

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

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 001-39138

JASPER THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

2200 Bridge Pkwy Suite #102
Redwood City, CA

(Address of Principal Executive Offices)

84-2984849

(I.R.S. Employer
Identification Number)

94065

(Zip Code)

(650) 549-1400

(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Voting Common Stock, par value \$0.0001 per share	JSPR	The Nasdaq Stock Market LLC
Redeemable Warrants, each whole warrant exercisable for one share of Voting Common Stock at an exercise price of \$11.50	JSPRW	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	Number of Shares Outstanding as of August 1, 2022
Voting Common Stock, \$0.0001 par value	36,687,133
Non-Voting Common Stock, \$0.0001 par value	1,296,022

JASPER THERAPEUTICS, INC.
FORM 10-Q FOR THE QUARTERLY PERIOD ENDED
JUNE 30, 2022

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JASPER THERAPEUTICS, INC.

As used in this Quarterly Report on Form 10-Q, unless the context requires otherwise, references to the “Company”, “Jasper”, “we”, “us”, “our”, and similar terms refer to Jasper Therapeutics, Inc., a Delaware corporation formerly known as Amplitude Healthcare Acquisition Corporation (“AMHC”), and its consolidated subsidiary. References to “Old Jasper” refer to the private Delaware corporation that is now our wholly-owned subsidiary and named Jasper Tx Corp. (formerly known as Jasper Therapeutics, Inc.).

Unless otherwise noted or the context requires otherwise, references to our “common stock” refer to our voting common stock, par value \$0.0001 per share.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Quarterly Report on Form 10-Q may constitute “forward-looking statements” for purposes of federal securities laws. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “*anticipate*,” “*believe*,” “*contemplate*,” “*continue*,” “*could*,” “*estimate*,” “*expect*,” “*intends*,” “*may*,” “*might*,” “*plan*,” “*possible*,” “*potential*,” “*predict*,” “*project*,” “*should*,” “*will*,” “*would*” and similar expressions (including the negative of any of the foregoing) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements in this Quarterly Report on Form 10-Q may include, for example, but are not limited to, statements about:

- our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future;
- our ability to research, discover and develop additional product candidates;
- the success, cost and timing of our product development activities and clinical trials;
- the potential attributes and benefits of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to obtain funding for our operations;
- our projected financial information, anticipated growth rate and market opportunity;
- our ability to maintain the listing of our public securities on the Nasdaq Capital Market;
- our public securities’ potential liquidity and trading;
- our success in retaining or recruiting, or changes required in, officers, key employees or directors;
- our ability to grow and manage growth profitably;
- the implementation, market acceptance and success of our business model, developments and projections relating to our competitors and industry;
- our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our ability to identify, in-license or acquire additional technology;
- our ability to maintain our existing license agreements and manufacturing arrangements; and
- the effect of the continuing COVID-19 pandemic on the foregoing.

These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading “*Risk Factors*” in Part II, Item 1A of this Quarterly Report on Form 10-Q. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the continuing COVID-19 pandemic, and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. Readers are cautioned not to place undue reliance on forward-looking statements because of the risks and uncertainties related to them and to the risk factors. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

JASPER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 60,814	\$ 84,701
Prepaid expenses and other current assets	2,472	3,130
Total current assets	63,286	87,831
Property and equipment, net	4,016	3,686
Operating lease right-of-use assets	2,070	1,147
Restricted cash	417	345
Other non-current assets	577	645
Total assets	\$ 70,366	\$ 93,654
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,997	\$ 3,919
Current portion of operating lease liabilities	784	505
Accrued expenses and other current liabilities	2,841	3,596
Total current liabilities	6,622	8,020
Non-current portion of operating lease liabilities	3,234	2,380
Common stock warrant liability	455	7,350
Earnout liability	525	5,743
Other non-current liabilities	749	643
Total liabilities	11,585	24,136
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock: \$0.0001 par value — 10,000,000 shares authorized at June 30, 2022 and December 31, 2021; none issued and outstanding at June 30, 2022 and December 31, 2021	-	-
Common stock: \$0.0001 par value — 492,000,000 shares authorized at June 30, 2022 and December 31, 2021; 37,981,317 and 37,855,114 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	138,838	136,964
Accumulated deficit	(80,061)	(67,450)
Total stockholders' equity	58,781	69,518
Total liabilities and stockholders' equity	\$ 70,366	\$ 93,654

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

JASPER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 8,135	\$ 5,156	\$ 16,323	\$ 9,576
General and administrative	3,828	3,262	8,418	5,096
Total operating expenses	<u>11,963</u>	<u>8,418</u>	<u>24,741</u>	<u>14,672</u>
Loss from operations	(11,963)	(8,418)	(24,741)	(14,672)
Change in fair value of earnout liability	625	-	5,218	-
Change in fair value of common stock warrant liability	845	-	6,895	-
Change in fair value of derivative liability	-	-	-	(3,501)
Other income, net	89	4	17	5
Total other income (expense), net	<u>1,559</u>	<u>4</u>	<u>12,130</u>	<u>(3,496)</u>
Net loss and comprehensive loss	<u>\$ (10,404)</u>	<u>\$ (8,414)</u>	<u>\$ (12,611)</u>	<u>\$ (18,168)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.29)</u>	<u>\$ (4.00)</u>	<u>\$ (0.35)</u>	<u>\$ (8.89)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>36,397,822</u>	<u>2,104,899</u>	<u>36,353,509</u>	<u>2,043,247</u>

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

JASPER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'
EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance as of January 1, 2022	-	\$ -	37,855,114	\$ 4	\$ 136,964	\$ (67,450)	\$ 69,518
Issuance of common stock upon exercise of stock options	-	-	19,073	-	13	-	13
Issuance of common stock upon exercise of common stock warrants	-	-	20	-	-	-	-
Vesting of founders' restricted stock	-	-	-	-	3	-	3
Stock-based compensation expense	-	-	-	-	778	-	778
Net loss	-	-	-	-	-	(2,207)	(2,207)
Balance as of March 31, 2022	-	\$ -	37,874,207	\$ 4	\$ 137,758	\$ (69,657)	\$ 68,105
Issuance of common stock upon exercise of stock options	-	-	17,138	-	13	-	13
RSU settlements	-	-	89,972	-	-	-	-
Vesting of founders' restricted stock	-	-	-	-	2	-	2
Stock-based compensation expense	-	-	-	-	1,065	-	1,065
Net loss	-	-	-	-	-	(10,404)	(10,404)
Balance as of June 30, 2022	-	\$ -	37,981,317	\$ 4	\$ 138,838	\$ (80,061)	\$ 58,781

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares ⁽¹⁾	Amount	Shares ⁽¹⁾	Amount			
Balance as of January 1, 2021	15,480,195	\$ 43,840	2,770,702	\$ 1	\$ 1,682	\$ (36,813)	\$ (35,130)
Issuance of common stock upon exercise of stock options	-	-	2,872	-	2	-	2
Issuance of Series A-1 redeemable convertible preferred stock for cash	4,042,565	10,750	-	-	-	-	-
Settlement of the redeemable convertible preferred stock tranche liability	-	11,659	-	-	-	-	-
Vesting of founders restricted stock	-	-	-	-	3	-	3
Stock-based compensation expense	-	-	-	-	327	-	327
Net loss	-	-	-	-	-	(9,754)	(9,754)
Balance as of March 31, 2021	19,522,760	\$ 66,249	2,773,574	\$ 1	\$ 2,014	\$ (46,567)	\$ (44,552)
Issuance of common stock upon exercise of stock options	-	-	95,654	-	68	-	68
Vesting of founders restricted stock	-	-	-	-	2	-	2
Stock-based compensation expense	-	-	-	-	295	-	295
Net loss	-	-	-	-	-	(8,414)	(8,414)
Balance as of June 30, 2021	19,522,760	\$ 66,249	2,869,228	\$ 1	\$ 2,379	\$ (54,981)	\$ (52,601)

(1) The shares of the Company's common and redeemable convertible preferred stock, prior to the Reverse Recapitalization (as defined in Note 1) have been retroactively restated to reflect the exchange ratio of 0.282378, except for 100 shares of Series A-2 redeemable convertible preferred stock as described in Note 3.

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

JASPER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six months ended June 30,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (12,611)	\$ (18,168)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	434	51
Non-cash lease expense	151	184
Stock-based compensation expense	1,843	622
Change in fair value of derivative liability	-	3,501
Change in fair value of common stock warrant liability	(6,895)	-
Change in fair value of earnout liability	(5,218)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	658	(671)
Other receivables	-	600
Other non-current assets	68	(669)
Accounts payable	(977)	1,630
Accrued expenses and other current liabilities	(911)	1,134
Operating lease liability	(222)	-
Other non-current liabilities	111	(200)
Net cash used in operating activities	<u>(23,569)</u>	<u>(11,986)</u>
Cash flows used in investing activities		
Purchases of property and equipment	(272)	(1,247)
Net cash used in investing activities	<u>(272)</u>	<u>(1,247)</u>
Cash flows from financing activities		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	-	10,750
Proceeds from exercise of common stock options	26	70
Payments of offering costs	-	(668)
Net cash provided by financing activities	<u>26</u>	<u>10,152</u>
Net decrease in cash, cash equivalents and restricted cash	<u>(23,815)</u>	<u>(3,081)</u>
Cash, cash equivalents and restricted cash		
Cash, cash equivalents and restricted cash at beginning of the period	85,046	20,183
Cash, cash equivalents and restricted cash at end of the period	<u>\$ 61,231</u>	<u>\$ 17,102</u>
Supplemental and non-cash items reconciliations:		
Accounts payable and accrued expenses for purchases of property and equipment	\$ 211	\$ -
Right-of-use asset obtained in exchange for lease liabilities	\$ 1,074	\$ -
Non-cash leasehold improvements	\$ 281	\$ 1,378
Vesting of founders' restricted stock	\$ 5	\$ 5
Deferred offering costs	\$ -	\$ 3,057
Settlement of derivative tranche liability	\$ -	\$ (11,659)

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

JASPER THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Description of Business

Jasper Therapeutics, Inc. (“Jasper” or the “Company”), formerly known as Amplitude Healthcare Acquisition Corporation (“AMHC”), is a clinical-stage biotechnology company dedicated to enabling cures through hematopoietic stem cell therapy. The Company is focused on the development and commercialization of safer and more effective conditioning agents and mRNA-based stem cell engineering to allow for expanded use of stem cell transplantation and ex vivo gene therapy, a technique in which genetic manipulation of cells is performed outside of the body prior to transplantation. The Company is also developing novel therapeutics directed at diseased hematopoietic stem cells. Its drug development pipeline includes multiple product candidates designed to improve hematopoietic stem cell therapy. The lead product candidate, JSP191, is in clinical development as a novel conditioning antibody that clears hematopoietic stem cells from bone marrow in patients prior to undergoing allogeneic stem cell therapy or stem cell gene therapy. The Company plans to initiate a registrational clinical study in acute myeloid leukemia patients undergoing stem cell transplantation by the end of the first quarter of 2023. The Company is also initiating a pilot study of JSP191 as a therapeutic in lower-risk myelodysplastic syndrome, which it expects to commence in the second half of this year. The Company is headquartered in Redwood City, California.

On September 24, 2021 (the “Closing Date”), the Company consummated the previously announced business combination (the “Business Combination” or “Reverse Recapitalization” for accounting purposes) pursuant to the terms of the Business Combination Agreement, dated as of May 5, 2021 (the “BCA”), by and among AMHC, Ample Merger Sub, Inc., a then-wholly-owned subsidiary of AMHC (“Merger Sub”), and the pre-Business Combination Jasper Therapeutics, Inc. (now named Jasper Tx Corp.) (“Old Jasper”). Pursuant to the terms of the BCA, on the Closing Date, (i) Merger Sub merged with and into Old Jasper, with Old Jasper as the surviving company in the Business Combination, and, after giving effect to such Business Combination, Old Jasper became a wholly owned subsidiary of AMHC and changed its name to “Jasper Tx Corp.”, and (ii) AMHC changed its name to “Jasper Therapeutics, Inc.”.

In addition, concurrently with the execution of the BCA, certain investors (“PIPE Investors”) entered into Subscription Agreements with AMHC whereby such investors subscribed for the purchase of an aggregate of 10,000,000 shares of AMHC’s Class A Common Stock at a price of \$10.00 per share for aggregate gross proceeds of \$100.0 million (“PIPE Financing”). The PIPE Financing was consummated concurrently with the closing of the Business Combination.

Please refer to Note 3, “Reverse Recapitalization”, for further details of the Business Combination.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception. During the six months ended June 30, 2022 and 2021, the Company incurred net losses of \$12.6 million and \$18.2 million, respectively. During the six months ended June 30, 2022 and 2021, the Company had negative operating cash flows of \$23.6 million and \$12.0 million, respectively. As of June 30, 2022 and December 31, 2021, the Company had an accumulated deficit of \$80.1 million and \$67.5 million, respectively. The Company expects to continue to incur substantial losses, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenues to support the Company’s cost structure.

The Company’s cash and cash equivalents of \$60.8 million as of June 30, 2022 are not sufficient for the Company to continue as a going concern for at least one year from the issuance date of these condensed consolidated financial statements. Additional funds are necessary to maintain current operations and to continue research and development activities. The Company’s management plans to monitor expenses and raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and licensing arrangements. The Company’s ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts, needed, the Company could be required to delay, scale back or abandon some or all of its development programs and other operations, which could materially harm the Company’s business, financial condition and results of operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The accompanying condensed consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the global novel coronavirus disease 2019 (“COVID-19”) outbreak a pandemic. The Company is following, and will continue to follow, recommendations from the U.S. Centers for Disease Control and Prevention as well as federal, state, and local governments regarding working-from-home practices for non-essential employees as well as return-to-work policies and procedures. The Company expects to continue to take actions as may be required or recommended by government authorities or as the Company determines are in the best interests of its employees and other business partners in light of the pandemic.

While the Company's operations to date have not been significantly impacted by the COVID-19 pandemic, it cannot at this time predict the specific extent, duration, or full impact that the continuing COVID-19 pandemic will have on its business, financial condition and operations, including ongoing and planned clinical trials and clinical development timelines. The Company experienced slower than anticipated patient enrollment in its severe combined immunodeficiency clinical trial in 2020 due to reluctance of these immunocompromised patients to travel and undergo hospitalization during the pandemic. The Company may continue to experience interruptions to its clinical trials due to the COVID-19 pandemic, including the spread of variants. The impact of the COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the pandemic, its impact on the Company's clinical trial enrollment, trial sites, contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and other third parties with whom it does business, its impact on regulatory authorities and the Company's key scientific and management personnel, progress of vaccination and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The condensed consolidated financial statements and accompanying notes are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") regarding interim financial reporting.

The accompanying condensed financial statements are consolidated for the three and six months ended June 30, 2022 and include the accounts of Jasper Therapeutics, Inc. (i.e., formerly known as AMHC) and its wholly-owned subsidiary, Jasper Tx Corp., following the Reverse Recapitalization as further discussed in Note 3, "Reverse Recapitalization". All intercompany transactions and balances have been eliminated upon consolidation.

All historical share data and per-share amounts were retrospectively adjusted to reflect the effect of the exchange ratio of 0.2823780 per one share, which was determined at the closing of the Reverse Recapitalization, except for the 100 shares of Series A-2 redeemable convertible preferred stock. The Series A-2 shares were not subject to the exchange ratio as a part of the recapitalization; rather, the shares were converted into 2,200,000 shares of common stock upon the closing of the business combination.

Certain information and footnote disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2021 included in the Company's Annual Report on the Form 10-K filed with the SEC on March 18, 2022. The information as of December 31, 2021, included in the condensed consolidated balance sheets was derived from the Company's audited financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for a fair statement of the Company's consolidated financial statements. The results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 or for any other interim period or for any other future year.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions and judgements that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include but are not limited to the valuation of common and redeemable convertible preferred stock before the Reverse Recapitalization, the determination of the incremental borrowing rate used for operating lease liabilities, valuation of derivative liability, valuation of earnout liability and the measurement of stock-based compensation expense. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Cash, Cash Equivalents, and Restricted Cash

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

	June 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 60,814	\$ 84,701
Restricted cash	417	345
Total cash, cash equivalents and restricted cash	\$ 61,231	\$ 85,046

Cash and cash equivalents consist of a checking account and investments in money market funds with an original maturity of three months or less at the time of purchase. The recorded carrying amount of cash and cash equivalents approximates their fair value. Restricted cash relates to the letter of credit secured in conjunction with the operating lease (Note 9).

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders adjusted for income (expenses), net of tax, related to any diluted securities, by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, common stock subject to repurchase, common stock subject to restricted stock awards, the Earnout Shares, the Common Stock Warrants and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities.

The Company considers all series of its redeemable convertible preferred stock, common stock subject to repurchase, common stock subject to restricted stock awards and the Earnout Shares to be participating securities as the holders are entitled to receive dividends on a pari passu basis in the event that a dividend is paid on common stock. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. For the three and six months ended June 30, 2022 and 2021, the diluted net loss per common share was the same as basic net loss per common share, as the impact of potentially dilutive securities was antidilutive to the net loss per common share. The Earnout Shares and common stock subject to restricted stock awards are contingently issuable shares and are not included in the diluted net loss per share calculation until contingencies are resolved.

Segment Reporting

The Company has determined it operates as a single operating and reportable segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources. All long-lived assets are located in the United States.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which removes certain exceptions to the general principles in Topic 740 and improves consistent application of and simplifies U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. For public companies, this ASU is effective for fiscal years beginning after December 15, 2020. For all other entities, this ASU is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company used the extended transition period for emerging growth companies and adopted this ASU on January 1, 2022. The adoption of this ASU did not have a material effect on the Company's condensed consolidated financial statements and related disclosures.

In November 2021, the FASB issued ASU No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*, which requires annual disclosures about certain types of government assistance received. ASU No. 2021-10 is effective for fiscal years beginning after December 15, 2021. The Company adopted this ASU on January 1, 2022. The adoption of this ASU resulted in additional disclosures related to the CIRM grant (Note 6). The adoption of this ASU did not have a material effect on the Company's condensed consolidated financial statements.

NOTE 3. REVERSE RECAPITALIZATION

On the Closing Date, the Company consummated the Business Combination in accordance with the BCA. Merger Sub merged with Old Jasper, with Old Jasper as the surviving company and as a wholly owned subsidiary of AMHC. AMHC was renamed Jasper Therapeutics, Inc., and Old Jasper was renamed Jasper Tx Corp.

In accordance with the BCA, at the closing of the Business Combination, each share of Old Jasper common stock and Old Jasper redeemable convertible preferred stock outstanding immediately prior to the closing was automatically cancelled, extinguished and converted into the number of shares of the Company's common stock or, in certain circumstances, the Company's non-voting common stock, based on Old Jasper's equity value of \$275.0 million divided by \$10.00. The exchange ratio agreed between the parties was one-for-0.282378 share of the Company's common stock for all Old Jasper stockholders, except for Amgen Inc. ("Amgen"). Amgen's 100 shares of Series A-2 redeemable convertible preferred stock were converted into 2,200,000 shares of the Company's common stock, which represented 8% of the Old Jasper equity value, as per the terms of the Amgen's agreement with Old Jasper. Each vested and unvested option to purchase shares of Old Jasper's common stock outstanding at the closing of the Business Combination was converted into a comparable option to purchase shares of the Company's common stock, with the same terms after giving effect of the exchange ratio. Each unvested award of restricted shares of Old Jasper common stock outstanding immediately prior to the closing was converted into a comparable right to receive restricted shares of the Company's common stock, after giving effect of the same exchange ratio.

