level of investment in property and equipment which increases the amount of depreciation. The net decrease in operating assets and liabilities cash flows were primarily attributable to payments for annual expenses paid during the first quarter of the year and amortized over the period of performance as well as payments to vendors that service our clinical trials.

### *Investing Activities*

During the nine months ended September 30, 2021, cash provided by investing activities was \$95.2 million, consisting primarily of proceeds from investments net of purchases of \$99.9 million and offset by purchases of property and equipment and capitalized software development costs of \$4.7 million.

During the nine months ended September 30, 2020, cash used in investing activities was \$54.8 million, consisting primarily of purchases of investments net of maturities of \$52.3 million and purchases of property and equipment of \$2.5 million.

### *Financing Activities*

During the nine months ended September 30, 2021, net cash provided by financing activities was \$132.0 million primarily from our secondary equity offering of \$131.3 million, \$1.0 million from the exercise of stock options less deferred offering costs of \$0.3 million.

During the nine months ended September 30, 2020, net cash provided by financing activities was \$134.3 million primarily from our secondary equity offering of \$133.6 million and \$0.7 million from the exercise of stock options.

## **Critical Accounting Policies and Significant Judgments and Estimates**

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

### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- ☐ vendors in connection with preclinical development activities;
- ☐ CMOs in connection with the production of preclinical and clinical trial materials; and
- ☐ CROs in connection with preclinical studies and clinical trials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct, and manage preclinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

## **Stock-Based Compensation**

We measure stock options granted based on their fair value on the grant date and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We apply the straight-line method of expense recognition to all awards with service-based vesting conditions. For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed.

We estimate the fair value of stock-based awards using the Black-Scholes option-pricing model, which requires subjective assumptions, including the volatility, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future. We do not estimate and apply a forfeiture rate as we have elected to account for forfeitures as they occur.

These assumptions are estimated as follows:

- *Fair Market Value of Common Stock.* The Company is traded on the Nasdaq Select Market. Fair value is determined by the stock price quoted on Nasdaq.
- *Volatility.* The expected volatility was based on the historical stock volatility of several comparable publicly traded companies over a period of time equal to the expected term of the options, as we do not have sufficient trading history to use the volatility of our own common stock.
- *Expected Term.* The expected term represents the period that our stock options are expected to be outstanding. We calculated the expected term using the simplified method based on the average of each option's vesting term and the contractual period during which the option can be exercised, which is typically 10 years following the grant date.
- *Risk-Free Interest Rate.* The risk-free interest rate was based on the yields of U.S. Treasury securities with maturities commensurate with the expected term of the award.
- *Expected Dividend Yield.* We have not paid dividends on our common stock nor do we expect to pay dividends in the foreseeable future.

## **Royalty Transfer Agreement**

In connection with the sale of Series A redeemable convertible preferred stock, certain investors are entitled to receive, in the aggregate, a royalty from us equal to one percent of (i) all global net sales of any of our products, if approved, and (ii) any license income on intellectual property that was in existence at the time of the Series A preferred stock financing. We have elected to account for this liability at fair value with changes recognized in the statement of operations. Given the early-stage nature of the underlying technology and inherent risks associated with obtaining regulatory approval and achieving commercialization, we ascribed no value to the royalty agreement at inception and as of September 30, 2021 and December 31, 2020. We continue to evaluate our scientific progress to assess our obligations under this agreement. There is substantial judgment involved in our assessment.

## **Recently Issued and Adopted Accounting Pronouncements**

A description of recently adopted accounting pronouncements that materially impacted our financial position is disclosed in Note 3 to our unaudited consolidated financial statements appearing elsewhere in this Quarterly Report.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

## **Item 4. Controls and Procedures**

### ***Evaluation of Disclosure Controls and Procedures***

We have established disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, or Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.

### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

## Item 1A. Risk Factors

*Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the Securities and Exchange Commission, or SEC, in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impact our business, prospects, financial condition and results of operations.*

*Those risk factors below denoted with a "\*" are newly added or have been materially updated from our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 16, 2021.*

### Risks Related to the Development of Our Product Candidates

#### Risks Related to Clinical Development

***Our approach to the discovery and development of product candidates based on our TRuC-T cell platform represents a novel approach to cancer treatment, which creates significant challenges for us.***

Our future success depends on the successful development of our product candidates, which target solid tumors and hematologic malignancies using the complete T cell receptor (TCR) complex without the need for human leukocyte antigen (HLA) matching. Advancing our product candidates based on our innovative TRuC-T cell platform creates significant challenges for us, including:

- ☐ educating medical personnel about the administration of TRuC-T cell therapies on a stand-alone basis or in combination with built-in immune and tumor modulators;
- ☐ educating medical personnel regarding the potential side effect profile of our product candidates, such as the potential adverse side effects related to cytokine release syndrome (CRS), neurotoxicity or autoimmune or rheumatologic disorders;
- ☐ administering chemotherapy to patients in advance of administering our product candidates, which may increase the risk of adverse side effects;
- ☐ sourcing clinical and, if licensed, commercial, supplies for the materials used to manufacture and process our product candidates;
- ☐ manufacturing viral vectors to deliver TRuC constructs to T cells;
- ☐ developing a robust and reliable TRuC-T cell manufacturing process and manufacturing capacity as well as a complete shipment lifecycle and supply chain, including efficiently managing shipment of patient cells from and to clinical sites;
- ☐ minimizing potential contamination to the cell product during production and effectively scaling manufacturing capacity to meet demand;
- ☐ managing costs of inputs and other supplies while scaling production;
- ☐ using medicines to manage adverse side effects of our product candidates, which may not adequately control the side effects and/or may have a detrimental impact on the potency of the treatment;

- obtaining and maintaining regulatory approval from the US Food and Drug Administration (FDA) for our product candidates; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

In developing our product candidates, we have not exhaustively explored different options in the design of the TRuC construct and in the method for manufacturing TRuC-T cells. We may find our existing TRuC-T cells and manufacturing process may be substantially improved with future design or process changes, necessitating development of new or additional TRuC constructs and further clinical testing and delaying commercial launch of our first products. For example:

- We have made several TRuC constructs and used preclinical studies to select product candidates to advance into clinical trials. The preclinical studies are limited in their ability to predict behavior of our product candidates in patients. As we gain experience working with TRuC constructs, we may decide to select other TRuC constructs for clinical development.
- We have used a lentiviral vector to deliver the TRuC construct to T cells. In the future, we may find that another viral vector or non-viral transfer process offers advantages. Switching from lentiviral to another delivery system would necessitate additional process development and clinical testing and delay the development of existing product candidates.
- The process by which patient cells are converted into a TRuC-T cell has many steps that can influence quality and activity. We have explored a subset of variables and expect to continue to improve and optimize the manufacturing process. Depending upon the nature of the process changes, we may be compelled to perform bridging studies and/or to re-start clinical development, causing delays in time to market and potentially introducing a risk of failure if new processes do not perform as expected.

***We are very early in our development efforts. Most of our product candidates are still in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.***

We are early in our development efforts. Most of our product candidates are still in preclinical development, and gavo-cel, our most advanced product candidate, is in a Phase 1/2 clinical trial. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- successful initiation and completion of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- receipt and related terms of marketing approvals and licensures from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supply of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of our products following licensure; and
- effectively competing with other therapies.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to successfully commercialize our product candidates, which would materially harm our business.

***We have limited experience as a company in conducting clinical trials.***

We have limited experience as a company in conducting clinical trials. Our Phase 1/2 clinical trial for gavo-cel began in 2019. Because of this limited experience, and other factors, we cannot be certain that our planned and ongoing preclinical studies will be completed on time, or that our planned and ongoing clinical trials will begin, enroll sufficient patients, produce data on expected timelines or be completed on expected timelines, if at all. Large-scale clinical trials require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations (CROs) and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control.

