

**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 September 30, 2017

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: 001-36781

Juno Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

**400 Dexter Avenue North, Suite 1200
Seattle, WA**

(Address of principal executive offices)

46-3656275

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

98109

(Zip Code)

(206) 582-1600

(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

The number of shares outstanding of the registrant's common stock as of October 30, 2017 was 114,172,897.

TABLE OF CONTENTS

PART I

	<u>Page</u>
Item 1. Financial Statements	3
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3. Quantitative and Qualitative Disclosures About Market Risk	28
Item 4. Controls and Procedures	29

PART II

Item 1. Legal Proceedings	30
Item 1A. Risk Factors	31
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	78
Item 3. Defaults Upon Senior Securities	78
Item 4. Mine Safety Disclosures	78
Item 5. Other Information	78
Item 6. Exhibits	79
Signatures	81

Juno Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 449,837	\$ 187,891
Marketable securities	477,697	544,684
Accounts receivable	34,335	13,286
Prepaid expenses and other current assets	10,588	26,471
Total current assets	<u>972,457</u>	<u>772,332</u>
Property and equipment, net	131,623	81,734
Long-term marketable securities	128,195	189,706
Goodwill	221,306	221,306
Intangible assets, net	77,162	77,986
Other assets	3,748	6,400
Total assets	<u>\$ 1,534,491</u>	<u>\$ 1,349,464</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,318	\$ 4,415
Accrued liabilities and other current liabilities	80,870	36,822
Success payment liabilities	84,603	22,786
Contingent consideration	2,166	7,605
Deferred revenue	27,947	43,264
Total current liabilities	<u>203,904</u>	<u>114,892</u>
Long-term debt, less current portion	10,010	—
Contingent consideration, less current portion	22,735	13,291
Deferred revenue, less current portion	104,022	120,054
Deferred tax liabilities	2,161	5,152
Tenant improvement allowance, deferred rent, and other long-term liabilities	43,886	18,374
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000 shares authorized; 0 shares issued and outstanding	—	—
Common stock, \$0.0001 par value, 495,000 shares authorized at September 30, 2017 and December 31, 2016; 113,445 and 103,403 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	12	11
Additional paid-in-capital	2,277,564	1,911,769
Accumulated other comprehensive income (loss)	2,504	(2,842)
Accumulated deficit	<u>(1,132,307)</u>	<u>(831,237)</u>
Total stockholders' equity	<u>1,147,773</u>	<u>1,077,701</u>
Total liabilities and stockholders' equity	<u>\$ 1,534,491</u>	<u>\$ 1,349,464</u>

See accompanying notes.

Juno Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	\$ 44,816	\$ 20,826	\$ 85,411	\$ 58,203
Operating expenses:				
Research and development	140,272	60,854	324,288	206,887
General and administrative	26,347	18,441	70,689	51,210
Total operating expenses	166,619	79,295	394,977	258,097
Loss from operations	(121,803)	(58,469)	(309,566)	(199,894)
Other-than-temporary impairment loss	—	—	—	(5,490)
Interest income, net	1,968	1,485	5,445	4,322
Other expenses, net	(83)	(507)	(1,187)	(871)
Loss before income taxes	(119,918)	(57,491)	(305,308)	(201,933)
Benefit for income taxes	1,785	594	4,238	9,131
Net loss	\$ (118,133)	\$ (56,897)	\$ (301,070)	\$ (192,802)
Net loss per share, basic and diluted	\$ (1.12)	\$ (0.56)	\$ (2.88)	\$ (1.91)
Weighted average common shares outstanding, basic and diluted	105,602	102,178	104,629	100,961

See accompanying notes.

Juno Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net loss	\$ (118,133)	\$ (56,897)	\$ (301,070)	\$ (192,802)
Other comprehensive income, net of tax:				
Foreign currency translation adjustments	1,210	263	3,834	673
Net unrealized gain (loss) on marketable securities	664	(239)	1,512	(519)
Reclassification adjustment for loss included in net loss	—	—	—	5,490
Total other comprehensive income	1,874	24	5,346	5,644
Comprehensive loss	\$ (116,259)	\$ (56,873)	\$ (295,724)	\$ (187,158)

See accompanying notes.