In connection with the Business Combination, the Company received \$95.3 million in net cash proceeds. This amount was comprised of \$5.5 million of cash held in AMHC's trust account from its initial public offering (after payment of redemptions and public offering expenses paid at the closing of the Business Combination) and \$100.0 million of cash received by AMHC in connection with the PIPE Financing, net of AMHC's transaction costs and placement agents' fees of \$9.0 million and operating expense payments of \$1.2 million. The Company incurred \$5.3 million of transaction costs, consisting of legal, professional, and banking fees, which were recorded as a reduction to additional paid-in capital.

NOTE 4. FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

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

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The fair value of Level 1 securities is determined using quoted prices in active markets for identical assets. Level 1 securities consist of highly liquid money market funds. In addition, restricted cash collateralized by money market funds is a financial asset measured at fair value and is a Level 1 financial instrument under the fair value hierarchy.

Financial assets and liabilities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data, such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. The Company had no financial instruments classified at Level 2 as of June 30, 2022 and December 31, 2021.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques and at least one significant model assumption or input is unobservable. Level 3 liabilities that are measured at fair value on a recurring basis included the derivative tranche liability, which was extinguished in February 2021, and earnout liability, which was recognized in connection with the Business Combination in September 2021.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at estimated fair value using Level 3 inputs. There were no transfers within the hierarchy during the three or six months ended June 30, 2022 and 2021.

The following tables set forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy (in thousands):

	June 30, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds	\$ 59,814	\$ -	\$ -	\$ 59,814
Total fair value of assets	\$ 59,814	\$ -	\$ -	\$ 59,814
Financial liabilities				
Common stock warrant liability	\$ 455	\$ -	\$ -	\$ 455
Earnout liability	-	-	525	525
Total fair value of financial liabilities	\$ 455	\$ -	\$ 525	\$ 980
	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds	\$ 83,701	\$ -	\$ -	\$ 83,701
Total fair value of assets	\$ 83,701	\$ -	\$ -	\$ 83,701
Financial liabilities				
Common stock warrant liability	\$ 7,350	\$ -	\$ -	\$ 7,350
Earnout liability	-	-	5,743	5,743
Total fair value of financial liabilities	\$ 7,350	\$ -	\$ 5,743	\$ 13,093

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial liabilities (in thousands):

	Derivative Tranche Liability	Earnout Liability
Fair Value as of January 1, 2021	\$ 8,158	\$ —
Change in the fair value included in other expense	3,501	—
Settlement of obligation	(11,659)	—
Fair Value as of June 30, 2021	<u>\$ —</u>	<u>\$ —</u>
Fair Value as of January 1, 2022	\$ —	\$ 5,743
Change in the fair value included in other income	—	(5,218)
Fair Value as of June 30, 2022	<u>\$ —</u>	<u>\$ 525</u>

The derivative tranche liability was measured using the option pricing method by estimating the value using the Black-Scholes model. The significant inputs used in the Black-Scholes model include the fair value of the redeemable convertible preferred stock, the risk-free interest rate, the expected volatility and the expected term when each tranche will be settled. The fair value of the derivative tranche liability equaled its intrinsic value, a difference between the issued redeemable convertible preferred stock shares' fair value and the price paid by investors, at the date of settlement in February 2021.

The estimated fair value of the earnout liability is determined using a Monte Carlo simulation model, which uses a distribution of potential outcomes on a monthly basis over the earnout period prioritizing the most reliable information available. The assumptions utilized in the calculation are based on the achievement of certain stock price milestones, including the current Company's common stock price, expected volatility, risk-free rate and expected term. The estimates of fair value are uncertain and changes in any of the estimated inputs used as of the date of this report could have resulted in significant adjustments to the fair value.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurement classified in Level 3 of the fair value hierarchy at June 30, 2022:

	Fair value (in thousands)	Valuation methodology	Significant unobservable input	
Earnout liability	\$ 525	Monte Carlo Simulation	Common stock price	\$ 1.93
			Expected term (in years)	2.24
			Expected volatility	91.00%
			Risk-free interest rate	2.89%

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurement classified in Level 3 of the fair value hierarchy at December 31, 2021:

	Fair value (in thousands)	Valuation methodology	Significant unobservable input	
Earnout liability	\$ 5,743	Monte Carlo Simulation	Common stock price	\$ 7.85
			Expected term (in years)	2.73
			Expected volatility	74.00%
			Risk-free interest rate	0.90%

NOTE 5. CONDENSED CONSOLIDATED BALANCE SHEET COMPONENTS***Prepaid expenses and other current assets***

The following table summarizes the details of prepaid expenses and other current assets as of the dates set forth below (in thousands):

	June 30, 2022	December 31, 2021
Prepaid insurance	\$ 866	\$ 2,074
Other prepaid expenses	511	171
Research and development prepaid expenses	625	139
Payroll tax credit receivable	397	548
Rent deposit	-	27
Other current assets	27	21
Other receivables	46	150
Total	<u>\$ 2,472</u>	<u>\$ 3,130</u>

Property and equipment, net

The following table summarizes the details of property and equipment, net as of the dates set forth below (in thousands):

	June 30, 2022	December 31, 2021
Leasehold improvements	\$ 2,477	\$ 2,056
Lab equipment	1,647	1,569
Office furniture & fixtures	473	208
Computer equipment	140	140
Capitalized software	90	90
Property and equipment, gross	4,827	4,063
Less: accumulated depreciation and amortization	(811)	(377)
Property and equipment, net	<u>\$ 4,016</u>	<u>\$ 3,686</u>

Depreciation and amortization expense was \$0.2 million and less than \$0.1 million for the three months ended June 30, 2022 and 2021, respectively, and \$0.4 million and less than \$0.1 million for the six months ended June 30, 2022 and 2021, respectively.

Accrued expenses and other current liabilities

The following table summarizes the details of accrued expenses and other current liabilities as of the dates set forth below (in thousands):

	June 30, 2022	December 31, 2021
Research and development accrued expenses	\$ 1,435	\$ 1,660
Accrued employee and related compensation expenses	746	1,151
Property and equipment accrual	141	-
License option liability, current	-	200
Other	519	585
Total	<u>\$ 2,841</u>	<u>\$ 3,596</u>

Other non-current liabilities

The following table summarizes the details of other non-current liabilities as of the dates set forth below (in thousands):

	June 30, 2022	December 31, 2021
CIRM grant liability	\$ 600	\$ 600
Accrued employee and related compensation expenses	111	-
Accrued tax liability	24	24
Restricted stock liability	14	19
Total	<u>\$ 749</u>	<u>\$ 643</u>

NOTE 6. CIRM GRANT

In November 2020, California Institute for Regenerative Medicine (“CIRM”) awarded the Company \$2.3 million in support of the research project related to a monoclonal antibody that depletes blood stem cells and enables chemotherapy-free transplants. The award is payable to the Company upon achievement of milestones over the next three years that are primarily based on patients’ enrollment to the Company’s clinical trials. CIRM may permanently cease disbursements if milestones are not met within four months of the scheduled completion date. Additionally, if CIRM determines, in its sole discretion, that the Company has not complied with the terms and conditions of the grant, CIRM may suspend or permanently cease disbursements. Funds received under this grant may only be used for allowable project costs specifically identified with the CIRM-funded project. Such costs can include but are not limited to salary for personnel, itemized supplies, consultants, and itemized clinical study costs. Under the terms of the grant, both CIRM and the Company will co-fund the research project and the amount of the Company’s co-funding requirement is predetermined as a part of the award. Under the terms of the CIRM grant, the Company is obligated to pay royalties and licensing fees based on 0.1% of net sales of CIRM-funded product candidates or CIRM-funded technology per \$1.0 million of CIRM grant. As an alternative to revenue sharing, the Company has the option to convert the award to a loan. In the event the Company exercises its right to convert the award to a loan, it would be obligated to repay the loan within ten business days of making such election. Repayment amounts vary dependent on when the award is converted to a loan, ranging from 60% of the award granted to amounts received plus interest at the rate of the three-month LIBOR rate plus 25% per annum. Since the Company may be required to repay some or all of the amounts awarded by CIRM, the Company accounted for this award as a liability. Given the uncertainty in amounts due upon repayment, the Company has recorded amounts received without any discount or interest recorded, and upon determination of amounts that would become due, the Company will adjust accordingly. In the absence of explicit US GAAP guidance on contributions received by business entities from government entities, the Company has applied to the CIRM grant the recognition and measurement guidance in Accounting Standards Codification Topic 958-605 by analogy. As of December 31, 2020, the Company met a milestone and had recorded \$0.6 million in other receivables for the milestone that was met and \$0.6 million in other long-term liabilities related to this grant. The Company received an aggregate of \$0.6 million from CIRM in January and March 2021. As of June 30, 2022, the Company recorded \$0.6 million in other long-term liabilities related to this grant. As of June 30, 2022, \$1.7 million is available for future distribution to the Company under the grant upon achievement of milestones.

NOTE 7. SIGNIFICANT AGREEMENTS

Amgen License Agreement

On November 21, 2019, the Company entered into a license agreement with Amgen (the “Amgen License Agreement”), pursuant to which the Company obtained an exclusive, sublicensable license for certain patents, data, and non-data know-how related to Amgen’s proprietary monoclonal antibody known as AMG 191, as renamed to JSP191 (“JSP191”).

The Amgen License Agreement terminates on a country-by-country basis on the 10th anniversary of the date on which the exploitation of the licensed products is no longer covered by a valid claim under a licensed patent in such country. On a country-by-country basis, upon the expiration of the term in each country with respect to the licensed products, the licenses to the Company by Amgen become fully paid and non-exclusive. The Company and Amgen have the right to terminate the agreement for a material breach as specified in the agreement.

Stanford License Agreement

In March 2021, the Company entered into a definitive license agreement (the “Stanford License Agreement”) with Stanford University (“Stanford”). The Company received a worldwide, exclusive license with a right to sublicense for JSP191 in the field of depleting endogenous blood stem cells in patients for whom hematopoietic cell transplantation is indicated. Stanford transferred to the Company certain know-how and patents related to JSP191 (together, the “Licensed Technology”). Under the terms of this agreement, the Company will use commercially reasonable efforts to develop, manufacture, and sell licensed product and to develop markets for a licensed product. In addition, the Company will use commercially reasonable efforts to meet the milestones as specified in the agreement over the six years from execution of the Stanford License Agreement and must notify Stanford in writing as each milestone is met.

The Company will pay annual license maintenance fees, beginning on the first anniversary of the effective date of the agreement and ending upon the first commercial sale of a product, method, or service in the licensed field of use, as follows: \$25,000 for each first and second year, \$35,000 for each third and fourth year, and \$50,000 at each anniversary thereafter ending upon the first commercial sale. The Company is also obligated to pay late-stage clinical development milestones and first commercial sales milestone payments of up to \$9.0 million in total. The Company will also pay low single-digit royalties on net sales of licensed products, if approved. The Company paid a \$25,000 license maintenance fee in March 2022, which was recognized as research and development expense in the condensed statements of operations and comprehensive loss for the six months ended June 30, 2022.

The Stanford License Agreement expires on a country-by-country basis on the last-to-expire valid claim of a licensed patent in such country. The Company may terminate the agreement by giving Stanford written notice at least 12 months in advance of the effective date of termination. The Company may also terminate the agreement solely with respect to any particular patent application or patent by giving Stanford written notice at least 60 days in advance of the effective date of termination. Stanford may terminate the agreement after 90 days from a written notice by Stanford, specifying a problem, including a delinquency on any report required pursuant to agreement or any payment, missing a milestone or for a material breach, unless the Company remediates the problem in that 90-day period.

NOTE 8. DERIVATIVE FINANCIAL INSTRUMENTS

Common Stock Warrants

The Common Stock Warrants are traded on the Nasdaq Capital Market and may only be exercised for a whole number of shares. The Common Stock Warrants became exercisable on October 24, 2021 and will expire on September 24, 2026, unless early redeemed or if the Company extends the exercise period. The fair value of \$7.9 million of Common Stock Warrants was recognized as a liability on September 24, 2021, the Closing Date, based on the closing market price. 130 Common Stock Warrants have been exercised from the Closing Date through June 30, 2022.

The Company recognized a gain of \$0.8 million and \$6.9 million for the three and six months ended June 30, 2022, respectively, classified within change in fair value of common stock warrant liability in the condensed consolidated statements of operations and comprehensive loss. The Common Stock Warrants’ fair value was \$0.5 million and \$7.4 million as of June 30, 2022 and December 31, 2021, respectively.

Contingent Earnout Liability

Upon the closing of the Business Combination and pursuant to the Sponsor Support Agreement, the Sponsor agreed to place the Earnout Shares into escrow, which will be released as follows: (a) 250,000 Earnout Shares will be released if, during the period from and after September 24, 2021 until September 24, 2024 (the “Earnout Period”), over any twenty trading days within any thirty day consecutive trading day period, the volume-weighted average price of the Company’s common stock (the “Applicable VWAP”) is greater than or equal to \$11.50, (b) 500,000 Earnout Shares will be released if, during the Earnout Period, the Applicable VWAP is greater than or equal to \$15.00, and (c) 300,000 Earnout Shares will be released if, during the Earnout Period, the Applicable VWAP is greater than or equal to \$18.00 (the “triggering events”).

The Earnout Shares placed in escrow are legally issued and outstanding shares that participate in voting and dividends. The Earnout Shares (along with related escrowed dividends, if any) will be forfeited and not released from escrow at the end of the Earnout Period unless the triggering events described above are achieved during the Earnout Period. Upon the closing of the Business Combination, the contingent obligation to release the Earnout Shares was accounted for as a liability classified financial instrument upon their initial recognition because the triggering events that determine the number of shares required to be released from escrow include events that were not solely indexed to the common stock of the Company. The earnout liability is remeasured each reporting period with changes in fair value recognized in earnings.

The estimated fair value of the earnout liability was \$0.5 million and \$5.7 million as of June 30, 2022 and December 31, 2021, respectively, based on a Monte Carlo simulation model. Assumptions used in the valuations are described in Note 4. No triggering event occurred as of June 30, 2022. The Company recognized a gain of \$0.6 million and \$5.2 million for the three and six months ended June 30, 2022, respectively, classified within change in fair value of earnout liability in the condensed consolidated statements of operations and comprehensive loss.

NOTE 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

In August 2020, the Company entered into a 68-month operating lease for laboratory and office space in Redwood City, California, with a lease commencement date in September 2020. In January 2022, the Company amended its operating lease in Redwood City, California to add an additional 5,611 rentable square feet with a lease commencement date on March 1, 2022. The total additional lease payments for the extra space from the commencement date are estimated at \$1.8 million. In March 2022, the Company entered into an agreement for 5,144 square feet of temporary office space in Redwood City, California, for use while the extra space leased in January 2022 is under construction. The Company pays \$26,000 monthly for the temporary office space rent.

The Company's operating lease will expire in August 2026. In conjunction with signing the lease, the Company secured a letter of credit in favor of the lessor in the amount of \$0.4 million. The funds related to this letter of credit are presented as restricted cash on the Company's condensed consolidated balance sheets. The lease agreement includes an escalation clause for increased base rent and a renewal provision allowing the Company to extend this lease for an additional 60 months at the prevailing rental rate, which the Company is not reasonably certain to exercise. In addition to base rent, the Company will pay its share of operating expenses and taxes.

To complete certain leasehold improvements, the lessor agreed to provide the Company a tenant improvement allowance of \$1.5 million as well as an option to take an additional allowance of \$0.4 million to be repaid over the lease term at an interest rate of 9% per annum, which the Company exercised. The Company recognized \$1.6 million in leasehold improvements covered by these allowances as of December 31, 2021. As of June 30, 2022, \$0.3 million of additional leasehold improvements covered by these allowances have been recognized. In accordance with the lease agreement, the lessor managed and supervised the construction of the improvements. In exchange for these services, the Company paid the lessor a fee equal to 5% of total construction costs. The leasehold improvements constructed are presented under property and equipment on the Company's condensed consolidated balance sheets and will be depreciated on a straight-line basis over the remaining lease term.

In addition to the construction management and supervision fee noted above, the Company pays variable costs related to its share of operating expenses and taxes. These variable costs are recorded as lease expense as incurred and presented as operating expenses in the condensed consolidated statements of operations and comprehensive loss.

The components of lease costs, which were included in the Company's statements of operations and comprehensive loss, are as follows (in thousands):

	Six Months Ended June 30,	
	2022	2021
Lease cost		
Operating lease cost	\$ 286	\$ 276
Short-term lease cost	123	165
Total lease cost	\$ 409	\$ 441

Supplemental information related to the Company's operating leases is as follows:

	Six Months Ended June 30,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	\$ 351	\$ -
Weighted average remaining lease term (years)	4.12	5.12
Weighted average discount rate	8.00%	8.00%

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of June 30, 2022 (in thousands):

Year ending December 31,	Amount
2022 (remainder)	\$ 511
2023	1,121
2024	1,154
2025	1,189
2026	743
Total undiscounted lease payments	4,718
Less imputed interest	(700)
Total discounted lease payments	4,018
Less current portion of lease liability	(784)
Noncurrent portion of lease liability	\$ 3,234

Stanford Sponsored Research Agreement

In September 2020, the Company entered into a sponsored research agreement with Stanford for a research program related to the treatment of Fanconi Anemia patients in Bone Marrow Failure requiring allogeneic transplant with non-sibling donors at Stanford Lucile Packard Children's Hospital (the "Research Project") using JSP191. Stanford will perform the Research Project and is fully responsible for costs and operations related to the Research Project. In addition, Stanford owns the entire right, title, and interest, in and to all technology developed using Stanford facilities and by Stanford personnel through the performance of the Research Project under this agreement (the "Fanconi Anemia Research Project IP"). Under this agreement, Stanford granted the Company an exclusive option to license exclusively Stanford's rights in the Fanconi Anemia Research Project IP (the "Fanconi Anemia Option") in the field of commercialization of JSP191. There is no license granted or other intellectual property transferred under this agreement until the Fanconi Anemia Option is exercised. As of June 30, 2022, the Company has not yet exercised the Fanconi Anemia Option.

As consideration for the services performed by Stanford under this sponsored research agreement, the Company agreed to pay Stanford a total of \$0.9 million over approximately 3 years upon the achievement of development and clinical milestones, including FDA filings and patients' enrollment. As of December 31, 2020, the Company had accrued \$0.3 million related to the achievement of the first milestone under this agreement, which was paid in February 2021. In February 2022, the second milestone was achieved. The Company paid \$0.3 million in March 2022 and recognized this as a research and development expense in the condensed statements of operations and comprehensive loss for the six months ended June 30, 2022. The third milestone is based on the progress of the clinical trials and will be recognized when achieved.

License Agreements

In March 2021, the Company entered into the Stanford License Agreement (Note 7), pursuant to which the Company is required to pay annual license maintenance fees, beginning on the first anniversary of the effective date of the agreement and ending upon the first commercial sale of a product, method, or service in the licensed field of use, as follows: \$25,000 for each first and second year, \$35,000 for each third and fourth year, and \$50,000 at each anniversary thereafter ending upon the first commercial sale. The Company is also obligated to pay late-stage clinical development milestones and first commercial sales milestone payments of up to \$9.0 million in total. The Company will also pay low single-digit royalties on net sales of licensed products. All products were in development as of June 30, 2022, and no such royalties were due as of such date. The Company paid a \$25,000 license maintenance fee in March 2022 and recognized this as a research and development expense in the condensed statements of operations and comprehensive loss for the six months ended June 30, 2022.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the six months ended June 30, 2022 and the year ended December 31, 2021, and, to the best of its knowledge, no material legal proceedings are currently pending.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of June 30, 2022 and December 31, 2021, the Company does not have any material indemnification claims that are probable or reasonably possible and consequently has not recorded related liabilities.