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.***

We cannot be certain that our preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

We may experience delays in obtaining the FDA's authorization to initiate clinical trials under future INDs, completing ongoing clinical studies of our product candidates due to a variety of factors, including the impact of COVID-19 at our clinical sites, and initiating our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- ☐ the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- ☐ delays in obtaining regulatory approval to commence a clinical trial;
- ☐ reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- ☐ obtaining institutional review board (IRB) approval at each clinical trial site;
- ☐ recruiting an adequate number of suitable patients to participate in a clinical trial;
- ☐ having subjects complete a clinical trial or return for post-treatment follow-up;
- ☐ clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- ☐ addressing subject safety concerns that arise during the course of a clinical trial;
- ☐ adding a sufficient number of clinical trial sites; or
- ☐ obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

For example, in February 2019, we received a request from the FDA's Center for Devices and Radiological Health (CDRH) for the submission of an investigational device exemption (IDE) application regarding our use of a commercially available in vitro diagnostic assay for screening mesothelin expression in tumors. The CDRH subsequently determined that we did not need to submit an IDE application, but such a requirement, or other unexpected FDA requests, could lead to future delays of our

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. In addition, costs to treat patients with relapsed or refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than those for more conventional therapeutic technologies or drug product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board (DSMB) for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates generally prove to be ineffective,



unsafe or commercially unviable, our entire pipeline and TRuC-T cell platform would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our business is highly dependent on our clinical trial for our lead product candidate, gavo-cel, and we must complete IND-enabling studies and clinical testing before we can seek regulatory approval and begin commercialization of any of our product candidates. We cannot be certain that we will be able to complete ongoing clinical trials, initiate future planned clinical trials, or advance our product candidates into additional trials, or to successfully develop, or obtain regulatory approval for, or successfully commercialize, any of our product candidates.***

Our business depends heavily on our ability to complete clinical development and non-clinical studies of our lead product candidate, gavo-cel, and our other product candidates, and to obtain regulatory approval of and successfully commercialize these and any future product candidates. There is no guarantee that any of our product candidates will proceed in preclinical or clinical development or achieve regulatory approval. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned or, if at all.

There is no guarantee that the results obtained in current preclinical studies, our Phase 1/2 clinical trial of gavo-cel, or our planned clinical trials will be sufficient to obtain regulatory approval or marketing authorization for such product candidates. The FDA may ultimately decide that the design, number and type of clinical trials, number of patients studied or results of our clinical trial for gavo-cel, even if positive, are not sufficient for regulatory approval in their respective target indications. Changes in the manufacturing process as we scale-up and optimize our process for manufacturing our product candidates could also delay development or require us to conduct additional clinical trials or non-clinical studies or could lead to different results than achieved with the earlier processes. We may not be able to initiate or complete our clinical trials or announce results from our clinical trials on the timelines we expect. We may experience slower than expected enrollment and randomization of patients in our clinical trials. These types of delays can lead to delays in completion of a trial and announcement of results. There is also the potential for slower than expected clinical site initiation, delays or problems in analyzing data, and the potential need for additional analysis or data or the need to enroll additional patients in any of our clinical trials. We may also encounter delays arising from unexpected adverse events in a trial or other unexpected hurdles or issues in the conduct of any trial. Negative results in the development of our lead product candidate may also impact our ability to obtain regulatory approval for our other product candidates, either at all or within anticipated timeframes because, although other product candidates may target different indications, the underlying technology platform, manufacturing process and development process is the same for all of our product candidates. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidate, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential, or may need to divert resources to other programs. For example, in October of 2021, in alignment with our pipeline prioritization on solid tumors, we deprioritized the development of TC-110, a product candidate in a Phase 1 clinical trial. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or limit the opportunities we are able to pursue. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

***Our preclinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.***

Before obtaining regulatory approvals for the commercial sale of our product candidates, including gavo-cel, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. We may not be able to demonstrate the efficacy and safety of gavo-cel or any of our other product candidates or any future product candidate at each stage of clinical development or we may encounter issues with any non-clinical studies required for regulatory submissions. Success in preclinical studies or in earlier stage clinical trials may not be repeated or observed in ongoing or future clinical trials involving TRuCs or other product candidates. The results of clinical trials or non-clinical studies of our product candidates at any stage may not support further development or may not be sufficient to obtain regulatory approval.

In 2020 we reported data in our Phase 1/2 clinical trial with gavo-cel for our first eight patients treated on study in dose escalation, including three partial responses according to RECIST 1.1 criteria, and our first ovarian cancer patient having achieved a confirmed partial response. Gavo-cel was also generally well tolerated with none of the first eight patients experiencing neurotoxicity or on-target, off-tumor toxicities and only two patients experiencing gavo-cel-related non-hematologic grade >2 toxicity: one who developed Cytokine Release Syndrome (CRS) grade 3, which was successfully managed with tocilizumab and corticosteroids and a second one who experienced grade 3 CRS and grade 3 pneumonitis that resolved upon administration tocilizumab and corticosteroid therapy. Several weeks after the resolution of the grade 3 CRS and grade 3 pneumonitis, this patient became septic due to a hospital-acquired drug-resistant fungal infection, which was deemed unrelated to gavo-cel by the Safety Review Team (SRT) overseeing the safety of our clinical trial. The SRT declared the grade 3 pneumonitis event as a dose limiting toxicity and recommended the expansion of the dose level 1 cohort from three to six patients. We completed dosing in the expanded cohort in 2020 and have continued treating patients at higher dose levels. While our data in the Phase 1/2 clinical trial has been positive with a manageable safety profile, these results may not be repeated or observed in future cohorts of patients treated in the currently ongoing clinical trial or in future clinical trials and may not be predictive of the results of later-stage clinical trials.

The drug-development process, including preclinical and clinical testing is expensive, can take many years to complete, and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. The outcome of the drug development process is inherently uncertain. Of the large number of drugs in development in the U.S., only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. Clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Accordingly, even if we have the requisite financial resources, when needed, to continue to fund our development efforts, we cannot assure you that any of our product candidates will be successfully developed or commercialized either in the U.S. or in any country outside the U.S. Even if we gain approval of any of our other product candidates, we may never be able to successfully commercialize the product or to meet our expectations with respect to revenues or profits.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising

results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. There can be significant variability in safety and efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Additionally, our preclinical studies comparing our product candidates to chimeric antigen receptor T (CAR-T) cells utilized CAR-T cells that we engineered, rather than the CAR-T cell therapies that are currently approved by the FDA. Although we believe, based on the results we observed in these preclinical studies, that our product candidates have the potential to improve upon the safety and efficacy of currently approved CAR-T cell therapies, these results may not be predictive of the outcome of our future preclinical studies and clinical trials, including any potential preclinical studies and clinical trials that may compare our product candidates to FDA-approved CAR-T cells.

***Since the number of patients that we plan to dose in our Phase 1/2 clinical trials is small, the results from these clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.***

The number of patients we plan to treat in our clinical trial for gavo-cel is small and the results from these clinical trial, once completed, may be less reliable than results achieved in larger clinical trials. For example, in the Phase 1 portion of our Phase 1/2 clinical trial of gavo-cel, we plan to evaluate the safety profile of gavo-cel and establish the recommended Phase 2 dose. In Phase 2, we intend to treat approximately 50 patients with non-small cell lung cancer (NSCLC), ovarian cancer, malignant pleural/peritoneal mesothelioma and cholangiocarcinoma. The preliminary results of clinical trials with smaller sample sizes, such as our Phase 1/2 clinical trial of gavo-cel, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of gavo-cel, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial Phase 1/2 clinical trial.

***We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

We may not be able to file INDs on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. In July 2018, a power failure that occurred during our third-party manufacturing run to produce virus for our Phase 1/2 clinical trial of gavo-cel caused us to abandon that manufacturing run and resulted in a month-long delay in the process of manufacturing the requisite virus to support our IND filing for gavo-cel and consequently a delay in the IND filing itself. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including impacts that have resulted or may result from the COVID-19 pandemic. The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before the manufacturing and infusion of our product candidates or clinical trial completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. In addition, patients may be unwilling to participate in our studies because of negative publicity from adverse events in the biotechnology industry or for other reasons. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Additionally, because some of 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.

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

***We cannot guarantee that our product candidates will show any functionality in the solid tumor microenvironment.***

There are no approved CAR-T or engineered TCR-T cell immunotherapies for solid tumors. We believe our TruC-T cell product candidates may be effective against solid tumors. While we plan to develop product candidates for use in solid tumors, including gavo-cel, we cannot guarantee that our product candidates will show any functionality in the solid tumor microenvironment. The cellular environment in which solid tumor cells thrive is generally hostile to T cells due to factors such as the presence of immunosuppressive cells, humoral factors and limited access to nutrients. Our TRuC-T cell-based product candidates may not be able to access the solid tumor, and even if they do, they may not be able to exert anti-tumor effects in a hostile tumor microenvironment. In addition, the safety profile of our product candidates may differ in a solid tumor setting. As a result, our product candidates may not demonstrate potency in solid tumors. If we are unable to make our product candidates function in solid tumors, our development plans and business may be significantly harmed.

***Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities, including IRBs, to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Because of our planned dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, which may stem from our product candidates specifically or may be due to an illness from which the clinical trial subject is suffering. In 2020 we reported data in our Phase 1/2 clinical trial with gavo-cel for our first eight patients treated on study in dose escalation, including three partial responses according to RECIST 1.1 criteria, and our first ovarian cancer patient having achieved a confirmed partial response. Gavo-cel was also generally well tolerated with none of the first eight patients experiencing neurotoxicity or on-target, off-tumor toxicities and only two patients experiencing gavo-cel-related non-hematologic grade >2 toxicity: one who developed Cytokine Release Syndrome (CRS) grade 3, which was successfully managed with tocilizumab and corticosteroids and a second one who experienced grade 3 CRS and grade 3 pneumonitis that resolved upon administration tocilizumab and corticosteroid therapy. Several weeks after the resolution of the grade 3 CRS and grade 3 pneumonitis, this patient became septic due to a hospital-acquired drug-resistant fungal infection, which was deemed unrelated to gavo-cel by the Safety Review Team (SRT) overseeing the safety of our clinical trial. The SRT declared the grade 3 pneumonitis event as a dose limiting toxicity and recommended the expansion of the dose level 1 cohort from three to six patients. We completed dosing in the expanded cohort in 2020 and have continued treating patients at higher dose levels. While our data in the Phase 1/2 clinical trial has been positive with a manageable safety profile, these results may not be repeated or observed in future cohorts of patients treated in the currently ongoing clinical trial or in future clinical trials and may not be predictive of the results of later-stage clinical trials.

Autoimmunity may occur after TRuC-T cell treatment. TRuC-T cells are generated from a patient's own T cells isolated from their peripheral blood. There is a theoretical risk that this process will expand a patient's own T cell that has autoreactivity, or that may recognize healthy cells, and upon re-infusion may trigger an autoimmune reaction resulting in damage to normal tissues and potentially even death. Autoimmune reaction triggered by an interaction between a patient's naturally occurring antibodies and engineered T cells is a theoretical safety risk of product candidates we develop using our TRuC-T cell platform. If a patient's self-generated antibodies were directed to a target expressed on the surface of cells in normal tissue (autoantibodies), engineered T cells would be directed to attack these same tissues, potentially resulting in off-tumor effects. These autoantibodies may be present whether or not the patient has an active autoimmune disease. In our clinical testing, we plan to take steps to minimize the likelihood that this occurs, for example by excluding patients with a history of severe autoimmune disease from our trials. There is no guarantee, however, that we will not observe autoimmune reactions in the future and no guarantee that if we do, that we will be able to implement interventions to address the risk.

Immunogenicity, which is the reaction between a patient's immune system and a foreign protein outside of the autoimmune context, is an additional theoretical safety risk of product candidates we develop using our TRuC-T cell platform. Patients' immune systems may recognize the TRuC construct on the TRuC-T cell as a foreign protein and fight against it, potentially rendering it ineffective, or even provoking an allergic/anaphylactoid response or other adverse side effects. The immunogenic potential of novel therapeutics like TRuC-T cells is difficult to predict. There is no guarantee that we will not observe immunogenic reactions in the future and no guarantee that if we do, that we will be able to implement interventions to address the risk.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities, or local regulatory authorities such as IRBs, could order us to cease clinical trials. Competent national health authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand the side effect profile of our product candidates for both our planned clinical trials and upon any commercialization of any product candidates, if licensed. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may significantly harm our business, financial condition and prospects.

***Our product candidates may target healthy cells expressing target antigens leading to potentially fatal adverse effects.***

Our product candidates target specific antigens that are also expressed on healthy cells. For example, our lead product candidate, gavo-cel, targets mesothelin, an antigen commonly found on mesotheliomas, ovarian cancers, and NSCLC, as well in healthy cells that line the pleura, pericardium and peritoneum. Our product candidates may target healthy cells, leading to serious and potentially fatal adverse effects. In our Phase 1/2 clinical trial of gavo-cel, we are using a dose escalation model to closely monitor the effect of gavo-cel on vital organs and other potential side effects. Even though we intend to closely monitor the side effects of our product candidates in both preclinical studies and clinical trials, we cannot guarantee that products will not target and kill healthy cells.

***Our product candidates may have serious and potentially fatal cross-reactivity to other peptides or protein sequences within the body.***

Our product candidates may recognize and bind to a peptide unrelated to the target antigen to which it is designed to bind. If this peptide is expressed within normal tissues, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse effects. Detection of any cross-reactivity may halt or delay any ongoing clinical trials for any TRuC-T cell based product candidate and prevent or delay regulatory approval. Unknown cross-reactivity of the TRuC-T cell binding domain to related proteins could also occur. We have also developed a preclinical screening process to identify cross-reactivity of the TRuC-T cell binders. Any cross-reactivity that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization.

***Our product candidates rely on the use of protein binding domains, or binders, to target specific cancers, which we may develop or which may be developed by third parties. We are limited in our ability to apply our product candidates to a wider range of potential target cancers by our ability to develop, partner for or acquire these binders on commercially reasonable terms.***

TRuC-T cell therapies require the use of antigen-specific protein binding domains, or binders, which guide the TRuC-T cells and bind to the antigens on the surface of a tumor to target specific types of cancers. Our ability to develop and commercialize our product candidates will depend on our ability to develop these binders or partner for such binders on commercially reasonable terms for use in clinical trials as well as the availability of such binders for use in commercialized products, if licensed. For example, we have a non-exclusive license for the mesothelin binder incorporated into the TRuC construct for gavo-cel from Harpoon Therapeutics, Inc. (Harpoon). However, we cannot be certain that our Harpoon license or potential future collaborations will provide us with a steady supply of binders that we can utilize in combination with the TRuC construct to develop future product candidates. If we are unable to enter into such collaborations on commercially reasonable terms or fail to realize the benefits of any such collaboration, we may be limited to using antibody fragments that we are able to independently develop which may limit the ability of our product candidates to target and kill cancer cells.



The failure to enter into a successful collaboration or to develop our own binders may delay our development timelines, increase our costs and jeopardize our ability to develop future product candidates as a commercially viable drug, which could result in delays in product development and harm our business.

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

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our TRuC T-cell platform. Our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. We may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our research, development or commercialization efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

#### Risks Related to Manufacturing

***Manufacturing and administering our product candidates are complex and we may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our TRuC-T cells for clinical trials or for commercial purposes could be delayed or stopped.***

The process of manufacturing and administering our product candidates is complex and highly regulated. The manufacture of our product candidates involves complex processes, including the manufacture of a lentiviral delivery vector containing the genetic information for our TRuC construct and manufacturing T cells containing the TRuC construct for the final product candidates. More specifically, the manufacture of our product candidates includes harvesting white blood cells from the patient, isolating certain T cells from the white blood cells, combining patient T cells with our lentiviral delivery vector through a process known as transduction, expanding the transduced T cells to obtain the desired dose, and ultimately infusing the modified T cells back into the patient's body. As a result of the complexities entailed in this process, our manufacturing and supply costs are likely to be higher than those at more traditional manufacturing processes and the manufacturing process is less reliable and more difficult to reproduce. Additionally, the number of facilities that are capable of harvesting patients' cells for the manufacture of our product candidates and other autologous cell therapy products and product candidates is limited. As the number of autologous cell therapy products and product candidates increases, the limited number of facilities capable of harvesting patients' cells could result in delays in the manufacture and administration of our product candidates and/or require us to prioritize among our clinical programs, potentially resulting in clinical trial delays.

We rely on third parties for the manufacture of our lentiviral vectors and our product candidates. These third-party manufacturers may incorporate their own proprietary processes into our lentiviral vector and product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates. In addition these third parties may have limited manufacturing capacity and we have less control over production methods, staffing and product quality when produced with third party manufacturers. In both cases, this can cause delays in planned manufacturing runs, require remanufacture due to failed runs and limit our ability to manufacture lentiviral vector and our product candidates as needed, resulting in delays for IND filings, clinical trials and non-clinical studies.