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

	Nine Months Ended September 30,	
	2017	2016
OPERATING ACTIVITIES		
Net loss	\$ (301,070)	\$ (192,802)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	15,652	10,433
Non-cash stock-based compensation	53,265	42,760
Non-cash expense in connection with equity issuance	—	23,226
Deferred income taxes	(4,242)	(9,114)
Change in fair value of success payment liabilities	61,817	(20,758)
Change in fair value of contingent consideration	4,005	(5,175)
Other-than-temporary impairment on marketable securities	—	5,490
Other	1,286	948
Changes in operating assets and liabilities:		
Accounts receivable	(21,048)	(10,285)
Prepaid expenses and other assets	17,615	179
Accounts payable, accrued liabilities and other liabilities	45,164	1,365
Deferred revenue	(31,375)	26,169
Tenant improvement allowance and deferred rent	26,762	7,197
Net cash used in operating activities	(132,169)	(120,367)
INVESTING ACTIVITIES		
Purchases of marketable securities and other investments	(419,087)	(623,243)
Sales and maturities of marketable securities	546,896	767,147
Acquisitions, net of cash acquired	—	(74,575)
Purchase of property and equipment	(56,903)	(17,795)
Net cash provided by investing activities	70,906	51,534
FINANCING ACTIVITIES		
Proceeds from long-term borrowings, net of financing costs	10,804	—
Payments of long-term debt and build-to-suit lease obligation	(92)	(274)
Proceeds from public offering of common stock, net of offering costs	272,417	—
Proceeds from issuance of common stock to strategic partner	32,783	47,000
Proceeds from employee stock purchase plan and exercise of stock options, net of tax withholdings	7,331	3,254
Repurchases of common stock	—	(10,073)
Net cash provided by financing activities	323,243	39,907
Effect of exchange rate changes on cash and cash equivalents	(34)	(52)
Net increase in cash and cash equivalents	261,946	(28,978)
Cash and cash equivalents at beginning of period	187,891	252,398
Cash and cash equivalents at end of period	\$ 449,837	\$ 223,420
SUPPLEMENTAL CASH FLOW INFORMATION		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 2,323	\$ 2,948
Issuance of common stock for acquisitions	\$ —	\$ 46,914
Issuance of common stock for success payments	\$ —	\$ 9,481

See accompanying notes.

Juno Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements

1. Significant Accounting Policies

Organization and Basis of Presentation

Juno Therapeutics, Inc. (the "Company") was incorporated in Delaware on August 5, 2013 as FC Therapeutics, Inc., and changed its name to Juno Therapeutics, Inc. on October 23, 2013. The Company is building a fully-integrated biopharmaceutical company focused on developing innovative cellular immunotherapies for the treatment of cancer. Founded on the vision that the use of human cells as therapeutic entities will drive one of the next important phases in medicine, the Company is developing cell-based cancer immunotherapies based on its chimeric antigen receptor ("CAR") and high-affinity T cell receptor ("TCR") technologies to genetically engineer T cells to recognize and kill cancer cells.

In September 2017, the Company completed a follow-on public offering (the "September 2017 follow-on public offering") whereby the Company sold 7,015,000 shares of common stock (inclusive of 915,000 shares of common stock sold by the Company pursuant to the full exercise of the underwriters' option to purchase additional shares) at a price to the public of \$41.00 per share. The Company received aggregate net proceeds from the September 2017 follow-on public offering of \$272.4 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Concurrent with the closing of the September 2017 follow-on public offering, the Company closed a private placement of 758,327 shares of its common stock, at price of \$41.00 per share, to a subsidiary of Celgene Corporation. The Company received aggregate proceeds from the concurrent private placement of \$31.1 million.

The Company is subject to a number of risks similar to other biopharmaceutical companies in the early stage, including, but not limited to, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's products, protection of proprietary technology, and the need to obtain adequate additional funding. If the Company, or any commercialization partner for the Company's product candidates, does not successfully commercialize any of the Company's product candidates, the Company will not be able to generate product revenue or achieve profitability. As of September 30, 2017, the Company had an accumulated deficit of \$1.13 billion.

The financial data as of December 31, 2016 is derived from the Company's audited financial statements included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 1, 2017 (the "2016 Annual Report"), and should be read in conjunction with the audited financial statements and notes thereto. The Company's significant accounting policies are described in Note 2 to the financial statements included in the 2016 Annual Report.

These unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position, results of operations and comprehensive loss and cash flows for the interim periods. The results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from such estimates. See Note 2 to the audited financial statements included in the 2016 Annual Report for additional discussion of these estimates and assumptions.