NOTE 10: COMMON STOCK

On September 24, 2021, upon the closing of the Business Combination, the Company issued (1) 13,037,901 shares of voting common stock in exchange for AMHC's outstanding shares of Class A common stock, (2) 23,482,387 shares of voting common stock and (3) 1,296,022 shares of non-voting common stock in exchange for outstanding shares of Old Jasper preferred stock and common stock.

The Company is authorized to issue 490,000,000 shares of voting common stock, 2,000,000 shares of non-voting common stock, and 10,000,000 shares of undesignated preferred stock. There were 36,685,295 shares of voting common stock, 1,296,022 shares of non-voting common stock and no shares of preferred stock issued and outstanding as of June 30, 2022.

Holders of the voting common stock and the non-voting common stock have similar rights, except that non-voting stockholders are not entitled to vote, including for the election of directors. Holders of voting common stock do not have conversion rights, while holders of non-voting common stock have the right to convert each share of non-voting common stock held by such holder into one share of voting common stock at such holder's election by providing written notice to the Company, provided that as a result of such conversion, such holder, together with its affiliates, would not beneficially own in excess of 9.9% of the Company's voting common stock following such conversion.

As of June 30, 2022 and December 31, 2021, the Company had shares of its common stock reserved for future issuance as follows:

	June 30, 2022	December 31, 2021
Outstanding and issued common stock options	6,023,166	2,660,383
Common stock warrants	4,999,863	4,999,883
Shares available for grant under 2021 Equity Incentive Plan	4,147,046	4,422,480
Shares available for grant under 2022 Inducement Equity Incentive Plan	1,295,672	-
Shares available for grant under 2021 Employee Stock Purchase Plan	928,551	550,000
Outstanding restricted stock units	5,000	-
Total shares of common stock reserved	<u>17,399,298</u>	<u>12,632,746</u>

NOTE 11. STOCK-BASED COMPENSATION

On September 23, 2021, the 2021 Equity Incentive Plan (“2021 Plan”) and the 2021 Employee Stock Purchase Plan (“ESPP”) became effective upon the prior approval of Old Jasper’s board of directors and stockholders. The 2021 Plan and ESPP provide for annual automatic increases in the number of shares reserved under each plan, beginning on January 1, 2022. The number of shares available for issuance under the 2021 Plan will increase annually in an amount equal to the least of (i) 2,750,000 shares, (ii) a number of shares equal to 4% of the total number of shares of all classes of common stock of the Company outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares determined by the Company’s Board of Directors (“Board”) no later than the last day of the immediately preceding fiscal year. The number of shares of common stock available for issuance under the ESPP will increase annually in an amount equal to the least of (i) 550,000 shares of common stock, (ii) a number of shares of common stock equal to 1% of the total number of shares of all classes of common stock of the Company on the last day of the immediately preceding fiscal year, or (iii) such number of shares determined by the Board. As of June 30, 2022, 5,895,669 shares were reserved for issuance under the 2021 Plan, of which 4,147,046 shares were available for future grant and 1,748,623 shares were subject to outstanding options and restricted stock units (“RSUs”), including performance-based awards. As of June 30, 2022, no shares have been issued under the ESPP and 928,551 shares were reserved and available for future issuance.

On March 14, 2022, the compensation committee of the board adopted the 2022 Inducement Equity Incentive Plan (the “2022 Inducement Plan”) under which the Company may grant equity awards to new employees. The only persons eligible to receive grants under the 2022 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq guidance. As of June 30, 2022, 3,000,000 shares were reserved for issuance under the 2022 Inducement Plan, of which 1,295,672 shares were available for future grant and 1,704,328 shares were subject to an outstanding stock option.

Under the 2021 Plan, the Company can grant incentive stock options, nonstatutory stock options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards and other awards to employees, directors and consultants. Under the 2022 Inducement Plan, the Company can grant nonstatutory stock options, restricted stock awards, stock appreciation rights, RSUs, performance awards and other awards, but only to an individual, as a material inducement to such individual to enter into employment with the Company or an affiliate of the Company, who (i) has not previously been an employee or director of the Company or (ii) is rehired following a bona fide period of non-employment with the Company. Under the ESPP, the Company can grant purchase rights to employees to purchase shares of common stock at a purchase price which equal to 85% of the fair market value of common stock on the offering date or on the exercise date, whichever is lower.

Stock options under the 2021 Plan and the 2022 Inducement Plan may be granted for periods of up to 10 years and at prices no less than 100% of the fair market value of the shares on the date of grant, provided, however, that the exercise price of an ISO (which cannot be granted pursuant to the 2022 Inducement Plan) granted to a 10% stockholder may not be less than 110% of the fair market value of the shares. Stock options granted to employees and non-employees generally vest ratably over four years.

Stock Options

The following table summarizes the activity under the 2021 Plan, the 2022 Inducement Plan and the 2019 Plan for the six months ended June 30, 2022:

	Shares Available for Grant	Options Outstanding		Weighted - Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
		Number of Shares	Weighted Average Exercise Price		
Balance, January 1, 2022	4,422,480	2,660,383	\$ 0.81	8.54	\$ 18,731,908
Shares authorized	4,514,204				
Options granted	(3,604,553)	3,604,553	\$ 3.48		
Options exercised	-	(36,211)	\$ 0.71		
Options cancelled/forfeited	205,559	(205,559)	\$ 3.11		
Balance, June 30, 2022	5,537,690	6,023,166	\$ 2.33	8.15	\$ 3,000,546
Vested and expected to vest, June 30, 2022		6,023,166	\$ 2.33	8.15	\$ 3,000,546
Exercisable – June 30, 2022		1,991,961	\$ 1.04	6.89	\$ 2,126,054

The aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options. The total intrinsic value of the options exercised during the six months ended June 30, 2022 was \$0.1 million.

The total fair value of options that vested during the six months ended June 30, 2022 was \$0.8 million. The weighted-average grant date fair value of options granted during the six months ended June 30, 2022 was \$1.91 per share.

Future stock-based compensation for unvested options as of June 30, 2022 was \$6.3 million, which is expected to be recognized over a weighted-average period of 3.0 years.

Restricted Stock Units (RSUs)

The following table provides a summary of RSUs activity under the 2021 Plan during the six months ended June 30, 2022:

	Number of Shares	Weighted Average Grant date Fair Value
Unvested restricted stock units at January 1, 2022	-	\$ -
Granted	94,972	3.54
Vested	(91,222)	3.54
Unvested restricted stock units at June 30, 2022	3,750	3.54
Vested and unreleased	1,250	3.54
Outstanding restricted stock units at June 30, 2022	5,000	\$ 3.54

Unamortized stock-based compensation for restricted stock units as of June 30, 2022 was less than \$0.1 million, which is expected to be recognized over a weighted-average period of 0.8 years.

Employee Stock Purchase Plan

The first offering period commenced in June 2022 and will end in December 2022. The Company did not issue any common stock shares under the ESPP as of June 30, 2022. The Company recorded less than \$0.1 million in accrued liabilities related to contributions withheld as of June 30, 2022.

Unamortized stock-based compensation for shares issuable under the ESPP as of June 30, 2022 was less than \$0.1 million, which is expected to be recognized over a weighted-average period of 0.5 years.

Stock-Based Compensation Expense

The following table presents stock-based compensation expenses related to options and RSUs granted to employees and non-employees, ESPP awards and restricted common stock shares issued to founders (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
General and administrative	\$ 480	\$ 129	\$ 1,036	\$ 257
Research and development	585	166	807	365
Total	\$ 1,065	\$ 295	\$ 1,843	\$ 622

On March 15, 2022, William Lis, who had been serving as the Company's Chief Executive Officer and Executive Chairman, transitioned to the position of non-employee Chairperson of the Board. During the three and six months ended June 30, 2022, in connection with Mr. Lis' transition, the Company recognized zero and \$0.4 million, respectively, of general and administrative expense on certain stock options and RSUs granted to Mr. Lis for his Chief Executive Officer and Executive Chairman services to the Company.

Valuation of Stock Options

The grant date fair value of stock options was estimated using a Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended June 30,	Six Months Ended June 30,	
	2022	2022	2021
Expected term (in years)	2.68 - 6.07	1.00 - 6.08	5.29 - 6.08
Expected volatility	57.39% - 58.66%	43.25% - 60.35%	75.27% - 75.79%
Risk-free interest rate	2.72% - 2.84%	1.40% - 2.84%	0.65% - 0.80%
Expected dividend yield	—	—	—

No stock options were granted during the three months ended June 30, 2021.

Valuation of ESPP Awards

The grant date fair value of ESPP awards was estimated using a Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022
Expected term (in years)	0.50	0.50
Expected volatility	75.60%	75.60%
Risk-free interest rate	1.81%	1.81%
Expected dividend yield	—	—

NOTE 12. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net loss attributable to common stockholders	\$ (10,404)	\$ (8,414)	\$ (12,611)	\$ (18,168)
Denominator:				
Weighted average common shares outstanding	37,886,129	2,825,583	37,877,390	2,799,115
Less: Weighted-average unvested restricted shares	(438,307)	(720,684)	(473,881)	(755,868)
Less: Shares subject to earnout	(1,050,000)	-	(1,050,000)	-
Weighted average shares used to compute basic and diluted net loss per share	36,397,822	2,104,899	36,353,509	2,043,247
Net loss per share attributable to common stockholders – basic and diluted	\$ (0.29)	\$ (4.00)	\$ (0.35)	\$ (8.89)

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have had an antidilutive effect were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Outstanding and issued common stock options	6,023,166	3,030,821	6,023,166	3,030,821
Common stock warrants	4,999,863	-	4,999,863	-
Unvested restricted common stock	400,036	682,413	400,036	682,413
Outstanding RSUs	5,000	-	5,000	-
Convertible preferred stock	-	21,722,660	-	21,722,660
Total	11,428,065	25,435,894	11,428,065	25,435,894

NOTE 13. RELATED PARTIES

The Company entered into consulting agreements with two founders, who also received founders' common stock shares for services and assigned patents. The Company recorded \$0.1 million and less than \$0.1 million for the founders' advisory and consulting services performed for the three months ended June 30, 2022 and 2021, respectively, and \$0.3 million and \$0.1 million for the founders' advisory and consulting services performed for the six months ended June 30, 2022 and 2021, respectively. These expenses were recorded as research and development expenses in the consolidated statements of operations and comprehensive loss. Also, the Company's Licensed Technology from Stanford (see Note 7) was created in the Stanford laboratory of Professor Judith Shizuru, one of the Company's founders.

In December 2020, the Company entered into a material transfer agreement with Zai Lab Limited where both companies will collaborate on a research project and share total expenses of up to \$0.3 million equally. The Company recorded zero and \$36,000 as a reduction to research and development expenses for expenses reimbursed by Zai Lab Limited for the six months ended June 30, 2022 and 2021, respectively. There were no such expenses incurred for the three months ended June 30, 2022 and 2021. The Company's chairman is a board member of Zai Lab Limited.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q (this "Quarterly Report") and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission on March 18, 2022. Certain of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors", in Part II, Item 1A of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section of this Quarterly Report entitled "Cautionary Note Regarding Forward-Looking Statements." The events and circumstances reflected in our forward-looking statements may not be achieved or may not occur, and actual results could differ materially from those described in or implied by the forward-looking statements contained in the following discussion and analysis. As a result of these risks, you should not place undue reliance on these forward-looking statements. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

Overview

We are a clinical-stage biotechnology company dedicated to enabling cures through hematopoietic stem cell therapy. We are focused on the development and commercialization of safer and more effective conditioning agents and mRNA-based stem cell engineering to allow for expanded use of stem cell transplantation and ex vivo gene therapy, a technique in which genetic manipulation of cells is performed outside of the body prior to transplantation. We are also developing novel therapeutics directed at diseased hematopoietic stem cells.

Our drug development pipeline includes multiple product candidates designed to improve hematopoietic stem cell therapy. Our lead product candidate, JSP191, is in clinical development as a novel conditioning antibody that clears hematopoietic stem cells from bone marrow in patients prior to undergoing allogeneic stem cell therapy or stem cell gene therapy. We plan to initiate a registrational clinical study in acute myeloid leukemia ("AML") patients undergoing stem cell transplantation by the end of the first quarter of 2023. Based on the single agent depletion observed in our Phase 1 study of myelodysplastic syndrome ("MDS") patients undergoing stem cell transplant, we are also initiating a pilot study of JSP191 as a therapeutic in lower-risk MDS, which we expect to commence in the second half of this year. Beyond JSP191, we are developing stem cell grafts transiently reprogrammed using mRNA that have a competitive advantage over endogenous hematopoietic stem cells ("HSCs"), enabling higher levels of engraftment designed to remove the need for highly toxic conditioning of the patient and lower the risk of other serious complications that limit current stem cell transplants. We plan to continue to expand our pipeline to include other novel stem cell therapies based on immune modulation, graft engineering and cell or gene therapies. Our goal is to expand the use of curative stem cell transplant and gene therapies for all patients, including children and the elderly.

Stem cell transplantation is among the most widely practiced forms of cellular therapy and has the potential to cure a wide variety of diseases, including cancers, genetic disorders, and autoimmune diseases. Yet currently, patients must receive highly toxic and potentially life-threatening conditioning agents to prepare their bone marrow for transplantation with either donor stem cells or their own gene-edited stem cells. Younger, fitter patients capable of surviving these toxic side effects are typically given myeloablative, or high-intensity, conditioning whereas older or less fit patients are typically given reduced intensity, but still toxic, conditioning which leads to less effective transplants. These toxicities include a range of acute and chronic effects to the gastrointestinal tract, kidneys, liver, lung, endocrine, and neurologic tissues. Depending upon the conditioning regimen, fitness of the patient, and compatibility between the donor and recipient, the risk of transplant-related mortality ranges from 10% to more than 50% in older patients. Less toxic ways to condition patients have been developed to enable transplant for older patients or those with major comorbidities, but these regimens risk less potent disease elimination and higher rates of disease relapse. Even though stem cell therapy can be one of the most powerful forms of disease cure, these limitations of non-targeted conditioning regimens have seen little innovation over the past decade.

Our lead product candidate, JSP191, is a monoclonal antibody designed to block the specific signal on stem cells required for survival. It is currently in development as a highly targeted conditioning agent prior to stem cell therapy as well as therapeutics in lower-risk MDS patients, which we expect to commence in the second half of 2022. We are also sponsoring two clinical studies of JSP191 as a conditioning agent prior to stem cell transplant. The first clinical study is an open label Phase 1/2 trial in two cohorts of severe combined immunodeficiency ("SCID") patients: patients with a history of a prior allogeneic transplant for SCID but with poor graft outcomes and newly diagnosed SCID patients. The primary endpoint in this study is to evaluate the safety and tolerability of JSP191. The secondary goal of this study is to evaluate the efficacy of JSP191 as a conditioning agent in conjunction with a stem cell transplant. Based on preliminary results from our ongoing Phase 1/2 clinical trial, we believe JSP191 has demonstrated the ability as a single agent to enable engraftment of donor HSCs as determined by donor chimerism, or the percentage of bone marrow cells in the patient that are of donor origin after transplant. Engraftment was observed in seven out of ten T-B-NK+ SCID patients with prior allogeneic transplant, as evidenced by CD15+ donor chimerism of more than 5% averaged from 12-24 weeks post-transplant. Increased naïve donor T cell production was observed in the majority of T-B-NK+ subjects, as well as clinical improvement. No JSP191 treatment-related serious adverse events ("SAEs") have been reported to date and pharmacokinetics have been consistent with earlier studies in healthy volunteers. We expect to complete enrollment in this Phase 1/2 clinical trial by mid-2023.

The FDA has granted rare pediatric disease designation to JSP191 as a conditioning treatment for patients with SCID. In addition, the FDA granted orphan drug designation to JSP191 for conditioning treatment prior to hematopoietic stem cell transplantation.

We also are evaluating JSP191 in an open label Phase 1 clinical trial in patients with MDS or AML undergoing donor stem cell transplant, but ineligible for myeloablative conditioning. The primary endpoints are to evaluate the safety, tolerability, and pharmacokinetic parameters of JSP191. Data from the initial dose finding Phase 1a portion of this trial as well as the Phase 1b dose expansion cohort have been reported. Initial results from the first twenty-four patients show that 0.6 mg/kg JSP191-based conditioning was well-tolerated with all twenty-four patients achieving successful primary engraftment. These initial results also show that twelve of twenty Phase 1a and 1b patients with MRD at screening achieved clearance of multimodality MRD using three methods of detection: conventional cytogenetics, flow cytometry, and next generation sequencing. No JSP191 related serious adverse events have been reported. As of reporting of these initial results, four patients have come off study due to relapse or progression. We presented these data at the 2022 Transplant and Cellular Therapy (TCT) meeting on April 26, 2022.

We have entered into a clinical collaboration with Stanford University (“Stanford”) to study JSP191-based conditioning in patients with Fanconi anemia undergoing stem cell transplant. This study is currently open for patient recruitment and the first patient was enrolled in the study in May 2022. We are also collaborating with the National Institutes of Health to conduct clinical trials of JSP191-based conditioning in patients with sickle cell disease (“SCD”), with chronic granulomatous disease (“CGD”) and with GATA-2 mutated MDS. We believe that JSP191 may also be useful for conditioning in allogeneic transplant for other diseases beyond which we are currently studying, including autoimmune diseases. We also believe that targeted JSP191-based conditioning may improve the efficacy and safety of gene therapies. We are working with Graphite Bio, Inc. (“Graphite Bio”) for gene therapy in patients with X-linked severe combined immunodeficiency (“X-SCID”) first as a non-clinical collaboration with an option to expand to clinical trials, as well as with AVROBIO, Inc. (“Avrobio”) for gene therapy in patients with Gaucher disease. We terminated our non-exclusive collaboration agreement with Aruvant Sciences GmbH (“Aruvant”) for gene therapy in patients with SCD in July 2022 as a result of Aruvant’s discontinuation of the development of ARU-1801, Aruvant’s investigational gene therapy for SCD.

We plan to evaluate JSP191 as a therapeutic for patients with disorders of the hematopoietic stem cell. MDS is a heterogeneous disorder of the bone marrow which typically occurs in an older population and can progress to AML. Lower-risk MDS patients typically suffer from anemia, thrombocytopenia or neutropenia and are given drug therapies such as an erythropoiesis stimulating agent (“ESA”) to stimulate production of new red blood cells to correct their deficiency. However, these agents do not target the diseased hematopoietic stem cell and patients who become refractory to ESA are dependent on routine blood transfusions, which is associated with poor survival. ESA-refractory low-risk MDS patients have few treatment options and are a significant unmet medical need.

JSP191 and other anti-CD117 monoclonal antibodies have been shown to deplete normal and diseased MDS human hematopoietic stem cells in clinical and pre-clinical studies. In studies of non-human primates and healthy volunteers, administration of a single dose of JSP191 resulted in depletion of healthy hematopoietic stem cells followed by recovery in approximately six weeks. Additional recent clinical data in MDS patients undergoing stem cell transplant showed depletion of hematopoietic stem cells after administration of JSP191 alone. By depleting diseased and healthy hematopoietic stem cells, we believe that JSP191 may allow for preferential recovery of healthy hematopoietic stem cells and restoration of normal hematopoiesis. We intend to study JSP191 monotherapy in lower-risk MDS patients with documented cytopenia who are refractory to ESA therapy.