Our manufacturing process is and will be susceptible to product loss or failure due to logistical issues, including manufacturing issues associated with the differences in patients' white blood cells, interruptions in the manufacturing process, contamination, equipment or reagent failure, power failures, supplier error and variability in patient characteristics. For example, in July 2018, a power failure that occurred during a manufacturing run to produce virus for our Phase 1/2 clinical trial of gavo-cel caused us to abandon that run, and resulted in a month-long delay in the process of manufacturing the requisite virus to support our IND filing for gavo-cel and consequently a delay in the IND filing itself. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If for any reason we lose a patient's white blood cells, or such material gets contaminated or processing steps fail at any point, the manufacturing process of the TRuC-T cells for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made or administered, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

As our product candidates progress through preclinical studies and clinical trials towards potential licensure and commercialization, it is expected that various aspects of the manufacturing and administration process will be altered in an effort to optimize processes and results. We have already identified some improvements to our manufacturing and administration processes, but these changes may not achieve the intended objectives, and could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. In addition, such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates.

Developing a commercially viable process is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. In addition, changes to our manufacturing process may also require further review and approval by the FDA, leading to delays in our clinical trials. Competitors have had difficulty reliably producing T-cell therapies in the commercial setting. If we experience similar challenges manufacturing product candidates to approved specifications, this may limit our product candidates' utilization and our ability to receive payment for these product candidates once approved. We may ultimately be unable to reduce the expenses associated with our product candidates to levels that will allow us to achieve a profitable return on investment.

We do not have our own clinical-scale manufacturing facility and are currently reliant on a limited number of manufacturers for our lentiviral vector and a single manufacturer to provide our needs for producing our TRuC-T cell product candidates. We are in the process of adding manufacturing capacity to support larger clinical trials for our product candidates both with additional third-party manufacturers and with our own manufacturing operations in Stevenage, United Kingdom and Rockville, Maryland. We plan to continue to pursue additional manufacturing capacity in the United States and in Europe to meet our future demands and may build our own manufacturing capabilities to meet the patient demand for our product candidates. These third-party manufacturing providers may not be able to provide adequate resources or consistent capacity to meet our clinical trial or commercial needs.

***\*We rely on third parties to manufacture our product candidates for our clinical trials.***

We rely on third parties for the manufacture of our lentiviral vectors and our product candidates. We do not currently have a facility that can be used as our clinical scale manufacturing facility for our product candidates or lentiviral vector and we expect to rely on outside vendors to meet these manufacturing needs. We have added to our third-party manufacturing capacity for our product candidates through our partnership with ElevateBio, LLC. This partnership reserves us our own GMP manufacturing suite with our own equipment and staffed with ElevateBio's employees at ElevateBio BaseCamp, a 140,000 square foot, world-class cell and gene therapy manufacturing facility based in Waltham, Massachusetts. However, this additional capacity may not be enough to support our clinical trials, and our own employees



will not be controlling and operating the facility. To mitigate the risk of third-party manufacturers we are also developing our own controlled and operated manufacturing facilities for our product candidates, both at our GMP manufacturing suite at the Cell and Gene Therapy Catapult Limited center in Stevenage, United Kingdom (Catapult) and at our 85,000 square foot manufacturing facility in Rockville, Maryland. The BaseCamp partnership enables us to establish additional near-term manufacturing capacity and technical capabilities in the United States, and the Rockville, Maryland facility, once operational, will support clinical and commercial production of our product candidates. However, even once we are producing clinical trial material at Catapult, we will still continue to rely on third party manufacturers to meet our clinical trial demands. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We plan to make changes as we work to optimize the manufacturing process. For example, we may switch or be required to switch from research-grade materials to commercial-grade materials in order to get regulatory approval of our product candidates. We cannot be sure that even minor changes in the process will result in therapies that are safe and effective and licensed for commercial sale.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA, as part of our BLA, or other foreign regulatory authorities following inspections by the FDA or other foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. We have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any 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. In addition, these third parties may have limited manufacturing capacity and we have less control over production methods, staffing and product quality when produced with third party manufacturers. In both cases, this can cause delays in planned manufacturing runs, require remanufacture due to failed runs and limit our ability to manufacture lentiviral vector and our product candidates as needed, resulting in delays for IND filings, clinical trials and non-clinical studies.

***\* We plan to establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on third parties for the manufacture of our product candidates and the use of third-party manufacturing suites, which will be costly, time-consuming, and which may not be successful.***

We are adding to our capacity for our larger clinical trials with third-party manufacturing capacity with ElevateBio and our own company-operated in-house manufacturing capacity in our suite at Catapult's GMP manufacturing center. We are also planning to establish our own commercial manufacturing facility for the manufacture of our product candidates at our 85,000 square foot facility in Rockville, Maryland. Adding capacity with our own company-operating manufacturing facilities should mitigate our reliance on third-party vendors for the manufacture of TRuC-T cells and ensure we can effectively manage our supply chain, quality, manufacturing costs and other associated production areas. We anticipate that our suite at Catapult, the partnership with ElevateBio will significantly increase our total manufacturing capacity. Ability to use our product candidates manufactured in our suite at Catapult for our clinical trials will depend on, among other factors, receiving appropriate approvals and clearance from the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), and the successful recruitment and training of appropriate personnel to support full operation of the manufacturing suite. While we are relying on consultants and other resources with MHRA licensing experience, as a company, we have no prior experience in gaining MHRA approval for a manufacturing facility, and our approval is dependent in part on the timely support, actions and compliance of Catapult, as well, which we are not able to control. Any delay in the MHRA approval or our ability to attract and train personnel may delay the manufacture of clinical trial material in our suite at Catapult, causing us to continue to rely on third-party manufacturing. In addition, the Cell and Gene Therapy Catapult facility contains suites for multiple companies. All companies in the facility must follow proper GMP guidelines in order to maintain the facility's compliance. Failure of another company to properly follow GMP guidelines could affect the

facility's GMP compliance and our ability to manufacture our product candidates for our clinical trials at the Cell and Gene Therapy Catapult facility.

The establishment of our own commercial manufacturing facility in Rockville, Maryland will be a costly and time-consuming process that will require significant additional capital to fund and we do not expect it to be operational in the near term. We have no experience as a company in setting up, building or managing a manufacturing facility or manufacturing suite, and may never be successful in developing our own manufacturing suite, manufacturing facility or manufacturing capability. We will need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, and eventual commercialization, if approved, of our product candidates. If we fail to recruit the required personnel and generally manage our growth effectively or fail to select the correct location, the development and production of our product candidates could be curtailed or delayed. Even if we are successful in establishing a manufacturing suite or manufacturing facility, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the FDA, the European Medicines Agency (EMA) and other foreign regulatory authorities may require us to submit samples of any lot of any licensed product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products. If we establish our own commercial manufacturing facility in the United States, our operations will be subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. We must first receive approval from the FDA prior to licensure to manufacture our product candidates, which we may never obtain. Even if licensed, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

***We may have difficulty validating our manufacturing process as we manufacture TRuC-T cells from an increasingly diverse patient population for our clinical trials.***

During our development of the manufacturing process, our TRuC-T cells have demonstrated consistency from lot to lot and from donor to donor. However, our sample size is small and the starting material is from healthy donors. Once we have experience with working with white blood cells taken from our patient population, we may encounter unforeseen difficulties due to starting with material from donors who are not healthy, including challenges inherent in harvesting white blood cells from unhealthy patients.

Although we believe our current manufacturing process is scalable for commercialization, we may encounter challenges in validating our process due to the heterogeneity of the product starting material. However, we anticipate that during the early phases of our clinical trials we will be able to adapt our process to account for these differences resulting in a more robust process. We cannot guarantee that

any other issues relating to the heterogeneity of the starting material will not impact our ability to commercially manufacturing our product candidates.

***The viral vectors used to manufacture our TRuC-T cells may incorrectly modify the genetic material of a patient's T cells, potentially triggering the development of a new cancer or other adverse events.***

Our TRuC-T cells are manufactured by using a viral vector to insert genetic information encoding the TRuC construct into the patient's T cells. The TRuC construct is then integrated into the natural TCR complex and transported to the surface of the patient's T cells. Because the viral vector modifies the genetic information of the T cell, there is a theoretical risk that modification will occur in the wrong place in the T cell's genetic code, leading to vector-related insertional oncogenesis, and causing the T cell to become cancerous. If the cancerous T cell is then administered to the patient with the TRuC-T cells, the cancerous T cell could trigger the development of a new cancer in the patient. We use lentiviral vectors to insert genetic information into T cells, which we believe have a lower risk of insertional oncogenesis as opposed to other types of viral vectors. However, the risk of insertional oncogenesis remains a concern for gene therapy and we cannot assure that it will not occur in any of our ongoing or planned preclinical studies or clinical trials. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of vectors used to carry the genetic material. The FDA has stated that lentiviral vectors possess characteristics that may pose high risks of delayed adverse events. If any such adverse events occur, further advancement of our preclinical studies or clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations.