Our mRNA stem cell grafts platform is designed to overcome key limitations of stem cell transplant and stem cell gene therapy. By using mRNA delivery and/or gene editing, we believe we can transiently reprogram donor or gene corrected stem cells to have a transient proliferative and survival advantage over a patient’s existing cells. We believe initial preclinical experiments by Jasper demonstrate multiple different mRNAs can be used to improve engraftment of modified stem cells. One approach engineers mRNA stem cell grafts that express variants of CXCR4 designed to improve stem cell homing and engraftment in the bone marrow. Another approach leverages expression of a modified stem cell factor receptor that can lead to cell line proliferation independent of stem cell factor (“SCF”) concentration, enabling our mRNA stem cell grafts to outcompete unmodified HSCs through better survival and engraftment. Also, since JSP191 only blocks signaling through the stem cell factor receptor, these grafts are not affected by JSP191 when used in combination. Other initial experiments have shown that mRNA can be used to express these receptor variants on the cell surface. We have identified other potential receptor modifications that prevent the binding of JSP191 but retain the ability to bind SCF, therefore allowing the mRNA stem cell grafts to proliferate normally even in the presence of JSP191.

We intend to become a fully integrated discovery, development, and commercial company in the field of hematopoietic stem cell therapy. We are developing our product candidates to be used individually or, in some cases, in combination with one another. As a result, we believe our pipeline could be tailored to the patient-specific disease so that a patient may receive more than one of our therapies as part of his or her individual allogeneic or gene-edited stem cell therapy. Our goal is to advance our product candidates through regulatory approval and bring them to the commercial market based on the data from our clinical trials and communications with regulatory agencies and payor communities. We expect to continue to advance our pipeline and innovate through our research platform.

We have an exclusive license agreement with Amgen Inc. (“Amgen”) for the development and commercialization of the JSP191 monoclonal antibody in all indications and territories worldwide. We also have an exclusive license agreement with Stanford for the right to use JSP191 in the clearance of stem cells prior to the transplantation of HSCs. We also entirely own the intellectual property for our mRNA stem cell grafts platform, which has been internally developed.

AMHC was incorporated in the State of Delaware in August 2019. Old Jasper was incorporated in the State of Delaware in March 2018 and did not have any significant operations or research and development activities until November 2019, when it entered into a license agreement with Amgen for a license to certain patents and know-how related to Amgen’s proprietary monoclonal antibody known as AMG-191, which we later renamed as JSP191.

Since Old Jasper’s inception in March 2018, we have devoted substantially all of our resources to performing research and development, enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and product candidates, performing business planning, establishing our intellectual property portfolio, raising capital and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and substantial losses for the foreseeable future as we continue our development of and seek regulatory approvals for our product candidates and commercialize any approved products, seek to expand our product pipeline and invest in our organization. We expect to incur increased expenses associated with operating as a public company, including significant legal, audit, accounting, regulatory, tax-related, director and officer insurance, investor relations and other expenses.

We have incurred significant losses and negative cash flows from operations since our inception. During the six months ended June 30, 2022 and 2021, we incurred net losses of \$12.6 million and \$18.2 million, respectively. We generated negative operating cash flows of \$23.6 million and \$12.0 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of \$80.1 million.

We had cash and cash equivalents of \$60.8 million as of June 30, 2022. Given our recurring losses from operations and negative cash flows, and based on our current operating plan, these funds would not be sufficient to fund our operations in the foreseeable future and we will need to raise additional financing. As a result, we concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date of our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. We may never achieve profitability, and unless we do and until then, we will need to continue to raise additional capital.

Our management plans to monitor expenses and raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and licensing arrangements. Our ability to access capital when needed is not assured and, if capital is not available to us when, and in the amounts, needed, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially harm our business, financial condition and results of operations.

We expect our expenses will increase substantially in connection with our ongoing and planned activities, as we:

- advance product candidates through preclinical studies and clinical trials;
- procure the manufacture of supplies for our preclinical studies and clinical trials;
- acquire, discover, validate, and develop additional product candidates;
- attract, hire and retain additional personnel;
- operate as a public company;
- implement operational, financial and management systems;
- pursue regulatory approval for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out; and
- obtain, maintain, expand, and protect our portfolio of intellectual property rights.

We do not currently own or operate any manufacturing facility. We rely on contract manufacturing organizations (“CMOs”) to produce our drug candidates in accordance with the FDA’s current good manufacturing practices (“cGMP”) regulations for use in our clinical studies. Under our license agreement with Amgen, we received a substantial amount of drug product to support initiation of our planned clinical trials of JSP191. Since November 2019, we have entered into development and manufacturing agreements with Lonza Sales AG (“Lonza”) relating to the manufacturing of JSP191 drug substance and drug product and product quality testing. The facility of Lonza in Slough, United Kingdom is responsible for production and testing of drug substance. The facility of Lonza in Stein, Switzerland is responsible for production and testing of drug product. Labelling, packaging and storage of finished drug product is provided by PCI Pharma Services, in San Diego, California.

Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from the sale of our product candidates, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Business Impact of the COVID-19 Pandemic

In March 2020, the World Health Organization declared the global COVID-19 outbreak a pandemic. The global COVID-19 pandemic continues to evolve rapidly, including with respect to the spread of variants, and we will continue to monitor it closely. While our operations to date have not been significantly impacted by the COVID-19 pandemic, we cannot at this time predict the specific extent, duration, or full impact that the continuing COVID-19 pandemic will have on our business, financial condition and operations, including ongoing and planned clinical trials and clinical development timelines, particularly as we advance our product candidates to clinical development, the continued spread of COVID-19 and its variants, including Omicron, and the measures taken by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our clinical trials, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, impede testing, monitoring, data collection and analysis and other related activities. The COVID-19 pandemic could also potentially affect the business of the FDA or other regulatory authorities, which could result in delays in meetings related to our ongoing and planned clinical trials. We experienced slower than anticipated patient enrollment in our SCID clinical trial in 2020 due to reluctance of these immunocompromised patients to travel and undergo hospitalization during the pandemic. We may continue to experience interruptions to our clinical trials due to the COVID-19 pandemic. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the pandemic, its impact on our clinical trial enrollment, trial sites, contract research organizations (“CROs”), CMOs, and other third parties with whom we do business, its impact on regulatory authorities and our key scientific and management personnel, progress of vaccination and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets or the overall economy are impacted for an extended period, our business may be materially adversely affected.

Business Impact of the Geopolitical Events

We are unable to predict the effect that geopolitical events, including the conflict in Ukraine and global inflation, may have on our operations. To the extent that geopolitical events adversely affect our business prospects, financial condition, and results of operations, they may also have the effect of exacerbating many of the other risks described or referenced in the section of our Form 10-Q titled “Risk Factors,” such as those relating to the supply of materials for our product candidates, and the timing and possible disruptions of our ongoing and future preclinical studies and clinical trials, and our access to the financial markets.

Components of Results of Operations

Operating Expenses

Research and Development

The largest component of our total operating expenses since our inception has been research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development employees, including stock-based compensation; expenses incurred under agreements with CROs and investigative sites that conduct preclinical and clinical studies; the costs of acquiring and manufacturing clinical study materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs; and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

External research and development costs include:

- costs incurred under agreements with third-party CROs, CMOs and other third parties that conduct preclinical and clinical activities on our behalf and manufacture our product candidates;
- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses;
- consulting fees associated with our research and development activities; and
- other costs associated with our research and development programs, including laboratory materials and supplies.

Internal research and development costs include:

- employee-related costs, including salaries, benefits and stock-based compensation expense for our research and development personnel; and
- other expenses and allocated overheads incurred in connection with our research and development programs.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates and expand our pipeline of product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved.

Our future research and development costs may vary significantly based on factors, such as:

- the scope, rate of progress, expense and results of our discovery and preclinical development activities;
- the costs and timing of our chemistry, manufacturing and controls activities, including fulfilling cGMP-related standards and compliance, and identifying and qualifying suppliers;
- per patient clinical trial costs;
- the number of trials required for approval;
- the number of sites included in our clinical trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable patients to participate in our clinical trials;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- patient drop-out or discontinuation rates;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities, including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;

- significant and changing government regulation and regulatory guidance;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of the current COVID-19 pandemic environment.

General and Administrative

General and administrative expenses consist primarily of personnel costs and expenses, including salaries, employee benefits, stock-based compensation for our executive and other administrative personnel; legal services, including relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; and facility and other allocated costs not otherwise included in research and development expenses. We expect our general and administrative expenses to increase substantially for the foreseeable future as we anticipate an increase in our personnel headcount to support expansion of research and development activities, as well as to support our operations generally. We also expect an increase in expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements; additional director and officer insurance costs; and investor and public relations costs.

Other Income (Expense), Net

Other income (expense), net includes changes in the fair value of common stock warrant liability and earnout liability, which were recorded at the closing of the Business Combination, changes in the fair value of our derivative tranche liabilities, which were settled in February 2021, foreign currency transactions gains and losses, and interest income. These financial instruments were classified as liabilities in our consolidated balance sheets and re-measured at each reporting period end until they are exercised, settled or have expired.

Results of Operations

Three Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended		Change	Change
	June 30,			
	2022	2021	\$	%
Operating expenses				
Research and development	\$ 8,135	\$ 5,156	\$ 2,979	58%
General and administrative	3,828	3,262	566	17%
Total operating expenses	<u>11,963</u>	<u>8,418</u>	<u>3,545</u>	<u>42%</u>
Loss from operations	(11,963)	(8,418)	(3,545)	42%
Change in fair value of earnout liability	625	-	625	100%
Change in fair value of common stock warrant liability	845	-	845	100%
Other income, net	89	4	85	*
Total other income, net	<u>1,559</u>	<u>4</u>	<u>1,555</u>	<u>*</u>
Net loss and comprehensive loss	<u>\$ (10,404)</u>	<u>\$ (8,414)</u>	<u>\$ (1,990)</u>	<u>24%</u>

* *not meaningful*

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended June 30,		Change \$	Change %
	2022	2021		
External costs:				
CRO, CMO and other third-party preclinical studies and clinical trials	\$ 2,087	\$ 2,470	\$ (383)	-16%
Consulting costs	1,224	812	412	51%
Other research and development costs, including laboratory materials and supplies	981	441	540	122%
Internal costs:				
Personnel-related costs	2,426	1,407	1,019	72%
Facilities and overhead costs	1,417	26	1,391	*
Total research and development expense:	<u>\$ 8,135</u>	<u>\$ 5,156</u>	<u>\$ 2,979</u>	58%

* *not meaningful*

Research and development expenses increased by \$3.0 million, from \$5.2 million for the three months ended June 30, 2021 to \$8.1 million for the three months ended June 30, 2022.

External clinical research organizations (“CRO”), contract manufacturing organization (“CMO”) and other third-party preclinical studies and clinical trials expenses decreased by \$0.4 million, from \$2.5 million for the three months ended June 30, 2021 to \$2.1 million for the three months ended June 30, 2022. The decrease is primarily due to decreased CMO product development and manufacturing expenses. Expenses related to professional consulting services increased by \$0.4 million, from \$0.8 million for the three months ended June 30, 2021 to \$1.2 million for the three months ended June 30, 2022. The increase is related to external consulting incurred to supplement our research and development personnel. Other external research and development costs increased by \$0.5 million from \$0.4 million for the three months ended June 30, 2021 to \$1.0 million for the three months ended June 30, 2022 due to increases in purchases of laboratory materials and supplies and other miscellaneous costs.

Our external costs by program for the three months ended June 30, 2022 and 2021 were as follows (in thousands):

	Three Months Ended June 30,	
	2022	2021
JSP191 platform	\$ 2,009	\$ 2,215
MDS/AML clinical trial	1,040	792
SCID clinical trial	519	542
Other	724	174
Total external costs	<u>\$ 4,292</u>	<u>\$ 3,723</u>

Personnel-related costs increased by \$1.0 million, from \$1.4 million for the three months ended June 30, 2021 to \$2.4 million for the three months ended June 30, 2022, due to an increase in headcount in our research and development organization in 2022 compared to 2021 period. Stock-based compensation expenses were \$0.6 million and \$0.3 million for the three months ended June 30, 2022 and 2021, respectively. Facilities and allocated overhead expenses increased by \$1.4 million, as we commenced using our laboratory space from July 2021 and increased our research and development headcount.

General and Administrative Expenses

General and administrative expenses increased by \$0.6 million, from \$3.3 million for the three months ended June 30, 2021 to \$3.8 million for the three months ended June 30, 2022. Employee payroll and related expenses increased by \$0.4 million, from \$0.7 million for the three months ended June 30, 2021 to \$1.1 million for the three months ended June 30, 2022, as a result of continued hiring of executives and administrative employees. Stock-based compensation expenses were \$0.5 million and \$0.2 million for the three months ended June 30, 2022 and 2021, respectively. Expenses related to professional services increased by \$0.1 million, from \$2.1 million for the three months ended June 30, 2021 to \$2.2 million for the three months ended June 30, 2022, due to increased spending on consulting, insurance costs, recruiting, legal, audit, accounting and other services to support our growing operations as a public company and as we continue to expand our operations to support our business strategy and product development.

Other Income, Net

Total other income, net increased by \$1.6 million from less than \$0.1 million net income for the three months ended June 30, 2021, to \$1.6 million net income for the three months ended June 30, 2022.

As of June 30, 2022, we have outstanding warrants to purchase an aggregate of 4,999,863 shares of our common stock, which were recognized upon the closing of the Business Combination on September 24, 2021. The warrants were concluded to be derivative financial instruments and are measured at fair value at each reporting period end until these are exercised, have expired or are redeemed. The warrants are publicly traded, and the fair value is estimated using the closing price of a warrant at the period end. We recognized \$0.8 million of other income related to the change in fair value of common stock warrants for the three months ended June 30, 2022, due to the decrease in the closing price of the warrants during the period.

Upon the closing of the Business Combination on September 24, 2021, we recognized earnout liability related to the Sponsor Earnout Shares placed in escrow. These shares will be released from escrow upon achieving agreed upon common stock price targets within the specified period. This liability is recorded at fair value using a Monte Carlo simulation model and is re-measured at each period end until shares are released or forfeited. The significant inputs used in the Monte Carlo model include the expected volatility of our common stock and the expected term when shares will be released. We recognized \$0.6 million of other income related to the change in the fair value of the earnout liability for the three months ended June 30, 2022, mainly due to the decrease in our common stock price during the period.

Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Six Months Ended		Change \$	Change %
	2022	2021		
Operating expenses				
Research and development	\$ 16,323	\$ 9,576	\$ 6,747	70%
General and administrative	8,418	5,096	3,322	65%
Total operating expenses	<u>24,741</u>	<u>14,672</u>	<u>10,069</u>	69%
Loss from operations	(24,741)	(14,672)	(10,069)	69%
Change in fair value of earnout liability	5,218	-	5,218	100%
Change in fair value of common stock warrant liability	6,895	-	6,895	100%
Change in fair value of derivative liability	-	(3,501)	3,501	-100%
Other income, net	17	5	12	*
Total other income (expense), net	<u>12,130</u>	<u>(3,496)</u>	<u>15,626</u>	-447%
Net loss and comprehensive loss	<u>\$ (12,611)</u>	<u>\$ (18,168)</u>	<u>\$ 5,557</u>	-31%

* *not meaningful*

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Six Months Ended June 30,		Change	Change
	2022	2021	\$	%
External costs:				
CRO, CMO and other third-party preclinical studies and clinical trials	\$ 5,505	\$ 4,184	\$ 1,321	32%
Consulting costs	2,151	1,779	372	21%
Other research and development costs, including laboratory materials and supplies	1,695	931	764	82%
Internal costs:				
Personnel-related costs	4,412	2,633	1,779	68%
Facilities and overhead costs	2,560	49	2,511	*
Total research and development expense:	<u>\$ 16,323</u>	<u>\$ 9,576</u>	<u>\$ 6,747</u>	70%

* *not meaningful*

Research and development expenses increased by \$6.7 million, from \$9.6 million for the six months ended June 30, 2021, to \$16.3 million for the six months ended June 30, 2022, mainly due to progression in the clinical trials, product development activities and hiring additional personnel.

External CRO, CMO and other third-party preclinical studies and clinical trials expenses increased by \$1.3 million, from \$4.2 million for the six months ended June 30, 2021 to \$5.5 million for the six months ended June 30, 2022. The increase is primarily related to an increase in our CRO expenses related to our ongoing SCID and MDS/AML clinical trials and increased CMO product development and manufacturing expenses. Expenses related to professional consulting services increased by \$0.4 million, from \$1.8 million for the six months ended June 30, 2021 to \$2.2 million for the six months ended June 30, 2022 and include costs related to external consulting incurred to supplement our research and development personnel. Other external research and development costs increased by \$0.8 million from \$0.9 million for the six months ended June 30, 2021 to \$1.7 million for the six months ended June 30, 2022 due to increases in purchases of laboratory materials and supplies and other miscellaneous costs.

Our external costs by program for the six months ended June 30, 2022 and 2021 were as follows (in thousands):

	Six Months Ended June 30,	
	2022	2021
JSP191 platform	\$ 4,600	\$ 4,222
MDS/AML clinical trial	1,988	1,404
SCID clinical trial	1,351	903
Other	1,412	365
Total external costs	<u>\$ 9,351</u>	<u>\$ 6,894</u>

Personnel-related costs increased by \$1.8 million, from \$2.6 million for the six months ended June 30, 2021 to \$4.4 million for the six months ended June 30, 2022, as we continue hiring employees in our research and development organization. Stock-based compensation expenses were \$0.8 million and \$0.6 million for the six months ended June 30, 2022 and 2021, respectively. Facilities and allocated overhead expenses increased by \$2.5 million, as we commenced using our laboratory space from July 2021 and increased our research and development headcount.

General and Administrative Expenses

General and administrative expenses increased by \$3.3 million, from \$5.1 million for the six months ended June 30, 2021 to \$8.4 million for the six months ended June 30, 2022. Employee payroll and related expenses increased by \$1.3 million, from \$1.2 million for the six months ended June 30, 2021 to \$2.5 million for the six months ended June 30, 2022, as a result of continued hiring of executives and administrative employees. Stock-based compensation expenses were \$1.0 million and \$0.3 million for the six months ended June 30, 2022 and 2021, respectively. Expenses related to professional services increased by \$1.6 million, from \$3.1 million for the six months ended June 30, 2021 to \$4.7 million for the six months ended June 30, 2022, due to increased spending on consulting, insurance costs, recruiting, legal, audit, accounting and other services to support our growing operations as a public company and as we continue to expand our operations to support our business strategy and product development.

Other Income (Expense), Net

Other income (expenses), net increased by \$15.6 million, from \$3.5 million net expense for the six months ended June 30, 2021 to \$12.1 million net income for the six months ended June 30, 2022.

As of June 30, 2022, we have outstanding warrants to purchase an aggregate of 4,999,863 shares of our common stock, which were recognized upon the closing of the Business Combination on September 24, 2021. The warrants were concluded to be derivative financial instruments and are measured at fair value at each reporting period end until these are exercised, have expired or are redeemed. The warrants are publicly traded, and the fair value is estimated using the closing price of a warrant at the period end. We recognized \$6.9 million of other income related to the change in fair value of common stock warrants for the six months ended June 30, 2022, due to the decrease in the closing price of the warrants during the period.

Upon the closing of the Business Combination on September 24, 2021, we recognized earnout liability related to the Sponsor Earnout Shares placed in escrow. These shares will be released from escrow upon achieving agreed upon common stock price targets within the specified period. This liability is recorded at fair value using a Monte Carlo simulation model and is re-measured at each period end until shares are released or forfeited. The significant inputs used in the Monte Carlo model include the expected volatility of our common stock and the expected term when shares will be released. We recognized \$5.2 million of other income related to the change in the fair value of the earnout liability for the six months ended June 30, 2022, mainly due to the decrease in our common stock price during the period.

We recognized a loss of \$3.5 million during the six months ended June 30, 2021 related to the change in fair value of our derivative tranche liability and did not have such expense in the 2022 period, as the derivative was settled in February 2021 and was no longer outstanding.

Liquidity and Capital Resources

Prior to the closing of the Business Combination, we funded our operations primarily from the issuance of redeemable convertible preferred stock shares and the issuance of convertible promissory notes. We received net cash proceeds of \$95.3 million at the closing of the Business Combination, which includes the remaining cash in our trust account after redemptions and the payment of the closing costs and \$100.0 million received from the PIPE Investors. As of June 30, 2022, we had \$60.8 million of cash and cash equivalents.

Future Funding Requirements – Going Concern

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, operate as a public company, further our research and development initiatives for our product candidates, scale our laboratory and manufacturing operations, and incur marketing costs associated with potential commercialization. We are subject to all the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We have incurred significant losses and negative cash flows from operations since our inception. As of June 30, 2022, we had an accumulated deficit of \$80.1 million. Given our recurring losses from operations and negative cash flows, and based on our current operating plan, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the issuance date of these condensed consolidated financial statements. We expect to finance our future cash needs through public or private equity or debt financings, collaborations or a combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders, and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt or making capital expenditures. Our ability to raise additional funds may be adversely impacted by negative global economic conditions and any disruptions to and volatility in the credit and financial markets in the United States and worldwide or other factors. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

Our future financing requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, preclinical and non-clinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and costs of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to conduct additional studies or generate additional data beyond that which we currently expect would be required to support a marketing application;
- the costs of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- any product liability or other lawsuits related to our product candidates;
- the revenue, if any, received from commercial sales of any product candidates for which we may receive marketing approval;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses incurred to attract, hire and retain skilled personnel; and
- the costs of operating as a public company.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with the development of our product candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

Cash Flows

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

	Six Months Ended	
	June 30,	
	2022	2021
Net cash used in operating activities	\$ (23,569)	\$ (11,986)
Net cash used in investing activities	(272)	(1,247)
Net cash provided by financing activities	26	10,152
Net decrease in cash and cash equivalents and restricted cash	<u>\$ (23,815)</u>	<u>\$ (3,081)</u>

Cash Flows Used in Operating Activities

Net cash used in operating activities was \$23.6 million and \$12.0 million for the six months ended June 2022 and 2021, respectively.

Cash used in operating activities in the six months ended June 30, 2022 was primarily due to our net loss for the period of \$12.6 million, adjusted by non-cash net gain of \$9.7 million and a net change of \$1.3 million in our net operating assets and liabilities. The non-cash amounts consisted of \$12.1 million net gain related to the changes in fair value of common stock warrant liability and the earnout liability, reduced by non-cash expenses, which included \$1.8 million related to stock-based compensation expense, \$0.4 million related to depreciation and amortization expense and \$0.2 million non-cash lease expense. The changes in our net operating assets and liabilities were primarily due to a decrease of \$1.0 million in accounts payable due to the timing of payments to our vendors, a decrease of \$0.9 million in accrued expenses and other current liabilities and a decrease of \$0.2 million in operating lease liability, partially offset by a decrease of \$0.7 million in prepaid expenses, an increase of \$0.1 million in other non-current liabilities and other current assets and a decrease of \$0.1 million in other non-current assets.

Cash used in operating activities during the six months ended June 30, 2021 was primarily due to our net loss for the period of \$18.2 million, adjusted by non-cash charges of \$4.4 million and a net change of \$1.8 million in our net operating assets and liabilities. The non-cash charges consisted of \$3.5 million related to changes in the fair value of the derivative tranche liabilities, \$0.6 million related to stock-based compensation expense, \$0.2 million of non-cash operating lease expense and \$0.1 million of depreciation expense. The changes in our net operating assets and liabilities were primarily due to an increase of \$1.6 million in accounts payable, an increase of \$1.1 million in accrued expenses and other current liabilities, an increase of \$0.7 million in prepaid expenses and other current assets, an increase of \$0.7 million in other non-current assets, a decrease of \$0.6 million in other receivables and a \$0.2 million decrease in other non-current liabilities. The increase in accounts payable and accrued liabilities resulted from the timing of payments to our service providers.

Cash Flows Used in Investing Activities

Cash used in investing activities was \$0.3 million and \$1.2 million for the six months ended June 2022 and 2021, respectively, which primarily consisted of purchases of the lab equipment and leasehold improvements.

Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2022 was less than \$0.1 million, which consisted of cash received from exercised of stock options.

Cash provided by financing activities for the six months ended June 30, 2021 was \$10.2 million, which consisted primarily of net proceeds from the issuance of Series A-1 redeemable convertible preferred stock shares upon the settlement of the second tranche liability of \$10.8 million and proceeds from exercise of common stock options of \$0.1 million, partially offset by a \$0.7 million payment of offering costs.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with CROs for clinical trials, with CMOs for clinical supplies manufacturing and with other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is cancelled within a specified time, and therefore are cancelable contracts. We do not expect any such contracts terminations and do not have any non-cancellable obligations under these agreements as of June 30, 2022.

We have contractual obligations and commitments as described in Note 9, *Commitments and Contingencies*, within our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Leases

In August 2020, we leased approximately 7,781 square feet of space for our headquarters in Redwood City, California. In January 2022, we amended our lease agreement and added 5,611 square feet, previously leased on a month-to-month basis, to our lease agreement. The lease will expire in August 2026, but we have an option to extend the term for an additional five years to August 2031. In addition to base rent, we pay our share of operating expenses and taxes. As of June 30, 2022, our rent commitments under the amended lease agreement are \$1.1 million within the next 12 months from June 30, 2022 and \$3.6 million for the remainder of the lease term.

Critical Accounting Policies and Significant Judgments and Estimates

Our critical accounting policies are disclosed in Note 2 of the notes to the consolidated financial statements included in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 18, 2022. Since the date of such financial statements, there have been no material changes to our significant accounting policies other than those described in Note 2 of the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Recently Issued Accounting Pronouncements

See Note 2 to the condensed consolidated financial statements for more information regarding recently issued accounting pronouncements.

JOBS Act

The Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”) exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a U.S. Securities Act of 1933, as amended, registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have opted to take advantage of the exemption for complying with new or revised accounting standards within the same time periods as private companies, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following November 22, 2024, (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 means the market value of our common equity that is held by non-affiliates exceeds \$700 million as of the last business day of its most recently completed second fiscal quarter; and (ii) the date on which we have issued more than \$1.00 billion in non-convertible debt securities during the prior three-year period. References herein to “emerging growth company” have the meaning associated with it in the JOBS Act.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We had cash and cash equivalents of \$60.8 million as of June 30, 2022, which consisted of checking account and money market funds. Historical fluctuations in interest rates have not been significant for us, and we believe a hypothetical 10% change in interest rates during any of the periods presented would not have had a material effect on our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report. We had no outstanding debt as of June 30, 2022. To minimize risk in the future, we intend to maintain our portfolio of cash equivalents in institutional market funds that are composed of U.S. Treasury and U.S. Treasury-backed repurchase agreements or short-term U.S. Treasury securities.

Foreign Currency Exchange Risk

All of our employees are currently located in the United States; however, we do utilize certain vendors outside of the United States for our manufacturing of drug substances and clinical supplies. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our condensed consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 10% change in exchange rates during any of the periods presented would not have a material effect on our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and in the future our clinical trial costs. We believe that inflation has not had a material effect on our interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the Securities and Exchange Commission under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q at the reasonable assurance level.

Changes in Internal Controls

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently party to, and none of our property is currently the subject of, any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below before deciding whether to invest in our common stock. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under “Cautionary Note Regarding Forward-Looking Statements”, you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described below are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission (the “SEC”) before making an investment decision regarding our common stock. Risk factors marked with an asterisk (*) below include a substantive change from or an update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 18, 2022.

- Risks Related to Our Financial Position and Need for Additional Capital, including, among others, that:
 - We have incurred significant net losses and negative operating cash flows since our inception. We expect to incur net losses for the foreseeable future and may never achieve or maintain profitability.
 - We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our research and product development programs or future commercialization efforts.
 - As a result of our history of losses and negative cash flows from operations, our condensed consolidated financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.
- Risks Related to Discovery, Development, Manufacturing and Commercialization, including, among others, that:
 - We are substantially dependent on the success of our most advanced product candidate, JSP191. If we are unable to complete development of, obtain approval for and commercialize our product candidates, including JSP191, in a timely manner or at all, our business will be harmed.
 - We may not be successful in our efforts to identify, develop and commercialize additional product candidates. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.
 - mRNA stem cell grafts are a novel technology that is not yet clinically validated for human use. The approaches we are taking to create mRNA stem cell grafts are unproven and may never lead to marketable products.

- If any of our product candidates cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidate, limit our commercial potential or result in significant negative consequences following any potential marketing approval.
 - Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities. In addition, our clinical trials to date have been limited in scope, and results received to date may not be replicated in expanded or additional future clinical trials.
 - We have never obtained regulatory approval for a drug, may never receive regulatory approval for any of our product candidates, and may therefore never generate revenues from product sales.
 - We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.
 - Risks Related to Regulatory Review, including, among others, that:
 - If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.
 - Stem cell transplant is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials or for patients that use any of our product candidates, if approved.
 - Risks Related to Our Relationships with Third Parties, including, among others, that:
 - We rely on third parties to conduct our preclinical and clinical trials and will rely on them to perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
 - We currently rely on a single manufacturer for our clinical supply of our product candidates. In the event of a loss of this manufacturer, or a failure by such manufacturer to comply with the U.S. Food and Drug Administration (“FDA”) regulations, we may not be able to find an alternative source on commercially reasonable terms, or at all.
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- Risks Related to Our Intellectual Property, including, among others, that:
 - We are highly dependent 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.
 - Our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology.
- Risks Related to Ownership of Our Common Stock and Warrants, including, among others, that we will incur significant increased expenses and administrative burdens as a public company, which could negatively impact our business, financial condition and results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

**We have incurred significant net losses and negative operating cash flows since our inception. We expect to incur net losses for the foreseeable future and may never achieve or maintain profitability.*

We are a clinical-stage biotechnology company dedicated to enabling cures through hematopoietic stem cell therapy and have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved 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. As a result, we are not profitable and have incurred losses and negative operating cash flows in each period since our inception. For the six months ended June 30, 2022 and 2021, we reported net losses of \$12.6 million and \$18.2 million, respectively. For the six months ended June 30, 2022 and 2021, we reported negative operating cash flows of \$23.6 million and \$12.0 million, respectively. As of June 30, 2022, we had an accumulated deficit of \$80.1 million. We have devoted all of our efforts to organizing and staffing our company, business and scientific planning, raising capital, acquiring and developing technology, identifying potential product candidates, undertaking research and preclinical studies of potential product candidates, developing manufacturing capabilities and evaluating a clinical path for our pipeline programs. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue the open label Phase 1/2 clinical trial for JSP191 for SCID, and the open label Phase 1 clinical trial for JSP191 in patients with MDS or AML;
- continue the clinical development of JSP191 in autoimmune diseases and other indications;
- continue our current research programs and development of other potential product candidates from our current research programs;
- seek to identify additional product candidates and research programs;
- initiate preclinical testing and clinical trials for any other product candidates we identify and develop;
- maintain, expand, enforce, defend and protect our intellectual property portfolio, and provide reimbursement of third-party expenses related to our patent portfolio;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;

- adapt our regulatory compliance efforts to incorporate requirements applicable to any approved product candidates;
- further develop our genome engineering capabilities;
- hire additional research and development and clinical personnel;
- hire commercial personnel and advance market access and reimbursement strategies;
- add operational, financial and management information systems and personnel, including personnel to support our product development;
- acquire or in-license product candidates, intellectual property and technologies;
- develop or in-license manufacturing and distribution technologies;
- should we decide to do so and receive approval for any of our product candidates, build and maintain, or purchase and validate, commercial-scale manufacturing facilities designed to comply with current Good Manufacturing Practices (“cGMP”) requirements; and
- incur additional legal, accounting and other expenses in operating as a public company.

As a company, we have not completed clinical development of any product candidate and expect that it will be several years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including identifying product candidates, completing preclinical testing and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements.

We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. Our product candidates and research programs are currently only in the early stages of development. Because of the numerous risks and uncertainties associated with developing product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

****We will need substantial additional funding, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our research and product development programs or future commercialization efforts.***

We expect to spend substantial amounts of cash to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any product candidates for which we receive regulatory approval. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and product development programs or future commercialization efforts. As of June 30, 2022, our cash and cash equivalents were \$60.8 million and we had an accumulated deficit of \$80.1 million. Our future financing requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates, including any COVID-19-related delays or other effects on our development programs;
- the costs of continuing to build our technology platform, including in-licensing additional genome engineering technologies for use in developing our product candidates;
- the costs of developing, acquiring or in-licensing additional targeted therapies to use in combination with JSP191 and other product candidates we may develop;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending intellectual property-related claims in the United States and internationally;
- the number and characteristics of product candidates that we develop or may in-license;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we enter into;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medical Agency (the “EMA”) and other comparable foreign regulatory authorities;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the costs of operating as a public company.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, even if we successfully develop product candidates and those are approved, we may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of product candidates or other research and development initiatives. Our license agreements and any future collaboration agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements. We could be required to seek collaborators for 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 product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

In addition, as AMHC was a shell company prior to the completion of our business combination with AMHC in September 2021 (the “Business Combination”), we are currently ineligible for new short-form registration statements on Form S-3 and will not be eligible to file such a registration statement until, among other things, at least 12 calendar months have lapsed since September 29, 2021, the date we filed a Current Report on Form 8-K disclosing that we ceased to be a shell company. Our inability to use Form S-3 may significantly impair our ability to raise necessary capital to run our operations and progress our product development programs. If we seek to access the capital markets through a registered offering during the period of time that we are unable to use Form S-3, we may be required to publicly disclose the proposed offering and the material terms thereof before the offering commences, we may experience delays in the offering process due to SEC review of a Form S-1 registration statement and we may incur increased offering and transaction costs and other considerations. Disclosing a public offering prior to the formal commencement of an offering may result in downward pressure on our stock price. If we are unable to raise capital through a registered offering, we would be required to conduct our equity financing transactions on a private placement basis, which may be subject to pricing, size and other limitations imposed under the rules of The Nasdaq Stock Market LLC, or seek other sources of capital.

As a result of our recurring losses from operations and recurring negative cash flows from operations, our management concluded that there is a substantial doubt about our ability to maintain liquidity sufficient to operate our business effectively, which raise substantial doubt about our ability to continue as a going concern. See the risk factor below titled, “*As a result of our history of losses and negative cash flows from operations, our condensed consolidated financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.*” Based on our current operating plan, we will need to raise additional financing to continue our products’ development for the foreseeable future, and until we become profitable. If we are unable to obtain funding when and as needed on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. 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.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We are a clinical stage company. Old Jasper was founded and commenced operations in March 2018. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates and undertaking preclinical studies and clinical trials. Although we have initiated clinical trials for JSP191, we have not yet demonstrated an ability to successfully complete clinical trials of our product candidates; obtained marketing approvals; manufactured a commercial-scale medicine or therapy, or arranged for a third party to do so on our behalf; or conducted sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions we 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 have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates. We do not anticipate generating revenues from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our future collaborators', ability to successfully:

- identify product candidates and complete research and preclinical and clinical development of any product candidates we may identify;
- seek and obtain regulatory and marketing approvals for any product candidates for which we complete clinical trials;
- launch and commercialize any product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualify for coverage and adequate reimbursement by government and third-party payors for any product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;

- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any product candidates for which we obtain regulatory and marketing approval;
- obtain market acceptance of product candidates as viable treatment options;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter, and perform our obligations in such arrangements;
- maintain, protect, enforce, defend and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how, in the United States and internationally;
- avoid and defend against third-party interference, infringement and other intellectual property claims in the United States and internationally; and
- attract, hire and retain qualified personnel.

Even if one or more of the product candidates we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate.

Many of the factors listed above are beyond our control, and could cause us to experience significant delays or prevent us from completing the development of our product candidates, obtaining regulatory approvals or commercializing our product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. A failure to become or remain profitable could result in a decline in the value of our company and could also cause you to lose all or part of your investment.

As a result of our history of losses and negative cash flows from operations, our condensed consolidated financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.

Our history of operating losses and negative cash flows from operations combined with our anticipated use of cash to fund operations raises substantial doubt about our ability to continue as a going concern beyond the 12-month period from the issuance date of our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. Based on our current operating plan, we will need to raise additional financing to continue our products' development for the foreseeable future, and until we become profitable. Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities or to raise additional capital to finance our operations.

The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence by investors and employees. Our condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our condensed consolidated financial statements, and it is likely that our investors will lose all or a part of their investment.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

As of December 31, 2021, we had net operating loss carryforwards for federal income tax purposes of \$53.1 million that can be carried forward indefinitely. As of December 31, 2021, we had net operating loss carryforwards for state income tax purposes of \$45.4 million that begin to expire in 2038. Portions of these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the “Tax Act”), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), U.S. federal net operating losses incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited. It is uncertain how various states will respond to the Tax Act and the CARES Act. For state income tax purposes, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is 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 income or taxes may be limited. Our existing net operating loss carryforwards may be subject to limitations arising out of previous ownership changes and we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes, including the Business Combination and related transactions. In addition, future changes in our stock ownership, including future offerings, as well as other changes that may be outside of our control, could result in additional ownership changes. We have completed a Section 382 analysis covering taxable periods from its inception through the year ended December 31, 2021. We experienced an ownership change on November 21, 2019 for both federal and California tax purposes related to its Series A redeemable convertible preferred stock financing. Any net operating loss generated for taxable periods in 2018 and through November 21, 2019 in excess of \$2.87 million will be permanently limited for California tax purposes. We reduced our California net operating loss deferred tax assets balance by the permanently limited amount of \$0.6 million. There would be no permanent loss of federal net operating loss based on the limits. We experienced an additional ownership change on September 24, 2021. However, we do not expect there are additional tax attributes that will expire unused before the expiration periods. There is a full valuation allowance for net deferred tax assets, including net operating loss carryforwards for the year ended December 31, 2021.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the current COVID-19 pandemic and future outbreaks of the disease, in regions where we or third parties on which we rely have concentrations of clinical trial sites or other business operations.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the current COVID-19 pandemic and future outbreaks of the disease, including any variants thereof. For example, enrollment in clinical trials may be delayed. Although we have reopened our offices and some employees have transitioned back to working on site, there is a lack of uniformity of restrictions and requirements among our clinical trial sites, and future restrictions could be imposed. We are subject to risk of outbreaks at our facilities, and potential exposure to employee claims regarding workplace safety, and unanticipated shutdowns or quarantines could be imposed in the future, which would disrupt our operations. This uncertainty and the evolving nature of policies and restrictions may negatively impact productivity, disrupt our business and further delay clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course, which could negatively impact our business, operating results and financial condition.

The spread of COVID-19, which has caused a broad impact globally, may affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it has resulted in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 or the global impacts thereof could materially affect our business and the value of our common stock. The global COVID-19 pandemic continues to evolve, and its ultimate impact or that of any similar health pandemic or epidemic is highly uncertain. We do not yet know the full extent of potential delays or impacts on our business, our planned and ongoing clinical trials, the hospitals and healthcare systems or the global economy as a whole. These effects could have an adverse impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Business disruptions caused by natural or man-made disasters, acts of war or other hostilities could seriously harm our future revenues and financial condition and increase our costs and expenses generally.