#### Risks Related to Commercialization

***The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.***

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. 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, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include hematopoietic stem cell transplantation in certain cancers, chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second or third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that we believe prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if licensed as a second or third or subsequent line of therapy, would be licensed for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. Consequently, the potentially addressable patient population for our product candidates may be extremely limited or may not be amenable to treatment with our product candidates.

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 a particular line of 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 scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients

that may be eligible for treatment with our product candidates may turn out to be much lower than expected.

***\*We face significant competition, and our operating results will suffer if we fail to compete effectively.***

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products or drugs that are able to achieve similar or better results. Our potential competitors include larger biotechnology and pharmaceutical companies with greater resources than us, academic institutions, governmental agencies, public and private research institutions and early stage or smaller companies. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are safety, potency, purity, tolerability, reliability, convenience of use, price and reimbursement.

The market opportunity in oncology has led to a number of collaborations GlaxoSmithKline plc (GlaxoSmithKline)/Adaptimmune Therapeutics PLC (Adaptimmune), Janssen Biotech, Inc. (Janssen)/ Nanjing Legend Pharmaceutical & Chemical Co., Ltd (Legend), bluebird bio, Inc. (bluebird)/ Regeneron Pharmaceuticals Inc. (Regeneron) and bluebird/Gritstone Oncology, Inc.) and major acquisitions (Gilead Sciences, Inc. (Gilead)/Kite Pharma Inc. (Kite), Bristol Myers Squibb Co (BMS)/Celgene Corporation (Celgene)/Juno Therapeutics, Inc. (Juno)) among companies focused on cellular cancer therapies. Specifically, we face significant competition from companies developing chimeric antigen receptor (CAR-T), TCR, and T cell directed bispecific antibody technologies. For our product candidates targeting mesothelin-expressing solid tumors, antibody-based approaches are being pursued by F. Hoffmann-La Roche Ltd, Bayer AG, Bristol-Myers Squibb Company, Selecta Biosciences, Inc., Novimmune SA, Harpoon Therapeutics, Inc., Amgen Inc., Abbvie Inc., and Morphotek, Inc., among others, and cell therapies are being pursued Tmunity Therapeutics, Inc., Atara Biotherapeutics, Inc., Memorial Sloan Kettering Cancer Center, the National Institutes of Health Clinical Center, Maxcyte, Inc., Legend Biotech Corp, Gracell Biotechnology Inc., CARISMA Therapeutics Inc., Refuge Biotechnologies, Inc., Adaptimmune Therapeutics PLC, Kiromic Biopharma, Inc. and several Chinese academic institutions. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Business—Competition."

***Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.***

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the

medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other engineered TCR-T cell and CAR-T cell therapies;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other adoptive cell therapies, engineered TCR-T cell and CAR-T cell products and public perception of other adoptive cell therapies, engineered TCR-T cell and CAR-T cell products;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such clinical trials to demonstrate that these therapies are safe and effective may limit market acceptance of our product candidates. If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other engineered TCR-T cell and CAR-T cell approaches, serious adverse events or deaths in other clinical trials involving engineered TCR, CAR-T or other T cell products or with our use of licensed engineered TCR-T cell or CAR-T cell products, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

## **Risks Related to Our Reliance On Third Parties**

### Third Party Risks Related to Our Product Development

***We plan to rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct our preclinical studies and clinical trials under

agreements with us. We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices (GCPs), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for 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 these third parties fail to comply with applicable GCP regulations, 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. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations, including cGTP regulations, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

***\* If or until we develop our own manufacturing facility, we expect to rely on the use of manufacturing suites in third-party GMP facilities or third parties to manufacture our product candidates. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.***

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture and process our product candidates, which is and will need to be done on a patient-by-patient basis. We are in the process of adding manufacturing capacity at a suite in Catapult's GMP manufacturing center, but staffing, training, and regulatory approval of the manufacturing suite may be delayed and the suite may never become operational. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.



Although we plan to establish our own manufacturing facility in Rockville, Maryland, and we will control our own manufacturing in our suite at Catapult, we will also continue to rely on third parties like Miltenyi and ElevateBio BaseCamp in part for our manufacturing capacity and may, in any event, never be successful in developing our own manufacturing facilities. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for current cGMP and cGTP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates, which can take several months or more, and we will need to demonstrate to regulatory authorities that clinical trial product manufactured at a new supplier is comparable to clinical trial product being produced by current manufacturers;
- our manufacturers may have little or no experience with autologous cell products, which are products made from a patient's own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, affecting quality of our product and requiring additional runs to remanufacture product that is suitable for use in clinical trials;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, cGTP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, pandemics and natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error and

availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping the product candidate back to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to patient material as it moves to the manufacturing facility, through the manufacturing process and back to the patient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

***Our manufacturing process needs to comply with FDA and MHRA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.***

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines and the MHRA's regulations and guidelines, including cGTPs. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA, MHRA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Our manufacturing operations in the UK are also dependent on meeting MHRA regulations and results from regular facility inspections. Any failure to follow cGMP, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our TRuC-T cells as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our TRuC-T cell programs, including leading to significant delays in the availability of our TRuC-T cells for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our TRuC-T cell product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our TRuC-T cell product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

***If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.



## Risks Related to Third Party Agreements

***We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.***

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- ☐ collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- ☐ collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- ☐ collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- ☐ collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- ☐ a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- ☐ collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- ☐ disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- ☐ collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- ☐ collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

***Our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.***

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. In addition, those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some of our raw materials are currently available from a single supplier, or a small number of suppliers. The type of cell culture media and cryopreservation buffer that we currently use in our manufacturing process for the TRuC-T cells for gavo-cel are each only available from a single supplier. In addition, the cell processing equipment and tubing that we use in our current manufacturing process is only available from a single supplier. We also use certain biologic materials, including certain activating antibodies, that are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and potentially modify some of our protocols if we change suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. Accordingly, if we no longer have access to these suppliers, we may experience delays in our clinical or commercial manufacturing which could harm our business or results of operations.

## **Risks Related to Our Financial Condition and Capital Requirements**

### Risks Related to Operating History

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

We are a clinical-stage immunotherapy company with a limited operating history. We commenced operations in May 2015, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies, establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials and initiating and conducting our first clinical trials. We have two product candidates in Phase 1/2 clinical trials and our other product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.***

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates. We have no products licensed for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through private placements of our preferred stock, our initial public offering and subsequent public offerings.

We have incurred significant net losses in each period since our inception in May 2015. For the year to date period ended September 30, 2021, we incurred a net loss of \$72.1 million. As of September 30, 2021, we had an accumulated deficit of \$321.8 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- conduct clinical trials and preclinical studies and clinical trials for our current and future product candidates based on our TRuC-T cell platform;
- continue our research and development efforts and submit IND applications for our lead product candidates;
- establish and expand our manufacturing capabilities for both clinical and commercial supplies of our product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- build commercial infrastructure to support sales and marketing for our product candidates;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- continue to operate as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for, and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We have not generated any revenue from our product candidates and may never be profitable.***

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any of our product candidates. We do not expect to generate significant revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Other than gavo-cel, all of our product candidates are in the preclinical stages of development and will require additional preclinical studies, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. gavo-cel, our most advanced mono TRuC-T cell product candidate targeting mesothelin-positive solid tumors, is in the early stages of a Phase 1/2 clinical trial and will require

additional regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Many of our TRuC-T cell product candidates are in early preclinical stages. We are in the early stages of our clinical trial for gavo-cel and we have not yet administered any of our other product candidates in humans and, as such, we face significant translational risk as our product candidates advance to the clinical stage. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- ☐ timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- ☐ our ability to complete IND-enabling studies and successfully submit INDs or comparable applications;
- ☐ whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- ☐ our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, potency, purity, of which potency and purity the FDA interprets to mean effectiveness, and acceptable risk to benefit profile of our product candidates or any future product candidates;
- ☐ the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- ☐ the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- ☐ the willingness of physicians, operators of clinics and patients to utilize or adopt any of product candidates or future product candidates to treat solid tumors and hematological malignancies;
- ☐ our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMP);
- ☐ our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- ☐ patient demand for our product candidates and any future product candidates, if licensed; and
- ☐ our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

#### Risks Related to Raising Additional Capital

***\* If we fail to obtain additional financing, we may be unable to continue our research and product development programs.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts (including net proceeds from public offerings of our common stock) to continue the clinical development of our product candidates, including our Phase 1/2 clinical trial of gavo-cel and ongoing and planned IND-enabling studies for our other product candidates. If licensed, we will require significant additional amounts in order to launch and commercialize our product candidates.