Our corporate headquarters are located in the San Francisco Bay Area, a region known for seismic activity. Our suppliers may also experience a disruption in their business as a result of natural or man-made disasters. A significant natural or man-made disaster, such as an earthquake, prolonged or repeated power outage, hurricane, flood, fire, drought or other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts, acts of war or the outbreak of hostilities against the U.S. or other countries globally, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Discovery, Development, Manufacturing and Commercialization

We are substantially dependent on the success of our most advanced product candidate, JSP191. If we are unable to complete development of, obtain approval for and commercialize our product candidates, including JSP191, in a timely manner or at all, our business will be harmed.

Our future success is dependent on our ability to timely advance and complete clinical trials, obtain marketing approval for and successfully commercialize our product candidates. We are not permitted to market or promote JSP191 or any other product candidate before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on several factors, including the following:

- the acceptance of individual investigational review boards (“IRBs”) and scientific review committees at each clinical trial site as to the adequacy of the preclinical data package to support clinical development of JSP191 and their overall general agreement with the use of JSP191 in the intended patient population in the intended manner;
- the willingness of clinical investigators to place patients in the clinical trials, and the willingness of patients to enroll in a clinical trial studying a first-in-human cell therapy;
- the initiation and successful patient enrollment and completion of additional clinical trials of JSP191 on a timely basis;
- the frequency and severity of adverse events in the clinical trials;
- the successful and timely completion of our ongoing Phase 1/2 clinical trial of JSP191 for the treatment of SCID and the ongoing Phase 1 clinical trial of JSP191 for AML or MDS;

- maintaining and establishing relationships with contract research organizations (“CROs”) and clinical sites for the clinical development of JSP191 both in the United States and internationally;
- successful completion of toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable;
- successful completion of clinical trials, under the FDA’s current Good Clinical Practices (“cGCPs”) and the FDA’s current Good Laboratory Practices;
- effective investigational new drug (“IND”) applications or Clinical Trial Authorizations that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- the results of clinical trials conducted by third parties in hematopoietic stem cell transplant (“HSCT”) if such trials result in changes to the standard of care for HSCT or otherwise cause us to change our clinical trial protocols;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party suppliers and manufacturers for clinical development of JSP191;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of JSP191, if it is approved;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors;
- our ability to obtain coverage and adequate reimbursement from third-party payors for our products, and patients’ willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and
- our ability to compete with other treatments.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize JSP191, which would materially harm our business. If we do not receive marketing approvals for JSP191, we may not be able to continue our operations.

We may not be successful in our efforts to identify, develop and commercialize additional product candidates. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.

The success of our business depends primarily upon our ability to identify, develop and commercialize additional product candidates based on, or complementary with, our technology platform. While we are currently conducting a Phase 1/2 clinical trial of JSP191 as a conditioning agent prior to allogeneic transplant for SCID patients, a Phase 1 clinical trial of JSP191 as a conditioning agent prior to allogeneic transplant for patients with AML or MDS, and are planning a registrational clinical trial of JSP191 as a conditioning agent prior to allogeneic transplant, all of our other product development programs, including our mRNA stem cell grafts platform, are still in the research or preclinical stage of development. Our research programs may fail to identify additional product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates, our potential product candidates may be shown to have harmful side effects in preclinical in vitro experiments or animal model studies, they may not show promising signals of efficacy in such experiments or studies or they may have other characteristics that may make the product candidates impractical to manufacture, unmarketable or unlikely to receive marketing approval. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. In addition, although we believe our technology platform will position us to rapidly expand our portfolio of product candidates beyond our current product candidates, our ability to expand our portfolio may never materialize.

If any of these events occur, we may be forced to abandon our research or development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations and prospects. 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, which would be costly and time-consuming.

****We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

mRNA stem cell grafts are a novel technology that is not yet clinically validated for human use. The approaches we are taking to create mRNA cell grafts are unproven and may never lead to marketable products.

We are developing mRNA stem cell grafts for transplant into the human body. Although there have been significant advances in the field of use of RNA or DNA to edit cells ex vivo prior to transplant in recent years, these technologies have only more recently been applied to HSCs, and our approach is new and unproven. The scientific evidence to support the feasibility of developing mRNA stem cell grafts is both preliminary and limited. Successful development of mRNA stem cell grafts by us will require solving a number of challenges, including:

- obtaining regulatory authorization from the FDA and other regulatory authorities;
- identifying appropriate molecular or genetic targets for modification within HSCs;
- developing and deploying consistent and reliable processes for procuring cells from consenting third-party donors, isolating HSCs from such donor cells, modifying target molecules within such HSCs, storing and transporting the resulting mRNA stem cell grafts for therapeutic use and finally infusing these mRNA stem cell grafts into patients;

- utilizing these mRNA stem cell graft product candidates in combination or in sequence with companion therapeutics, which may increase the risk of adverse side effects;
- avoiding potential complications of mRNA stem cell graft transplants, including failure to engraft, rejection by host or lack of functionality, any of which could result in serious side effects or death;
- educating medical personnel regarding the potential side effect profile of our product candidates, particularly those that may be unique to our mRNA stem cell grafts;
- understanding and addressing variability in the quality of a donor's cells, which could ultimately affect our ability to manufacture product in a reliable and consistent manner;
- developing processes for the safe administration of mRNA stem cell graft product candidates, including long-term follow-up and registries, for all patients who receive these product candidates;
- relying on third parties to find suitable healthy donors;
- manufacturing product candidates to our specifications and in a timely manner to support our clinical trials and, if approved, commercialization;
- sourcing clinical and, if approved by applicable regulatory authorities, commercial supplies for the materials used to manufacture and process product candidates;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment; and
- establishing sales and marketing capabilities ahead of and after obtaining any regulatory approval to gain market acceptance, and obtaining coverage, adequate reimbursement and pricing by third-party payors and governmental healthcare programs.

We may decide to alter or abandon our initial mRNA stem cell grafts platform as new data become available and we gain experience in developing mRNA stem cell grafts. We cannot be sure that our programs will yield satisfactory products that are safe and effective, scalable or profitable in our initial indication or any other indication we pursue.

Moreover, actual or perceived safety issues, including as a result of adverse developments in our mRNA stem cell graft platform or in genome engineering programs undertaken by third parties or of the adoption of novel approaches to treatment, may adversely influence the willingness of subjects to participate in our clinical trials, or, if one of our product candidates is approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics or of patients to provide consent to receive a novel treatment despite its regulatory approval. The FDA or other applicable regulatory authorities may require specific post-market studies or additional information that communicates the benefits or risks of our products. New data may reveal new risks of our product candidates at any time prior to or after regulatory approval.

If any of our product candidates cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidate, limit our commercial potential or result in significant negative consequences following any potential marketing approval.

Undesirable side effects or adverse events caused by JSP191 and our other product candidates, and our mRNA stem cell grafts or other cell-based companion therapeutics we may develop, could cause us or regulatory authorities 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 comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trials or result in potential product liability claims.

There have been no clinical trials of mRNA stem cell grafts. In the genetic medicine field, there have been several significant adverse events from genetically engineered treatments in the past, including reported cases of leukemia and death. There can be no assurance that our mRNA stem cell grafts will not cause undesirable side effects, as improper modification of a patient's DNA could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells.

A significant risk in any genetically engineered product candidate is that "off-target" gene alterations may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. Although we and others have demonstrated the ability to improve the specificity of gene alterations in a laboratory setting, we cannot be certain that off-target alterations will not occur in any of our planned or future clinical trials, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical trials.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further clinical development of the product candidates.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities. In addition, our clinical trials to date have been limited in scope, and results received to date may not be replicated in expanded or additional future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. There can be no assurance that any of our current or future preclinical and clinical trials will ultimately be successful or support further preclinical or clinical development of any of our product candidates. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for their product candidates. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Any such adverse events may cause us to delay, limit or terminate planned clinical trials, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

In some instances, there can be significant variability in safety or efficacy results between different 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 dosing regimen and other clinical trial procedures and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidate, and, correspondingly, our business and financial prospects would be negatively impacted.

If we experience delays or difficulties in the enrollment of patients in clinical trials, the cost of developing product candidates could increase and our receipt of necessary regulatory approvals could be delayed or prevented.

Patient enrollment is a significant factor in the timing of clinical trials. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials. We or our collaborators may not be able to continue clinical trials for JSP191 or any other product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to the biotechnology, gene therapy or genome engineering fields, competitive clinical trials for similar patient populations, clinical trials in competing products or for other reasons. As a result, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of product candidates may be delayed.

Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- size of the patient population and process for identifying patients;
- design of the trial protocol;
- availability and efficacy of approved medications for the disease under investigation;
- availability of genetic testing for potential patients;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- perceived risks and benefits of genome engineering as a treatment approach;
- perceived risks and benefits of the companion therapeutics that may be administered in combination or in sequence with JSP191;
- efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients, especially for those conditions that have small patient pools;
- the requirement for HSCT to be performed in centers that specialize in this procedure; and
- changes to diagnostic technologies, methodologies or criteria used to identify HSCT patients at high risk for relapse.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor. We may 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.

Enrollment delays in our clinical trials may result in increased development costs for JSP191 or any other product candidates we may develop, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We have never obtained regulatory approval for a drug, may never receive regulatory approval for any of our product candidates, and may therefore never generate revenues from product sales.

As a company, we have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all future product candidates for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any current or future product candidates. If the FDA does not approve any future product candidates, it may require that we conduct additional costly clinical, preclinical or manufacturing validation studies before the FDA will reconsider one or more of our applications. Depending on the extent of these or any other FDA-required studies, approval of any product candidates or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing JSP191 or any other product candidate, generating revenues and achieving and obtaining or sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any new drug application or other application we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payers and operators of major clinics, and we may not be successful in attaining such market acceptance.

Even with the requisite approvals from the FDA in the U.S., the EMA in the European Union and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including our management's time and financial resources, and may not be successful. Ethical, social and legal concerns about genetic medicines generally and genome engineering technologies specifically could result in additional regulations restricting or prohibiting the marketing of our product candidates. Even if any product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any product candidate we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidate as demonstrated in clinical trials;
- the efficacy and safety of other products that are used in combination or in sequence with our product candidates;
- the potential and perceived advantages of our product candidates compared to alternative treatments;

- the limitation to our targeted patient population and limitations or warnings contained in approved labeling by the FDA or other regulatory authorities;
- the ability to offer our products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the EMA or other regulatory agencies;
- public attitudes regarding genetic medicine generally and genome engineering technologies specifically;
- the willingness of the target patient population to try novel biologics and of physicians to prescribe these treatments, as well as their willingness to accept an intervention that involves the alteration of the patient's gene;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- availability of third-party coverage and sufficiency of reimbursement; and
- the prevalence and severity of any side effects.

Even if a product candidate is approved, such product may not achieve an adequate level of acceptance, we may not generate significant product revenues, and we may not become profitable.

If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We have limited marketing capabilities and limited experience in the sale, marketing or distribution of pharmaceutical products. In addition, we do not have a large sales, promotion and marketing budget. As a result of our limited marketing capabilities, to achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- restricted or closed distribution channels that make it difficult to distribute our product candidates to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

We may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.

The development and commercialization of new drug and biologic products is highly competitive. Moreover, the genome engineering and oncology fields are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We will face competition with respect to JSP191 and any other product candidates that we develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have product candidates and research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for our product candidates. This may include other types of therapies, such as small molecule, antibody and/or protein therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our product candidates or that would render our product candidates obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates against competitors.

Competitors of JSP191 for our conditioning program for CD-117, a receptor for stem cell factor (“SCF”) that is expressed on the surface of hematopoietic stem and progenitor cells, include the following:

- Magenta Therapeutics, Inc., which is developing an Amanitin Anti-CD117 antibody drug conjugate and is in clinical development;
- Gilead Sciences, Inc., which is developing an antibody to CD117 that is not conjugated to any toxin and is used in combination with an antibody to CD47 and has started initial Phase I clinical studies;
- Actinium Pharmaceuticals, Inc., which is developing an antibody to CD45 that is linked to radioisotope iodine-131 and is in Phase III clinical studies;
- Molecular Templates Inc., which is developing an antibody to CD45 that is conjugated to engineered Shiga-toxin and is in preclinical development; and
- Celldex Therapeutics, Inc., which is developing an antibody to inhibit tyrosine kinase KIT found in mast cells and is in Phase I/II clinical studies in indications unrelated to conditioning.

Competitors for our mRNA stem cell grafts platform include the following:

- Gamida Cell Ltd., which is developing an umbilical cord blood-derived cell product that uses a small molecule to inhibit differentiation and enhance functionality of *ex vivo*-expanded HSCs;
- ExCellThera Inc., which is focused on *ex vivo* expansion of stem cells using a pyrimido-indole derivative small molecule;
- Angiocrine Bioscience, Inc., which is expanding cord blood and gene-modified HSCs using an endothelial cell feeder layer;

- Sana Biotechnology, Inc., which is developing hypoimmune cells designed to evade rejection and enable persistence of allogeneic cells;
- Vor Biopharma, Inc., which is developing treatment-resistant marrow cells that enable CD33 targeted therapy; and
- Ensoma Inc., which is developing viral vectors for delivery of cell modification payload, in vivo.

Adverse public perception of genetic medicines, and genome engineering in particular, may negatively impact regulatory approval of, and/or demand for, our potential products.

Some of our mRNA stem cell grafts or other cell-based therapeutics we develop may be created by altering the human genome. The clinical and commercial success of our potential products will depend in part on public understanding and acceptance of the use of genome engineering for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that genome engineering is unsafe, unethical or immoral, and, consequently, our current or future product candidates may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

In addition, genome engineering technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of genome engineering technology to human embryos or the human germline. For example, in the United States, germline alteration for clinical application has been expressly prohibited since enactment of a December 2015 FDA ban on such activity. Prohibitions are also in place in the United Kingdom, across most of Europe, in China and many other countries around the world. In the United States, the National Institutes of Health has announced that the agency would not fund any use of gene engineering technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey-Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing genome engineering technologies, even if not ultimately attributable to product candidates we may identify and develop, and the accompanying publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

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

- the inability to commercialize any products that we may develop;
- decreased demand for our product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients; and
- loss of revenue.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercializes any product. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our product candidates are complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates, or otherwise harm our business.

Our product candidates require processing steps that are more complex than those required for most chemical and other biological pharmaceuticals. Moreover, unlike chemical and other biological pharmaceuticals, the physical and chemical properties of a gene-engineered cell therapies cannot be fully characterized. As a result, assays of the finished product candidate may not be sufficient to ensure that the product candidate will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our clinical trials. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. In addition, our product candidates will require complicated delivery modalities, such as electroporation, which will introduce additional complexities into the manufacturing process.

mRNA stem cell grafts consist of engineered human cells, and the process of manufacturing such product candidates is complex, concentrated with a limited number of suppliers, highly regulated and subject to numerous risks. Manufacturing such product candidates involves harvesting cells from a donor or from the patient, altering the cells *ex vivo* using genome engineering technology, cryopreservation, storage and eventually shipment and infusing the cell product into the patient's body. Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with the collection of starting material from the donor, shipping such material to the manufacturing site, shipping the final product back to the clinical trial recipient, preparing the product for administration, infusing the patient with the product, manufacturing issues or different product characteristics resulting from the differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth and variability in product characteristics. Our manufacturing process, like that of a number of other cell therapy companies, is also characterized by limited numbers of suppliers, and in some cases sole source suppliers, with the manufacturing capabilities and know-how to create or source the materials, such as donor marrow cells and electroporation machines, used in our cell manufacturing. While we pursue multiple sources for the critical components of our manufacturing process, we may not be successful in securing these additional sources at all or on a timely basis. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which our product candidates or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

In addition, the FDA, the EMA and other regulatory authorities may require us to submit samples of any lot of approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other regulatory authorities may require that we not distribute a lot until the 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 clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations and prospects.

If we or any contract research organizations, contract manufacturers or suppliers that we engage 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 and any contract research organizations, contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. Although we believe that our and such third parties' procedures for handling, storing and disposing of these materials and waste comply with legally prescribed standards, 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development and research efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. For example, our products are considered to contain genetically modified organisms or cells, which are regulated in different ways depending upon the country in which preclinical research or clinical trials are conducted. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any third-party contract research organizations, contract manufacturers and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Regulatory Review

**If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.*

Before obtaining marketing approval from regulatory authorities for the sale of JSP191 and any other product candidates we identify and develop, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

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

- delays in reaching a consensus with regulators on trial design;
- regulators, IRBs, independent ethics committees or scientific review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching or failing to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective CROs and clinical trial sites;
- clinical trials of product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development or research programs;
- difficulty in designing well-controlled clinical trials due to ethical considerations that may render it inappropriate to conduct a trial with a control arm that can be effectively compared to a treatment arm;
- difficulty in designing clinical trials and selecting endpoints for diseases that have not been well-studied and for which the natural history and course of the disease is poorly understood;
- the number of patients required for clinical trials of JSP191 and any other product candidates we may develop may be larger than we anticipate; enrollment of suitable participants in these clinical trials, which may be particularly challenging for some of the rare genetically defined diseases we are targeting in our most advanced programs, may be delayed or slower than we anticipate; or patients may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, IRBs or independent ethics committees may require that we or our investigators suspend or terminate clinical research or clinical trials for various reasons, including noncompliance with regulatory requirements, a finding of undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks or after an inspection of our clinical trial operations or trial sites;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with product candidates that are viewed to outweigh their potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

If we or our collaborators, if any, are required to conduct additional clinical trials or other testing of product candidates beyond those that we currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our collaborators may:

- be delayed in obtaining marketing approval for any such product candidates or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution in the form of a Risk Evaluation and Mitigation Strategy (“REMS”) or through modification to an existing REMS;
- be sued; or
- experience damage to our reputation.

Product development costs will also increase if we or our collaborators experience delays in clinical trials or other testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize product candidates, could allow our competitors to bring products to market before we do and could impair our ability to successfully commercialize product candidates, any of which may harm our business, financial condition, results of operations and prospects.

Further, disruptions at the FDA and other agencies may prolong 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, including the FDA, have furloughed critical employees and stopped 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.

Stem cell transplant is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials or for patients that use any of our product candidates, if approved.

Stem cell transplant has the potential to cure patients across multiple diseases, but its use carries with it risks of toxicity, serious adverse events and death. Because many of our therapies are used to prepare or treat patients undergoing stem cell transplant, patients in our clinical trials or patients that use any of our product candidates may be subject to many of the risks that are currently inherent to this procedure. In particular, stem cell transplant involves certain known potential post-procedure complications that may manifest several weeks or months after a transplant and that may be more common in certain patient populations. For example, up to 20% of patients with inherited metabolic disorders treated with a transplant experience primary engraftment failure, resulting in severe complications, including death. Another example is autoimmune cytopenia, a known and severe frequent complication of the transplant procedure in patients with non-malignant diseases, such as inherited metabolic diseases, that can result in death. There is also a risk of graft-versus-host disease, a potentially serious complication in which the grafted cells attack and damage the patient's healthy cells, which can be severe and sometimes life-threatening. If these or other serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of stem cell transplant or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects are continually monitored per the clinical trial's approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our product candidates, we would follow the trial protocol's requirements, which call for our data safety monitoring committee to review all available clinical data in making a recommendation regarding the trial's continuation.