In February 2019, we completed our initial public offering (IPO) raising gross proceeds of approximately \$86.3 million, inclusive of the exercise of the underwriters' overallotment option. On July 31, 2020, we completed a stock offering raising gross proceeds of approximately \$142.6 million. On January 22, 2021, we completed a stock offering raising gross proceeds of \$140.0 million. As of September 30, 2021, we had cash, cash equivalents and short-term investments of approximately \$295.7 million. Our existing cash, cash equivalents and short-term investments may not be sufficient to fund all of our efforts that we plan to undertake.

We believe that our existing cash, cash equivalents and investments, including our net proceeds from the IPO and secondary offerings, will be sufficient to fund our operations through 2023. However, we have based this estimate on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

#### **Risks Related to the Current Novel Coronavirus (COVID-19) Pandemic on the Company**

***\*The current outbreak of novel coronavirus, or COVID-19, has caused, and could continue to cause, severe disruptions in the U.S., regional and global economies and could seriously harm our development efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.***

Public health pandemics or outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China and has since spread to several other countries, including the United States and European countries, with infections and deaths reported globally. To date, the COVID-19 pandemic has caused widespread disruptions to the U.S. and global economy and has contributed to significant volatility and negative pressure in financial markets. The global impact of the outbreak is continually evolving, particularly in light of new variants of COVID-19, and, as additional cases of the virus are identified, many countries, including the U.S., have reacted by instituting quarantines, restrictions on travel and mandatory closures of businesses. Certain states and cities, including where we or the third parties with whom we engage operate, have also reacted by

instituting quarantines, restrictions on travel, “shelter in place” rules, restrictions on types of business that may continue to operate and/or restrictions on the types of construction projects that may continue.

The extent to which the COVID-19 pandemic impacts our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the actions taken to contain the pandemic or mitigate its impact, as well as the effect of any relaxation of current restrictions within the Cambridge community or regions in which our partners and clinical sites are located, and the direct and indirect economic effects of the pandemic and containment measures, among others. The rapid development and fluidity of this situation precludes any prediction as to the full adverse impact of the COVID-19 pandemic. Nevertheless, the COVID-19 pandemic may adversely affect our business, financial condition and results of operations, and it has had, and may continue to have, the effect of heightening many of the risks described in this Quarterly Report on Form 10-Q, including but not limited to the below.

- The COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our ongoing clinical trials. We remain in active dialog with our contract research organizations, or CROs, and clinical sites to minimize the impact of this pandemic to our gavo-cel Phase 1/2 clinical trial without adversely impacting the safety of patients. Despite our best efforts, it may prove difficult to continue to treat patients in a timely manner and activation of new sites could be delayed, particularly for our clinical trial sites in areas with high rates of community spread.
- Other potential impacts of the COVID-19 pandemic on our various clinical trials include patient dosing and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials, interruption or delays in the operations of the FDA or other reasons related to the COVID-19 pandemic. If the COVID-19 pandemic continues, other aspects of our clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our studies or we may have to pause enrollment or we may choose to or be required to pause enrollment and or patient dosing in our ongoing clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue.
- We currently rely on third parties, including our CROs, and our contract manufacturing organizations, or CMOs, and other contractors and consultants to, among other things, conduct our preclinical studies and clinical trials, manufacture raw materials, manufacture and supply our product candidates, ship clinical trial samples, perform quality testing and supply other goods and services to run our business. If any such third party is adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, which could limit our ability to manufacture our product candidates for our clinical trials and conduct our research and development operations. For example, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials for the manufacture of our product candidates, which could lead to delays in these trials.
- Our manufacturing suite at Catapult in Stevenage, UK is now operational. However, our ability to manufacture our product candidates at Catapult for our clinical trials will depend on, among other factors, receiving appropriate approvals and clearance from the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA). Limited MHRA resources and a focus on the COVID-19 pandemic may delay the MHRA’s review and approval of our manufacturing suite, and affect our expected manufacturing timelines.
- Governmental authorities may modify or expand current “shelter-in-place” advisories or other similar local restrictions and further limit our laboratory operations. Our employees may have



limited or no access to our laboratory for an extended period of time and, as a result, this could delay timely completion of preclinical activities, including conducting Investigational New Drug, or IND-, enabling studies or our ability to select future development candidates, and initiation of additional clinical trials for our other product candidates.

- Material shortages may affect our research and development and manufacturing activities and timelines. Increased demand for personal protective equipment, plastics used for pipettes and other laboratory consumables, and other laboratory supplies has led to shortages of some of these materials that we need for our research and development activities, and that our third-party manufacturers need to produce our product candidates. In addition, COVID-19 restrictions on manufacturers and their employees has led to a shortage of personnel to manufacture, package and ship laboratories supplies and consumables, further limiting the available supply. If we, our contract research organizations, our vendors and our third-party manufacturers are not able to obtain materials needed for our laboratory operations, our research and development and the manufacture of our product candidates could be delayed.
- Certain government agencies, such as health regulatory agencies and patent offices, within the U.S. or internationally may experience disruptions in their operations as a result of the COVID-19 pandemic. The Food and Drug Administration, or FDA, and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.
- The trading prices for our common stock and those of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

## Risks Related to Our Intellectual Property

### Risks Related to Protecting Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we may in the future also license or purchase patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as

the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the field of cellular therapy has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific 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 endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly 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. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the U.S. Patent and Trademark Office (USPTO) or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.



***If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.***

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Currently, our patents and patent applications are directed to our TRuC-T cells and accompanying technologies. We seek or plan to seek patent protection for our TRuC-T cell platform and product candidates by filing and prosecuting patent applications in the United States and other countries as appropriate. The claims of our patent applications are directed toward various aspects of our product candidates and research programs including compositions of matter, methods of use, and processes. These patent applications, if issued, are expected to expire on various dates from 2036 through 2041, in each case without taking into account any possible patent term adjustments or extensions.

We anticipate additional patent applications will be filed both in the United States and in other countries, as appropriate. However, we cannot predict:

- ☐ if and when patents will be issued;
- ☐ the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- ☐ whether any of our intellectual property will provide any competitive advantage;
- ☐ whether any of our patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- ☐ whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- ☐ whether we will need to initiate or defend litigation or administrative proceedings which may be costly regardless of whether we win or lose.

Additionally, we cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the USPTO, or by patent offices in

foreign countries, or that the claims in any of our issued patents will be considered patentable by courts in the United States or foreign countries.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

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

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

- ☐ others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our patents;
- ☐ the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- ☐ we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- ☐ we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- ☐ others may independently develop similar or alternative technologies or duplicate any of our technologies;
- ☐ it is possible that our pending patent applications will not result in issued patents;
- ☐ it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;

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

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. For example, significant elements of our products, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets that are not publicly disclosed. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our products, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

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

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

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

#### Risks Related to Third Party Intellectual Property

***We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.***

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. For example, we have a non-exclusive license for the mesothelin binder incorporated into the TRuC construct for gavo-cel from Harpoon. Harpoon has the ability to terminate our license in the event we materially breach our agreement with Harpoon and fail to cure this breach within sixty days. If the license with Harpoon is terminated, we would need to partner for another mesothelin binder or independently develop our own mesothelin binder. In addition, we cannot prevent Harpoon from also licensing the mesothelin binder we use in gavo-cel to a third-party. If Harpoon licenses the mesothelin binder to another immuno-oncology company, that company could develop a competitive product to gavo-cel.

We are currently, and expect in the future to be, party to material license or collaboration agreements. These agreements typically impose numerous obligations, such as diligence and payment obligations. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. These licenses do and future licenses may include provisions that impose obligations and restrictions on us. This could delay or otherwise negatively impact a transaction that we may wish to enter into.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- 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 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 acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

***If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.***

We are a party to a license agreement with Harpoon, pursuant to which we in-license key patent and patent applications for use in one or more of our product candidates. This existing license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, Harpoon may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

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

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that

our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If gavo-cel or another product candidate is licensed by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates, if licensed, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is “clear and convincing,” a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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



***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.***

Presently we have rights to certain intellectual property, through licenses from third parties and under patent applications that we own or will own, related to gavo-cel and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain TRuC constructs we may not be able to obtain intellectual property to broad TRuC-T cell or engineered TCR-T cell constructs.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antibodies that will be used with our product candidates may be covered by the intellectual property rights of others.