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any product candidates we develop in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any jurisdiction, which would materially impair our ability to generate revenue.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union on December 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or the European Union for any product candidates, which could significantly and materially harm our business.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially adversely affect our business, financial condition, results of operations and prospects.

Marketing approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates we may develop in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be unrealized.

Even if we obtain regulatory approval of any of our product candidates, the approved products may be subject to post-approval studies and will remain subject to ongoing regulatory requirements. If we fail to comply, or if concerns are identified in subsequent studies, our approval could be withdrawn, and our product sales could be suspended.

If we are successful at obtaining regulatory approval for JSP191 or any of our other product candidates, regulatory agencies in the U.S. and other countries where a product will be sold may require extensive additional clinical trials or post-approval clinical trials that are expensive and time-consuming to conduct. These studies may be expensive and time-consuming to conduct and may reveal side effects or other harmful effects in patients that use our therapeutic products after they are on the market, which may result in the limitation or withdrawal of our drugs from the market. Alternatively, we may not be able to conduct such additional trials, which might force us to abandon our efforts to develop or commercialize certain product candidates. Even if post-approval studies are not requested or required, after our products are approved and are on the market, there might be safety issues that emerge over time that require a change in product labeling, additional post-market studies or clinical trials, imposition of distribution and use restrictions under a REMS or withdrawal of the product from the market, which would cause our revenue to decline.

Additionally, any products that we may successfully develop will be subject to ongoing regulatory requirements after they are approved. These requirements will govern the manufacturing, packaging, marketing, distribution, and use of our products. If we fail to comply with such regulatory requirements, approval for our products may be withdrawn, and product sales may be suspended. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and/or damage to our reputation.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established cellular therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval. The FDA and other governing bodies may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our product candidates.

Because our product candidates and technology platform involve genetic and cellular engineering, we are subject to many of the challenges and risks that other genetically engineered biologics and cellular therapies face, including:

- regulatory requirements or guidance regarding the requirements governing genetic and cellular engineering products have changed and may continue to change in the future;
- to date, only a limited number of products that involve genetic or cellular engineering have been approved globally;
- improper modulation of a gene sequence, including unintended alterations or insertion of a sequence into certain locations in a patient's chromosomes, could lead to cancer, other aberrantly functioning cells or other diseases, as well as death;
- corrective expression of a missing protein, or deletion of an existing protein, in patients' cells could result in the protein or cell being recognized as foreign, and lead to a sustained immunological reaction against the expressed protein or expressing cells, which could be severe or life-threatening;
- regulatory agencies may require extended follow-up observation periods of patients who receive treatment using genetic or cellular engineering products including, for example, the FDA's recommended 15-year follow-up observation period for these patients, and we will need to adopt such observation periods for our product candidates if required by the relevant regulatory agency, which could vary by country or region; and
- the fields of genetic and cellular engineering are subject to a number of intellectual property disputes.

The regulatory requirements that will govern any mRNA stem cell grafts or other novel genetically engineered product candidates we develop may change. Within the broader genetic medicine field, we are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies ("OTAT") within its Center for Biologics Evaluation and Research ("CBER") to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In addition to FDA oversight and oversight by IRBs under guidelines promulgated by the National Institutes of Health ("NIH"), gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical study can begin at any institution, that institution's IRB and its IBC assess the safety of the research and identify any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene or cellular therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual gene or cellular therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial even if the FDA has reviewed the trial and approved its initiation.

The same applies in the European Union. The EMA's Committee for Advanced Therapies ("CAT") is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a cell or gene therapy or other novel therapeutic medicinal candidate that is submitted to the Committee for Medicinal Products for Human Use ("CHMP") before CHMP adopts its final opinion. In the European Union, the development and evaluation of an advanced therapeutic medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for these medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene and cell therapy products may be applied to our mRNA stem cell grafts, but that remains uncertain at this point.

Adverse developments in post-marketing experience or in clinical trials conducted by others of gene therapy products, cell therapy products or products developed through the application of a genome engineering technology may cause the FDA, the EMA and other regulatory bodies to revise the requirements for development or approval of our mRNA stem cell grafts may develop or limit the use of products utilizing genome engineering technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates, such as our mRNA stem cell grafts, can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome engineering technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our product candidate development, research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. Currently, OTAT requires a 15-year follow-up for each patient who receives a genetically engineered cell or gene therapy. This requirement applies to all patients treated in trials during clinical development prior to approval. Following approval, such prolonged follow-up could continue to be required. As we advance our product candidates and research programs, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our mRNA stem cell grafts and any other product candidates we identify and develop.

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

From time to time, we may publish interim top-line or preliminary results from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. In particular, we have announced, and may in the future announce, interim results from our ongoing, open label Phase 1/2 and Phase 1 clinical trials of JSP191. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and us in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact public perception of our future product candidates.

Our potential therapeutic products involve introducing genetic material into patients' cells. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. For example, in 2003, trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy, and we cannot assure that it will not occur in any of our planned or future clinical trials. In addition, there is 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 products used to carry the genetic material. If any such adverse events occur, commercialization of our product candidates or further advancement of our clinical trials could be halted or delayed, which would have a negative impact on our business and operations.

We may seek Fast Track or other accelerated review designations for some or all of our product candidates. We may not receive such designation, and even for those product candidates for which we do, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that product candidates will receive marketing approval.

We may seek Fast Track or other accelerated review designations for some or all of our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for FDA Fast Track designation, for which sponsors must apply. If granted, a Fast Track or other accelerated review designation makes a product candidate eligible for more frequent interactions with the FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that we can submit completed sections of our marketing application for review prior to completion of the entire submission. Marketing applications of product candidates with a Fast Track or other accelerated review designation may qualify for priority review under the policies and procedures offered by the FDA, but a Fast Track or other accelerated review designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion with respect to whether or not to grant this designation. Thus, even if we believe a particular product candidate is eligible for this designation, the FDA may decide not to grant it. Moreover, even if we do receive a Fast Track or another accelerated review designation, we or our collaborators may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw a Fast Track or other accelerated review designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek priority review designation for our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

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 may seek a Breakthrough Therapy Designation for our product candidates if the clinical data support such a designation for one or more 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. Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for 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 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 approval compared to drugs considered for approval 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 such qualification.

The regenerative medicine advanced therapy (“RMAT”) designation by the FDA 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 may seek an RMAT designation for our product candidates if the clinical data support such a designation for one or more product candidates. An RMAT is defined as cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine therapy. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. A biologics license application for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval. An RMAT may be eligible for priority review if it treats a serious condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment of the condition. An RMAT may be eligible for accelerated approval through surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

Designation as an RMAT is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a RMAT, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for our product candidates may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for RMAT designation, the FDA may later decide that the biological products no longer meet the conditions for such qualification.

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or EMA from approving other competing products.

Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we may seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the “same drug” for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA issued recent draft guidance suggesting that it would not consider two genetic medicine products to be different drugs solely based on minor differences in the transgenes or vectors within a given vector class. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

In 2017, Congress passed the FDA Reauthorization Act of 2017 (the “FDARA”). FDARA, among other things, codified the FDA’s pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to any drug and biologic that received orphan drug designation before enactment of FDARA in 2017 but has not yet been approved or licensed by the FDA. 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.

****Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to cleared or approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have furloughed critical FDA employees and stopped 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. Increased cases associated with a COVID-19 variant led the FDA to again pause inspections, although the FDA announced in February 2022 that it would resume routine domestic surveillance inspections and that it would proceed with certain foreign surveillance inspections where country conditions permit. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Relationships with Third Parties

We rely on third parties to conduct our preclinical and clinical trials and will rely on them to perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

Although we have recruited a team that has experience with clinical trials, as a company, we have limited experience in conducting clinical trials. Moreover, we do not have the ability to independently conduct preclinical studies and clinical trials, and we have relied upon, and plan to continue to rely upon, medical institutions, clinical investigators, contract laboratories and other third parties, or our CROs, to conduct preclinical studies and future clinical trials for our product candidates. We expect to rely heavily on these parties for execution of preclinical and future clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our preclinical and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including cGCPs for conducting, monitoring, recording and reporting the results of preclinical and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, 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, the FDA will determine that any of our future clinical trials will comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in the FDA's current cGMPs requirements. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design our planned clinical trials for our product candidates, for the foreseeable future CROs will conduct all of our planned clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less day-to-day control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs 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, regulatory requirements or for other reasons, any preclinical studies or clinical trials with which such CROs are associated with may be extended, delayed or terminated. In such cases, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates in the subject indication could be harmed, our costs could increase and our ability to generate revenue could be delayed.

We currently rely on a single manufacturer for our clinical supply of our product candidates. In the event of a loss of this manufacturer, or a failure by such manufacturer to comply with FDA regulations, we may not be able to find an alternative source on commercially reasonable terms, or at all. In addition, third-party manufacturers and any third-party collaborators may be unable to successfully scale-up manufacturing of our current or future product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

We do not have any manufacturing facilities at the present time. We currently rely on third-party manufacturers, including Lonza Sales AG ("Lonza") as a single source supplier, for the manufacture and supply of our materials for preclinical studies, and expect to continue to do so for future clinical testing and for commercial supply of JSP191 and any other product candidates that we may develop and for which we or our collaborators obtain marketing approval. Our agreement with Lonza includes certain limitations on our ability to enter into supply arrangements with any other supplier without Lonza's consent. In addition, Lonza has the right to increase the prices it charges us for certain supplies depending on a number of factors, some of which are outside of our control. We may be unable to maintain or establish any agreements with third-party manufacturers or suppliers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers or suppliers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing or supply agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and

- reliance on the third party for regulatory compliance, quality assurance, safety and pharmacovigilance and related reporting.

In addition, pursuant to our Exclusive License Agreement with Amgen Inc., Lonza Biologics, Inc. has been engaged to manufacture JSP191 for us. The agreement provides that in the event we wish to change the manufacturer of JSP191 to a different party, we must obtain Amgen Inc.'s prior consent. As a result, our ability to obtain any alternative supplier of JSP191 may be further limited.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers or suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business, financial condition, results of operations and prospects.

Our product candidates may compete with other product candidates and products for access to manufacturing facilities and other supplies. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Also, prior to the approval of our product candidates, we would need to identify a contract manufacturer that could produce our products at a commercial scale and that could successfully complete FDA pre-approval inspection and inspections by other health authorities. Agreements with such manufacturers or suppliers may not be available to us at the time we would need to have that capability and capacity.

Any performance failure on the part of our existing or future manufacturers or suppliers, or any decision by a manufacturer or supplier to remove our products from the market or restrict access to our products, could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant or guaranteed supply for many of the materials we currently use in our clinical trials or preclinical studies, and we may have difficulty or be unable to establish alternative sources of these materials.

We may enter into collaborations with third parties for the research, development and commercialization of certain product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may seek third-party collaborators for the research, development and commercialization of certain product candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our current or future product candidates or research programs pose numerous risks to us, including the following:

- Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

- Collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such products.
- Collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates our agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q apply to the activities of our collaborators.

These relationships, or those like them, 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.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of JSP191 or any other product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to develop product candidates or bring them to market and generate product revenue.

Risks Related to Our Intellectual Property

We are highly dependent 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 the patents, know-how and proprietary technology licensed from third parties for the development and, if approved, commercialization of JSP191. Any termination of these licenses, or a finding that such intellectual property lacks legal effect, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates.

For example, we rely on our worldwide exclusive license agreement with Amgen Inc., whereby we license a patent portfolio from Amgen Inc. applicable to our targeted conditioning program that contains patent families directed to humanized C-kit antibody. We also rely on our license agreement with Stanford, whereby we license a patent portfolio applicable to our targeted conditioning and Stem Cell Graft programs that contains patent families directed to immunodepletion of endogenous stem cell niche for engraftment.

Each of our license agreements with third parties impose certain obligations on us, including obligations to use diligent efforts to meet development thresholds and payment obligations. Non-compliance with such obligations may result in termination of the respective license agreement or in legal and financial consequences. If any of our licensors terminates its respective license agreement, we may not be able to develop or commercialize JSP191 or any other product candidates covered by these agreements. Termination of our license agreements or reduction or elimination of our rights under them may result in us having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop, commercialize or sell the affected product candidate or may cause us to lose our rights under the agreement.

In addition, our licensors may make decisions in prosecuting, maintaining, enforcing and defending any licensed intellectual property rights that may not be in our best interest. Moreover, if our licensors take any action with respect to any licensed intellectual property rights, for example, any licensed patents or patent applications, that results in a successful challenge to the licensed intellectual property by a third party, such patents may be invalidated or held to be unenforceable, and we may lose our rights under such patents, which could materially harm our business.

Further, the agreements under which we currently license intellectual property from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us with the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates.

Our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology.

Our commercial success depends in large part on our ability to obtain, maintain and protect intellectual property rights through patents, trademarks and trade secrets in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary position, we own and have in-licensed certain intellectual property rights, including certain issued patents and patent applications, and have filed and may file provisional and non-provisional patent applications in the United States or abroad related to our product candidates that are important to our business. Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of the filing of one or more of our related provisional patent applications. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. Moreover, the patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent application, prosecution, and enforcement processes are subject to numerous risks and uncertainties, and there can be no assurance that we, our licensors, or any of our future collaborators will be successful in protecting our product candidates by obtaining, defending, and/or asserting patent rights. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office (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;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

In some instances, agreements through which we license intellectual property rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain or successfully enforce necessary or desirable patent protection from those patent rights. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

Moreover, some of our in-licensed patents and patent applications may be, and some of our future owned and licensed patents may be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The patent protection we obtain for our product candidates may not be sufficient enough to provide us with any competitive advantage or our patents may be challenged.

Our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or may not prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Currently, a significant portion of our patents and patent applications are in-licensed, though similar risks would apply to any patents or patent applications that we now own or may own or in-license in the future.

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, whether current or future, 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.

In addition, the determination of patent rights with respect to clinical compositions of matter and treatment methods commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than U.S. law does. If these changes were to occur, they could have a material adverse effect on our ability to generate revenue.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first party to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first party to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter parties review, supplemental examinations, or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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.

Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products or pursue similar strategies in the United States or other jurisdictions, in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Other parties have developed or may develop technologies that may be related to or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same materials, formulations or methods, or by claiming subject matter that could dominate our patent position. In addition, certain parts or all of the patent portfolios licensed to us are, or may be, licensed to third parties and such third parties may have or may obtain certain enforcement rights. If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our licensed patents have, or that any of our pending owned or licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage, nor can we provide any assurance that our licenses will remain in force.

In addition, 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.

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

In addition to the protection afforded by patents, we rely upon trade secret protection, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights under these agreements may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim against a third party that illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing or unwilling to protect trade secrets. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. Competitors and other third parties could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating 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 markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. Our company name and logo, as well as our product candidate names “JSP191” and “JSP502”, are not registered trademarks. If we seek to register any of our trademarks, during trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, 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 to seek to cancel 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. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may not be successful in acquiring or in-licensing necessary rights to key technologies underlying JSP191 or any future product candidates we may develop.

We currently have rights to intellectual property, through licenses from third parties, to develop JSP191, and we expect to seek to expand our intellectual property footprint related to our product candidate pipeline in part by in-licensing the rights to key technologies. The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to develop additional product candidates and technologies. Although we have succeeded in licensing technologies from third-party licensors, including Amgen Inc. and Stanford, in the past, we can give no assurance that we will be able to in-license or acquire the rights to other technologies relevant to our product candidates from third parties on acceptable terms or at all.

In order to market our product candidates, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. However, it may be unclear who owns the rights to intellectual property we wish to obtain, or we may be unable to secure such licenses or otherwise acquire or in-license intellectual property rights from third parties that we identify as necessary for product candidates we may develop and technology we employ. For example, we employ a range of genome engineering technologies that are owned by third parties in our preclinical studies, as well as to manufacture the supply of mRNA stem cell grafts or other cell therapies used for clinical trials and, if approved, for commercialization of our product candidates. We currently conduct our preclinical research and clinical trials under 35 U.S.C. § 271(e)(1), which provides a safe harbor from patent infringement for uses of patented technology reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.

The licensing or acquisition of third-party intellectual property rights is a highly competitive area, and other companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. Such companies may have a competitive advantage over us, e.g., due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product discovery and development efforts and have a material adverse effect on our business.

Our commercial success depends in part on us avoiding infringement, misappropriation and other violations 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 and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including *inter partes* review and post grant review have been implemented. This reform will bring uncertainty to the possibility of challenge to our patents in the future. 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, and 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 and may file patent infringement claims or lawsuits against us, and if we are found to infringe such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all.

There may be third-party patents with patent rights to materials, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our product candidates. Because 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. Further, we or our licensors may fail to identify even those relevant third-party patents that have issued or may incorrectly interpret the relevance, scope or expiration of such patents. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or scope of a patent or a pending application may be incorrect. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, materials 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 materials, formulations or methods, including without limitation, 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.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would involve a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion, which may result in significant cost and may impede our inability to pursue any affected products or product candidates. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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.

Some intellectual property that we have in-licensed may have been discovered through government-funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Any of the intellectual property rights that we have licensed or may license in the future and that have been generated through the use of U.S. government funding are subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 (“Bayh-Dole Act”). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government would have the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any such intellectual property rights to a third party if it determines that:

- adequate steps have not been taken to commercialize the invention;
- government action is necessary to meet public health or safety needs; or
- government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”).

The U.S. government also has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh-Dole Act at all times, or be able to rectify any lapse in compliance with these requirements.

In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent’s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, defending and enforcing patents on our 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 drugs and may export otherwise infringing drugs to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These drugs may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce 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, which could adversely affect our business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension (PTE) and data exclusivity for JSP191 or any other product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and conditions of any FDA marketing approval of our 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, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended; the extension cannot extend the total patent term beyond 14 years from approval; and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

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

We employ individuals who were previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may also be subject to claims that patents and applications that we may file to protect inventions of our employees or consultants are rightfully owned by their former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing would harm our business, financial condition, results of operations, and prospects.

Risks Related to Other Legal Compliance Matters

If any of our product candidates are approved, an unfavorable reimbursement determination in any of the major markets could have a negative impact on us. Further, an unfavorable change in such regimes (e.g., price controls) could have a negative impact on us.

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. In the U.S., recently enacted 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 medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and 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. For example, in May 2019, the Centers for Medicare & Medicaid Services (“CMS”) issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization for Medicare Part B drugs, beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019.

Congress and the Biden administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures 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. Also, increasingly, 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. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or 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 reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the U.S. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new medicines, 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 medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines 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 medicines from countries where they may be sold at lower prices than in the U.S. Any such reductions could negatively impact our net product sales, if any of our product candidates are ever approved.

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.

The FDA and other regulatory agencies closely regulate the post approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off label use, and if we do not market our medicines for their approved indications, we may be subject to enforcement action for off label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown problems with our medicines, third-party manufacturers, or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such medicines, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine;

- requirements to conduct post marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of medicines;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our medicines;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations, and prospects.