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

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

#### Risks Related to Intellectual Property Litigation

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

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

infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

#### Risks Related to Intellectual Property Laws

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

Some of our patent applications have been allowed or may be allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that cause withdrawal of the allowance of a patent application. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will re-allow the application in view of the new material. Further, periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.***

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are



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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

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

Certain of our key patent families have been filed in the United States, however, we have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of the TRuC-T cell platform outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

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 biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

The intellectual property landscape around adoptive cell therapy is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. We are aware of certain third-party patents and third-party patent applications in this landscape that may, if issued as patents, be asserted to encompass our technology.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.***

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are

successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

***If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or 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.

## **Risks Related to Government Regulation**

### Risks Related to Regulatory Approval

***The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.***

We have not previously submitted a Biologics License Application (BLA) to the FDA or similar licensure applications to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and licensure may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- ☐ the availability of financial resources to commence and complete the planned trials;
- ☐ reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- ☐ obtaining approval at each clinical trial site by an IRB or ethics committee;
- ☐ recruiting suitable patients to participate in a clinical trial;
- ☐ having patients complete a clinical trial or return for post-treatment follow-up;
- ☐ clinical trial sites deviating from trial protocol or dropping out of a trial;
- ☐ adding new clinical trial sites; or
- ☐ manufacturing sufficient quantities of qualified materials under cGMPs, including current Good Tissue Practices (cGTPs), and applying them on a subject by subject basis for use in clinical trials.

We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or other regulatory authorities 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 other 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 product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Securing regulatory approval also requires the submission of information about the biologic manufacturing process and inspection of manufacturing facilities by the relevant regulatory authority. The FDA or comparable foreign regulatory authorities may find deficiencies or fail to approve our manufacturing processes or facilities, whether run by us or our commercial manufacturing organizations (CMOs). In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy, or REMS, program in order to license our product candidates, which could entail 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 product candidates 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 cGMPs, cGTPs and good clinical practices (GCPs) for any clinical trials that we conduct post-licensure. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- ☐ restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- ☐ revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- ☐ imposition of a REMS, which may include distribution or use restrictions;
- ☐ requirements to conduct additional post-market clinical trials to assess the safety of the product;
- ☐ fines, warning letters or holds on clinical trials;
- ☐ refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA'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 cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.***

The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite licensure from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory authorities can delay, limit or deny licensure of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates are safe, potent and pure;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for licensure;
- the FDA's or the applicable foreign regulatory agency's findings of deficiencies or failure to approve the manufacturing processes or facilities of third-party manufacturers upon which we rely;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain licensure of our product candidates in the United States or elsewhere; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Of the large number of biological products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Even if we eventually complete clinical testing and receive licensure from the FDA or applicable foreign regulatory authorities for any of our product candidates, the FDA or the applicable foreign regulatory agency may grant licensure contingent on the performance of costly additional clinical trials which may be required after licensure. The FDA or the applicable foreign regulatory agency also may license our product candidates for a more limited indication or a narrower patient population than we

originally requested, and the FDA, or applicable foreign regulatory agency, may not license our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates.

In addition, even if the trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

***A variety of risks associated with marketing our product candidates, if approved, internationally could materially adversely affect our business.***

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other 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 taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

***We may seek orphan drug status for gavo-cel and some of our other future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than



200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic 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 if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We received orphan drug designation for the treatment of mesothelioma and cholangiocarcinoma with gavo-cel. We may seek orphan drug designation for some or all of our other future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even when we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek licensure for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations.

The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

***A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.***

We plan to seek a Breakthrough Therapy designation for gavo-cel and may seek Breakthrough Therapy designation for some or all of our future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including Accelerated Approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or

licensure compared to candidate products considered for licensure under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for gavo-cel and some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

***A Fast Track designation by the FDA, even if granted for gavo-cel or any other future product candidate(s), may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.***

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to FDA for FDA Fast Track designation for a particular indication. We plan to seek Fast Track designation for gavo-cel and may seek Fast Track designation for certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

***Accelerated approval by the FDA, even if granted for gavo-cel or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.***

We plan to seek approval of gavo-cel, and may seek approval of future product candidates using FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

***Regulatory requirements in the United States and abroad governing cell therapy products have changed frequently and may continue to change in the future, which could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all.***

Regulatory requirements in the United States and abroad governing cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. Recently, the National Institutes of Health proposed to revise its guidelines for overseeing gene therapy research, including deleting the protocol



registration and reporting requirements for certain therapies and eliminating Recombinant DNA Advisory Committee review and reporting requirements for human gene transfer research.

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

In both domestic and foreign markets, successful sales of our product candidates, if licensed, will depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

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

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. 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 product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain licensure in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union (EU), the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, in 2010, Patient Protection

and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the former Trump Administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. In January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012 (ATRA), which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. The former Trump administration's budget proposal for fiscal year 2021 included a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. In addition, the former Trump administration previously issued a plan to lower drug prices and reduce out of pocket costs of drugs. Under this blueprint for action, the Trump administration indicated that the U.S. Department of Health and Human Services ("HHS")

would take steps to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already implemented certain of these measures, while others are pending. For example, in May 2019, the Centers for Medicare and Medicaid Services (“CMS”) issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. The U.S. Department of Health and Human Services, or HHS, already started the process of soliciting feedback on some of these measures and is immediately implementing others under its existing authority. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

It is unclear how these and future developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

In 2020, former President Trump released several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these recent executive and administrative actions, yet Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from

other countries and bulk purchasing. In addition, regional health care 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 health care programs. These measures could reduce the ultimate demand for our products, once licensed, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

***The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.***

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

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

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

***\* Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions,

which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020 when foreign and domestic inspections were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, FDA has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

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

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

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

***Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many

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

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

#### Risks Related to Government Regulations Internationally

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a



product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***The withdrawal of the United Kingdom from the European Union, commonly referred to as "Brexit," may disrupt import and export processes between the United Kingdom and the European Union, potentially delaying time-sensitive shipments and adversely affecting our GMP manufacturing operations at Catapult, and may affect the future regulatory regime regarding GMP manufacturing of our product candidates.***

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as "Brexit." Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which European Union pharmaceutical law remained applicable to the United Kingdom, which ended on December 31, 2020. During this 11-month period, the UK continued to follow all of the EU's rules and its trading relationship remained the same. The United Kingdom and the European Union have signed a EU-UK Trade and Cooperation Agreement (the TCA), which became provisionally applicable on January 1, 2021 and will become formally applicable once ratified by both the United Kingdom and the European Union. This agreement provides details on how some aspects of the United Kingdom and European Union's relationship will operate going forwards however there are still many uncertainties. This lack of clarity on future United Kingdom laws and regulations and their interaction with European Union laws and regulations could add legal risk, uncertainty, complexity and cost to our operations.

We have contracted with the Cell Therapy Catapult Limited (Catapult) to occupy a suite with our own personnel in their GMP manufacturing center in Stevenage, United Kingdom. There is a risk that Brexit may disrupt import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and European Union customs agencies that may delay time-sensitive shipments of equipment and materials from the European Union that are required for GMP manufacturing in our Catapult suite. It is also possible that Brexit may negatively affect our ability to attract and retain employees for our operations at Catapult, particularly those from the European Union.

In addition, because the regulatory framework in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products, and the approval of product candidates, in the United Kingdom, now that the United Kingdom legislation has the potential to diverge from European Union legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom in the long term. The Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines and medical devices regulator, has recently published detailed

guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK's regulatory position on medicinal products evolves over time.

Given the lack of comparable precedent, it is unclear what longer term financial, trade and legal implications the withdrawal of the United Kingdom from the European Union will have and how such withdrawal would affect us. The long-term impact of Brexit, including on our business and our industry, will depend on how the terms of the TCA take effect in practice and any further terms that are negotiated in relation to the United Kingdom's future relationship with the European Union. We are continuing to closely monitor the Brexit developments in order to determine, quantify and proactively address changes as they become clear.

## **Risks Related to Employee Matters and Managing Growth**

### Risks Related to Employee Matters

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer and President, our Chief Financial Officer, our Chief Scientific Officer, our Chief Medical Officer, our Chief Technical Officer and our Chief People Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facility in Cambridge, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have



established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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 federal civil False Claims Act or federal civil money penalties statute. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. We continue to evaluate what effect, if any, the rule will have on our business;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (for example, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals 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 HHS information related to payments or other transfers of value made to physicians (currently defined to include doctors, dentists, optometrists,

podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, diminished profits and future earnings, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, 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, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010, or the Bribery Act. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation (GDPR), which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking

certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. 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. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. This and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our products, if approved, in some markets and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity, which could have an adverse effect on our reputation and business.

#### Risks Related to Growing Our Organization

##### ***We will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of November 2, 2021, we had 164 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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

Further, we anticipate growth in our business operations, which would necessitate the addition of new laboratory and/or office space. This future growth could create strain on our organizational, administrative, and operational infrastructure, including laboratory operations and quality control. There is no guarantee that we will be able to manage the expansion of our facilities and operations, or that our systems, procedures or controls will be adequate to support our expanded facilities and operations. There is also no guarantee that we will be able to build out, acquire, or enter into agreements to lease facilities to support our growth.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if licensed, we may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, if licensed. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

## **Risks Related to our Common Stock**

### Risks Related to Volatility in the Trading of Our Common Stock

***Our stock price has been and will likely continue to be volatile. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.***

The trading price of our common stock is likely to be highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including:

- the timing and results of clinical trials of gavo-cel and any other product candidates and our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;

- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed your purchase price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

***An active, liquid and orderly trading market for our common stock may not be sustained.***

In February 2019, we closed our IPO and our common stock began trading on The Nasdaq Global Select Market. Prior to our IPO, there was no public trading market for shares of our common stock. Although we completed our IPO and our common stock is listed and trading on The Nasdaq Global Select Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***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.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market the trading price of our common stock could decline. As of September 30, 2021, we have a total of 38,220,444 shares of common stock outstanding. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2018 Plan and our 2018 Employee Stock Purchase Plan adopted in connection with the IPO will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act of 1933, as amended (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.

The holders of 7,600,116 shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. 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.

Risks Related to Our Status as an “Emerging Growth Company” and a Smaller Reporting Company.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act) enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our Annual Report, our other periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our Annual Report, our other periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some



investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

We are considered a “smaller reporting company” under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may 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 common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds \$250 million if or our annual revenues are \$100 million or more, or until our public float exceeds \$700 million if our annual revenues are less than \$100 million.

#### Risks Related to Insider Control

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

As of November 2, 2021, our executive officers, directors, and 5% stockholders beneficially owned approximately 50% of our voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

#### Risks Related to Operating as a Public Company

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

As a public company, we have incurred and will continue to 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 Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the Securities and Exchange Commission (SEC), annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We are taking advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and to made 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 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.

#### Risks Related to Our Charter and Bylaws

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

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

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

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



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

Our amended bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. In addition, our amended and restated bylaws will further provide that unless we consent in writing to the selection of an alternate forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with U.S. federal securities laws and the rules and regulations thereunder.

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

#### Risks Related to Tax and Accounting

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our most recent private placements and other transactions that have occurred over the past three years, we may have experienced, and, may experience, an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2020, we have cumulative net operating loss carryforwards of approximately \$126.4 million and \$129.0 million available to reduce federal and state taxable income, respectively, of which \$122.3 million of federal net operating losses will carryforward indefinitely, with the remaining federal and state losses beginning to expire in 2035. In addition, we have cumulative federal and state tax credit carryforwards of \$5.6 million and \$2.4 million, respectively, available to reduce federal and state income taxes which will begin to expire in 2035 and 2031, respectively. Our net operating loss carryforwards and

tax credit carryforwards may be limited as a result of certain ownership changes, as defined under Sections 382 and 383 of the Code. This limits the annual amount of these tax attributes that can be utilized to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to an ownership change. Subsequent ownership changes may affect the limitation in future years. Under the Tax Cuts and Jobs Act, federal net operating losses generated after December 31, 2017 will not be subject to expiration.

***If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

### **General Risk Factors**

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

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

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

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, 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 further 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, or do not improve, 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 these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

In February 2019, we raised aggregate net cash proceeds of approximately \$77.1 million in our IPO. On July 31, 2020, we completed the sale of 9.2 million shares of stock in at a public offering price of \$15.50 per share. We raised net cash proceeds of approximately \$133.6 million from the offering. On January 22, 2021, we completed the sale of approximately 4.6 million shares of common stock in at a public offering price of \$30.50 per share. We raised net cash proceeds of approximately \$131.3 million from the offering. As of September 30, 2021, we had cash, cash equivalents and short-term investments of \$295.7 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and short-term investments since September 30, 2021, no assurance can be given that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

***Changes in tax law could adversely affect our business and financial condition.***

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act (the TCJA), was enacted in 2017 and significantly reformed the Internal Revenue Code of 1986, as amended. The TCJA, among other things, included significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, a limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses to 80% of current year taxable income and the elimination of net operating loss carrybacks (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”). Additionally, on March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted earnings for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

***Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.***

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. Cyber-attacks, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, viruses, and social engineering (including phishing) are prevalent in our industry, as well as many others. In addition, we may experience attacks, unavailable systems, unauthorized access to systems or data or

disclosure due to employee theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state supported actors, and advanced persistent threat intrusions. Electronic security attacks designed to gain access to personal, sensitive or confidential data are constantly evolving, and such attacks continue to grow in sophistication. The techniques used to sabotage or to obtain unauthorized access to our platform, systems, networks, or physical facilities in which data is stored or through which data is transmitted change frequently, and we may be unable to implement adequate preventative measures or stop security breaches while they are occurring. Despite our efforts, we may in future become, the target of cyber-attacks by third parties seeking unauthorized access to our data or to disrupt our operations or ability to conduct our business. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical pandemics or epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

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

- ☐ decreased demand for our product candidates or products that we may develop;
- ☐ injury to our reputation;
- ☐ withdrawal of clinical trial participants;
- ☐ initiation of investigations by regulators;
- ☐ costs to defend the related litigation;
- ☐ a diversion of management's time and our resources;
- ☐ substantial monetary awards to trial participants or patients;
- ☐ product recalls, withdrawals or labeling, marketing or promotional restrictions;

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

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

*Recent sales of unregistered securities*

Not Applicable.

*Use of Proceeds from Initial Public Offering*

Not applicable.

*Issuer Purchases of Equity Securities*

Not applicable.

## **Item 3. Defaults Upon Senior Securities**

Not applicable.

## **Item 4. Mine Safety Disclosure**

Not applicable.

## **Item 5. Other Information**

Not applicable.

## ITEM 6. EXHIBITS

Number	EXHIBIT DESCRIPTION	FORM	FILE NO.	EXHIBIT	FILING DATE	FILED HEREWITH
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant</a>	8-K	001-38811	3.1	2/25/2019	
3.2	<a href="#">Amended and Restated By-laws of the Registrant</a>	8-K	001-38811	3.2	2/25/2019	
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) / Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended</a>					X
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) / Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended</a>					X
32.1+	<a href="#">Certifications of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover page formatted as Inline XBRL and contained in Exhibit 101					
+	The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.					

## SIGNATURES

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

Date: November 10, 2021

**TCR<sup>2</sup> Therapeutics Inc.**

By: /s/ Mayur (Ian) Somaiya  
Mayur (Ian) Somaiya  
Chief Financial Officer  
(Principal Financial Officer and Duly Authorized Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO  
RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Garry E. Menzel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TCR<sup>2</sup> Therapeutics Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.
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Date: November 10, 2021

/s/ Garry E. Menzel

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Garry E. Menzel

President, Chief Executive Officer and Director  
(Principal Executive Officer)

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO  
RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Mayur (Ian) Somaiya, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TCR<sup>2</sup> Therapeutics Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
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(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

/s/ Mayur (Ian) Somaiya

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Mayur (Ian) Somaiya

Chief Financial Officer

(Principal Financial Officer and Duly Authorized Officer)

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**CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL  
FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Quarterly Report on Form 10-Q of TCR<sup>2</sup> Therapeutics Inc. (the "Company") for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his or her 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.

Dated: November 10, 2021

/s/ Garry E. Menzel

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Garry E. Menzel

President, Chief Executive Officer and Director  
(Principal Executive Officer)

/s/ Mayur (Ian) Somaiya

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Mayur (Ian) Somaiya

Chief Financial Officer  
(Principal Financial Officer and Accounting Officer)

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