Additionally, if any of our product candidates receives marketing approval, the FDA could require it to adopt a Risk Evaluation and Mitigation Strategy, to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to healthcare practitioners. Furthermore, if we or others later identify undesirable side effects caused by any of our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way such product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include, but are not limited to, the following:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering, or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, in cash or in kind, to induce, or in return for, either the referral of an individual, for the purchase, lease, order or recommendation of any item, good, facility or service for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal false claims, including the False Claims Act that can be enforced through whistleblower actions, false statements and civil monetary penalties laws, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which, prohibits, among other things, executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false, fictitious, or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;
- the federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the CMS within the U.S. Department of Health and Human Services, information related to payments or other transfers of value made during the previous year to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such obligations include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws also require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures. Certain state laws also require the reporting of information related to drug pricing. Further, certain state and local laws require the registration of pharmaceutical sales representatives.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices, including certain of our advisory board arrangements with physicians, some of whom are compensated in the form of stock or stock options, may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The European Union has strict laws governing the provision of benefits or advantages to healthcare professionals in order to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products. Such laws and associated codes of practice set out the rules and requirements that the provision of hospitality, sponsorship, gifts and promotional items must meet before they can be accepted by healthcare professionals. The provision of benefits or advantages to healthcare professionals is also governed by the national anti-bribery laws of European Union Member States. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to healthcare professionals in certain European Union Member States may be publicly disclosed. Moreover, agreements with healthcare professionals often must be the subject of prior notification and approval by the healthcare professionals' employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Healthcare and other reform legislation, may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize JSP191 and any other product candidates we may develop and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been, and continue to be, ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. Such changes could prevent or delay marketing approval of JSP191 and any other product candidates that we may develop, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Although we cannot predict what healthcare or other reform efforts will be successful, such efforts may result in more rigorous coverage criteria, in additional downward pressure on the price that we, or our future collaborators, may receive for any approved products or in other consequences that may adversely affect our ability to achieve or maintain profitability.

Within the United States, the federal government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the ACA and the ongoing efforts to modify or repeal that legislation. The ACA substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. There are, and may continue to be, judicial challenges, including review by the United States Supreme Court. We cannot predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

Federal and state governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, waivers from Medicaid drug rebate law requirements, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The private sector has also sought to control healthcare costs by limiting coverage or reimbursement or requiring discounts and rebates on products. We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures could significantly decrease the available coverage and the price we might establish for our potential products, which would have an adverse effect on our net revenues and operating results.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations for biological products will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval and decision-making processes may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

****The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.***

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal 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 products. To those ends, in October 2020, the FDA issued final guidance that describes procedures drug manufacturers can follow to facilitate importation of prescription drugs, including biological products, that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country.

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 organizations 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 approved, 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.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. 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 candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and commercial partners, and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA, the EMA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We may be subject to numerous laws and regulations in each jurisdiction outside of the United States in which we may operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act (the “FCPA”), prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Similarly, the U.K. Bribery Act 2010 has extra-territorial effect for companies and individuals having a connection with the United Kingdom. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition and results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (the "GDPR"), which took effect across all member states of the European Economic Area (the "EEA") in May 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 increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act — which went into effect on January 1, 2020 — is creating similar risks and obligations as those created by the GDPR, though the California Consumer Privacy Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). In March 2020, the California State Attorney General proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General commenced enforcement actions against violators beginning July 1, 2020. In addition, a new California privacy law, the California Privacy Rights Act (the "CPRA") was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Further, a new Virginia privacy law, Virginia Consumer Data Protection Act, or VCDPA, was signed into law on March 2, 2021 and is also scheduled to take effect on January 1, 2023, and the Colorado Privacy Act, or CPA, will take effect on July 1, 2023. The VCDPA and CPA will impose many similar obligations regarding the processing and storing of personal information as the California Consumer Privacy Act and the CPRA. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition and results of operations.

We and our partners may be subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and changes in such laws, regulations, policies or how they are interpreted or changes in contractual obligations could adversely affect our business.

There are numerous U.S. federal and state data privacy and protection laws and regulations that apply to the collection, transmission, processing, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to properly protect the privacy and security of health-related information or other sensitive or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents.

****Previously enacted state laws in California seek to impose gender and diversity quotas for boards of directors of public companies headquartered in California.***

In September 2018, California enacted Senate Bill 826 (“SB 826”), which generally required public companies with principal executive offices in California to have at least two female directors on its board of directors if the company has at least five directors, and at least three female directors on its board of directors if the company has at least six directors. On May 13, 2022, the Los Angeles Superior Court declared SB 826 unconstitutional and, although it is unclear whether this decision may be appealed, the State of California is currently precluded from enforcing SB 826.

Additionally, on September 30, 2020, California enacted Assembly Bill 979 (“AB 979”), which generally required public companies with principal executive offices in California to include specified numbers of directors from “underrepresented communities”. A director from an “underrepresented community” means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. By December 31, 2021, each public company with principal executive offices in California was required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors would be required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors would need to have a minimum of three directors from underrepresented communities. On April 1, 2022, the Los Angeles Superior Court declared AB 979 unconstitutional and, although it is unclear whether this decision may be appealed, the State of California is currently precluded from enforcing AB 979.

If the State of California successfully appeals the court decisions regarding SB 826 or AB 979, we cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender or diversity quotas as previously required by SB 826 or AB 979, and our board of directors does not currently satisfy the quota previously required under SB 826 and, as currently constituted, would not satisfy the quota previously required by December 31, 2022 under AB 979. A failure to comply with any such quota requirement could result in fines from the California Secretary of State, and our reputation may be adversely affected.

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

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

In addition, the SEC has announced proposed rules that, among other matters, will establish a framework for reporting of climate-related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.

Risks Related to Employee Matters, Managing Growth and Information Technology

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to continue developing and to identify and develop new or next generation product candidates will be impaired, which could result in delays in the development process, loss of market opportunities, make us less competitive and have a material adverse effect on our business, financial condition and results of operations.

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, particularly our Chief Executive Officer, the members of our executive team, and key scientific and medical personnel employees. The loss of the services of any of our executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business.

We conduct our operations at our facility in the San Francisco Bay Area. 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.

To induce 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. In addition, we may experience employee turnover as a result of the ongoing “great resignation” occurring throughout the U.S. economy, which has impacted job market dynamics. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. Although we have employment agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We and our management have a limited track record as an operating company. Failures in the operational execution of the expected business plans may have a material impact on our commercial prospects. Further, if we are not able to attract and retain highly-qualified personnel, we may not be able to successfully implement our business strategy.

Our management team has worked together for only a limited period of time and has a limited track record of executing our business plan as a team. In addition, we have recently filled a number of positions in our finance and accounting staff. Accordingly, certain key personnel have only recently assumed the duties and responsibilities they are now performing, and it is difficult to predict whether our management team, individually and collectively, will be effective in operating our business. These changes may cause speculation and uncertainty regarding our commercial prospects and may cause or result in:

- disruption of our business or distraction of our employees and management;
- difficulty in recruiting, hiring, motivating, and retaining talented and skilled personnel;
- stock price volatility; and
- difficulty in negotiating, maintaining, or consummating business or strategic relationships or transactions.

If we are unable to mitigate these risks or to attract and retain highly qualified personnel, our revenue, operating results and financial condition may be adversely impacted.

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

As of June 30, 2022, we had 35 full-time employees. As our development, manufacturing and commercialization plans and strategies develop and we continue our operations as a public company, we expect to need and are actively recruiting additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and international regulatory 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 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 management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by 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. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or if 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 for further development and commercialization of our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

We have limited director and officer insurance and commercial insurance policies. Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks; we may not be able to obtain appropriate insurance coverage; and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Our internal computer systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

Our internal computer systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we seek to protect our information technology systems from system failure, accident and security breach, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

Although we take such steps to help protect confidential and other sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, failures, or breaches due to third-party action, employee negligence or error, malfeasance, or other incidents or disruptions. For example, we could be the target of phishing attacks seeking confidential information regarding our employees. Furthermore, while we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some health-related and other personal information or confidential information may be transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit health-related and other personal information or confidential information to us.

To the extent that we or these third parties are found to have violated such laws, rules or regulations or that any disruption or security breach were to result in a loss of, or damage to, us or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

As widely reported, global credit and financial markets have experienced volatility and disruptions in the past several years and especially in 2020 and 2021 and year to date 2022 due to the impacts of the COVID-19 pandemic, and, more recently, the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, 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 assurances 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, 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 share price and could require us to delay or abandon clinical development plans.

****The impact of the Russian invasion of Ukraine on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.***

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and several European and Asian countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the war in Ukraine may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

Risks Related to Ownership of Our Common Stock and Warrants

**If our operations and performance do not meet the expectations of investors or securities analysts or for other reasons, the market price of our securities may decline, and the market price of our common stock may continue to be volatile.*

Any of the factors listed below could have a negative impact on your investment in our securities, and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the impacts of the ongoing COVID-19 pandemic and related restrictions;
- the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia and the impact thereof on the markets generally, including any adverse effects on macroeconomic conditions such as inflation;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our business or management;
- recruitment or departure of key personnel;

- overall performance of the equity markets;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the U.S. or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, Nasdaq and pharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. The trading price of our common stock is, and is likely to continue to be, volatile. For example, from September 24, 2021, the date of the closing of the Business Combination, to June 30, 2022, our closing stock price ranged from \$1.73 to \$16.42 per share. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the prices at which they purchased their shares. Moreover, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

Insiders have substantial control over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

As of June 30, 2022, our directors and executive officers and their affiliates beneficially owned approximately 36.5% of the outstanding shares of our common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control, even if that change in control would benefit our other stockholders. This significant concentration of ownership may also adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders.

We will incur significant increased expenses and administrative burdens as a public company, which could negatively impact our business, financial condition and results of operations.

We face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of those requirements will require us to carry out activities we had not done previously. For example, we have adopted new charters for our board committees and adopted some new disclosure controls and procedures. In addition, expenses associated with SEC reporting requirements will be incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of us. It may also be more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand our business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could negatively impact our business.

Absent an applicable exemption, we are required to provide a management’s attestation on internal controls over financial reporting, and we were not previously required to do this as a private company. The standards required for a public company under Section 404(a) of the Sarbanes-Oxley Act are significantly more stringent than those required of us when we were a privately held company. Management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements. If we are not able to implement the additional requirements of Section 404(a) in a timely manner or with adequate compliance, we may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our securities.

We are an “emerging growth company” within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We are an “emerging growth company” as defined in Section 2(a)(19) of the U.S. Securities Act of 1933, as amended (the “Securities Act”), as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including, but not limited to, (a) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (b) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (c) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following November 22, 2024, (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 means the market value of our common equity that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; and (ii) the date on which we have issued more than \$1.00 billion in non-convertible debt securities during the prior three-year period. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be; there may be a less active trading market for our securities; and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have opted to take advantage of the exemption for complying with new or revised accounting standards within the same time periods as private companies, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our condensed consolidated financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a “smaller reporting company,” which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. If we cease to be an emerging growth company and do not qualify as a smaller reporting company, we will no longer be able to take advantage of certain exemptions from reporting discussed above, including not being able to take advantage of extended transition periods for the adoption of new or modified accounting standards, and, absent other exemptions or relief available from the SEC, we will also be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act if we are no longer a non-accelerated filer at such time. We will incur additional expenses in connection with such compliance, and our management will need to devote additional time and effort to implement and comply with such requirements.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us. If no or few analysts commence coverage of us, the trading price of our securities would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our securities, the price of our securities could decline. If one or more of these analysts cease to cover our securities, we could lose visibility in the market for our securities, which in turn could cause the price of our securities to decline.

****Future sales, or the perception of future sales, by us or our stockholders in the public market, the issuance of rights to purchase our common stock, including pursuant to the Equity Incentive Plan and the ESPP, and future exercises of registration rights could result in the additional dilution of the percentage ownership of our stockholders and cause the market price for our common stock to decline.***

The sale of shares of our common stock, convertible securities or other equity securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. In addition, if we sell shares of our common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock.

Pursuant to the Jasper Therapeutics, Inc. 2021 Equity Incentive Plan (the “Equity Incentive Plan”), which became effective on September 23, 2021, we are authorized to grant equity awards to our employees, directors and consultants. In addition, pursuant to the Jasper Therapeutics, Inc. 2021 Employee Stock Purchase Plan (the “ESPP”), which became effective on September 23, 2021, we are authorized to sell shares to our employees. A total of up to 4,400,000 and up to 550,000 shares of our common stock were initially reserved for future issuance under the Equity Incentive Plan and the ESPP, respectively. In addition, the Equity Incentive Plan and ESPP provide for annual automatic increases in the number of shares reserved thereunder, in each case, beginning on January 1, 2022. On January 1, 2022, pursuant to the foregoing provisions, 1,514,204 and 378,551 shares of common stock were added to the shares reserved for future issuance under the Equity Incentive Plan and the ESPP, respectively. As a result of such annual increases, our stockholders may experience additional dilution, which could cause the price of our common stock to fall.

On March 14, 2022, the Compensation Committee of our board of directors adopted the 2022 Inducement Equity Incentive Plan (the “2022 Inducement Plan”). The maximum number of shares available for grant under the 2022 Inducement Plan is 3,000,000 shares of common stock. The 2022 Inducement Plan has not been and will not be approved by our stockholders. Under the 2022 Inducement Plan, we can grant nonstatutory stock options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards and other awards, but only to an individual, as a material inducement to such individual to enter into employment with us or an affiliate of ours, who (i) has not previously been an employee or director of ours or (ii) is rehired following a bona fide period of non-employment with us.

As of June 30, 2022, options to purchase an aggregate of 2,575,215 shares of our common stock were outstanding that were previously issued under the Jasper Therapeutics, Inc. 2019 Equity Incentive Plan (the “2019 EIP”). We assumed the 2019 Plan in connection with the Business Combination and no further awards will be granted under the 2019 EIP. However, shares of our common stock subject to outstanding awards granted under the 2019 EIP that (a) are not issued because the award or any portion of the award expires or otherwise terminates without all of the shares covered by the award having been issued, (b) are withheld or reacquired to satisfy the exercise, strike or purchase price or (c) are withheld or reacquired to satisfy a tax withholding obligation will also be added to the number of shares of our common stock available for issuance pursuant to the Equity Incentive Plan. As of June 30, 2022, a total of 93,916 shares of common stock had been added to the number of shares of our common stock available for issuance pursuant to the Equity Incentive Plan as a result of the cancellation of certain options previously granted under the 2019 EIP.

Pursuant to the Amended and Restated Registration Rights Agreement entered into in connection with the Business Combination, certain of our stockholders can demand that we register their registrable securities under certain circumstances and will each also have piggyback registration rights for these securities. In addition, we are required to file and maintain an effective registration statement under the Securities Act covering such securities and certain of our other securities. We filed a registration statement on October 18, 2021, which was amended on March 29, 2022, in order to satisfy the foregoing obligations and registered for resale an aggregate of 33,081,493 shares of our common stock, including up to 4,999,883 shares of our common stock issuable upon exercise of our outstanding warrants. The registration of these securities permits the public sale of such securities, subject to certain contractual restrictions on transfer imposed by the Amended and Restated Registration Rights Agreement and the Business Combination Agreement, which contractual restrictions on transfer terminated on March 23, 2022. The presence of these additional shares of our common stock trading in the public market may have an adverse effect on the market price of our securities.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of our common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

Because there are no current plans to pay cash dividends on our common stock for the foreseeable future, you may not receive any return on investment unless you sell shares of our common stock for a price greater than that which you paid for it.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our common stock unless you sell your shares of our common stock for a price greater than that which you paid for it.

Anti-takeover provisions in our Certificate of Incorporation and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our Second Amended and Restated Certificate of Incorporation (our “Certificate of Incorporation”) contains provisions that could delay or prevent a change of control of us 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 our board of directors 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 chairman of our board of directors, the chief executive officer, the president, 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 our board of directors to issue preferred stock on terms determined by our board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of our common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our Certificate of Incorporation and Second Amended and Restated Bylaws (our “Bylaws”) could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving us. 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 Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the DGCL, our Certificate of Incorporation or Bylaws; (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of our Certificate of Incorporation or Bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court’s having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that the federal district courts of the United States of America shall be exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our Certificate of Incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions, and the provisions may not be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions that are subject to these exclusive forum provisions, particularly if the stockholder does not reside in or near Delaware. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business.

Any exercise of the outstanding warrants to purchase shares of our common stock would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

Outstanding warrants to purchase shares of our common stock became exercisable in accordance with the terms of the Warrant Agreement, dated November 19, 2019, between Continental Stock Transfer & Trust Company, as warrant agent, and us (the "Warrant Agreement") commencing on October 24, 2021 (the "Public Warrants"). As of June 30, 2022, Public Warrants to purchase 4,999,863 shares of our common stock were outstanding. The exercise price of these Public Warrants is \$11.50 per share. To the extent such Public Warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of our common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such Public Warrants may be exercised could adversely affect the prevailing market prices of our common stock. However, there is no guarantee that the Public Warrants will ever be in the money prior to their expiration, and as such, the Public Warrants may expire worthless. See below risk factor, "*The Public Warrants may never be in the money, and they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment.*"

The Public Warrants may never be in the money, they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment.

The Public Warrants were issued in registered form under the Warrant Agreement. The Warrant Agreement provides that the terms of the Public Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision or correct any mistake, but requires the approval by the holders of at least 50% of the then-outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then-outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Public Warrants, convert the Public Warrants into cash, shorten the exercise period, or decrease the number of shares of our common stock purchasable upon exercise of a Public Warrant.

We may redeem your unexpired Public Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your Public Warrants worthless.

We have the ability to redeem outstanding Public Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per Public Warrant, provided that the last reported sales price of our common stock equals or exceeds \$18.00 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations, and the like) for any 20 trading days within a 30-trading-day period ending on the third trading day prior to the date we send the notice of redemption to the warrant holders. If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force you to: (i) exercise your Public Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so; (ii) sell your Public Warrants at the then-current market price when you might otherwise wish to hold your Public Warrants; or (iii) accept the nominal redemption price that, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of your Public Warrants.

In addition, we may redeem your Public Warrants at any time after they become exercisable and prior to their expiration at a price of \$0.10 per Public Warrant upon a minimum of 30 days' prior written notice of redemption; provided that holders will be able to exercise their Public Warrants prior to redemption for a number of our common stock determined based on the redemption date and the fair market value of our common stock. The value received upon exercise of the Public Warrants (1) may be less than the value the holders would have received if they had exercised their Public Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the Public Warrants.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Description	Registrant's Form	Date Filed with the SEC	Exhibit Number
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant.	8-K	9/29/2021	3.1
3.2	Second Amended and Restated Bylaws of the Registrant.	8-K	9/29/2021	3.2
4.1	Form of Warrant Agreement, dated November 19, 2019, by and between the Registrant and Continental Stock Transfer & Trust Company, as warrant agent.	8-K	11/25/2019	4.1
4.2	Specimen Warrant Certificate.	S-1/A	11/6/2019	4.3

31.1* [Certification of the Principal Executive Officer pursuant to Rule 13a-14\(a\) or 15d-14\(a\) of the Securities Exchange Act of 1934.](#)

31.2* [Certification of the Principal Financial Officer pursuant to Rule 13a-14\(a\) or 15d-14\(a\) of the Securities Exchange Act of 1934.](#)

32.1** [Certification 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.](#)

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.

101.SCH* Inline XBRL Taxonomy Extension Schema Document.

101.CAL* Inline XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF* Inline XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB* Inline XBRL Taxonomy Extension Label Linkbase Document.

101.PRE* Inline XBRL Taxonomy Extension Presentation Linkbase Document.

104* Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

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.

JASPER THERAPEUTICS, INC.

Date: August 12, 2022

By: /s/ Ronald Martell
Ronald Martell
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2022

By: /s/ Jeet Mahal
Jeet Mahal
Chief Operating Officer and
Chief Financial Officer
(Principal Accounting and Financial Officer)

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Ronald Martell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jasper 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Ronald Martell

Ronald Martell

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

Dated: August 12, 2022

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jeet Mahal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jasper 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Jeet Mahal

Jeet Mahal

Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

Dated: August 12, 2022