The Company utilizes significant estimates and assumptions in determining the estimated success payment and contingent consideration liabilities and associated expense or gain at each balance sheet date. A small change in the Company's stock price may have a relatively large change in the estimated fair value of the success payment liability and associated expense or gain. Changes in the probabilities and estimated timing of milestones used in the calculation of the contingent consideration liability may have a relatively large impact on the resulting liability and associated expense or gain.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Compensation—Stock Compensation (Topic 718)*. The guidance was effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The Company adopted this standard on January 1, 2017. The guidance required the Company to recognize all excess tax benefits previously unrecognized, along with any valuation allowance, on a modified retrospective basis as a cumulative-effect adjustment to accumulated deficit as of the date of adoption. As of January 1, 2017, the Company's deferred tax asset for net operating losses increased by \$7.1 million but was offset by a full valuation allowance, so there was no impact to accumulated deficit on the condensed consolidated balance sheets. Additionally, the guidance required the Company to make a policy election to either estimate share-based payment forfeitures or recognize them as they occur, and apply the change from the policy election on a modified retrospective basis as a cumulative-effect adjustment to accumulated deficit as of the date of adoption. The Company elected to recognize forfeitures as they occur. Prior to the adoption of this guidance, the estimate for forfeitures was immaterial and as such there was no material impact to accumulated deficit on the condensed consolidated balance sheets upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The new guidance requires lessees to recognize the assets and liabilities arising from leases on the balance sheet and additional qualitative and quantitative disclosures will be required. The amendment is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. The Company plans to adopt this standard on January 1, 2019 and is evaluating the impact of adopting the new accounting guidance on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance primarily affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. This guidance is effective for annual and interim periods beginning after December 15, 2017, and with early adoption permitted for certain provisions of the guidance. The Company will adopt this standard on January 1, 2018 and the adoption of this guidance is not expected to have a material effect on its consolidated financial statements.

In 2014, the FASB issued ASU No. 2014-09, *Revenue From Contracts With Customers (Topic 606)*, amended by ASU No. 2015-14. This new standard will replace all current GAAP guidance on this topic and establishes principles for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. This guidance can be applied either retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. In 2015, the FASB voted to defer the effective date to reporting periods beginning after December 15, 2017, with early adoption permitted. The Company plans to adopt this standard on January 1, 2018, using the modified retrospective method. Under the modified retrospective method, the Company will recognize the cumulative effect of the adoption of ASU 2014-09 as an adjustment to accumulated deficit and deferred revenue on the initial date of application. As of September 30, 2017, the majority of the Company's revenue is generated from upfront license payments and reimbursement revenue under its collaboration arrangement with Celgene Corporation and its wholly owned subsidiary Celgene Switzerland LLC (together, "Celgene") and license and milestone payments associated with the Novartis sublicense agreement. Based on its review of current contracts, the Company expects the implementation of ASU No. 2014-09 to result in a deferral of revenue for a portion of certain milestone payments associated with the Novartis sublicense.

2. Collaboration and License Agreements

See Note 5 of the financial statements included in the 2016 Annual Report for additional information related to the Company's collaboration and license agreements.

Celgene

The Company is party to a Master Research and Collaboration Agreement ("Celgene Collaboration Agreement") with Celgene pursuant to which the Company and Celgene agreed to collaborate on researching, developing, and commercializing novel cellular therapy product candidates and other immunology and immunology therapeutics, including, in particular, CAR and TCR product candidates. In April 2016, Celgene exercised its opt-in right to develop and commercialize product candidates from the Company's CD19 program outside North America and China. As a result, the Company and Celgene entered into a license agreement (the "Celgene CD19 License") pursuant to which Celgene received an exclusive, royalty-bearing license to develop and commercialize therapeutic CAR product candidates from the Company's CD19 program in all territories outside of North America and China. The Company is also party to a Share Purchase Agreement (the "Celgene Share Purchase Agreement") with Celgene.

[Table of Contents](#)

In March 2017, Celgene exercised its annual right to purchase additional shares of the Company's common stock to "top-up" its ownership interest in the Company. The top-up right that was triggered by the filing of the Company's 2016 Annual Report permitted Celgene to top-up its ownership stake in the Company to 9.76%. Celgene purchased 75,568 shares at a price of \$22.39 per share, for an aggregate purchase price of \$1.7 million, to top-up its ownership stake of the Company's common stock to the permitted amount of 9.76%. The top-up right that will be triggered by the filing of the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2017 will again permit Celgene to top-up its ownership stake of the Company's common stock to 9.76%.

In September 2017, concurrent with the closing of the September 2017 follow-on public offering, the Company closed a private placement of 758,327 shares of its common stock, at a price of \$41.00 per share, with Celgene for an aggregate purchase price of \$31.1 million.

The Company recognized revenue in connection with the Celgene Collaboration Agreement and the Celgene CD19 License of \$19.7 million and \$20.7 million for the three months ended September 30, 2017 and 2016, respectively, and \$60.0 million and \$43.4 million for the nine months ended September 30, 2017 and 2016, respectively.

Fred Hutchinson Cancer Research Center

In October 2013, the Company entered into a collaboration agreement with the Fred Hutchinson Cancer Research Center ("FHCRC") focused on research and development of cancer immunotherapy products and a license agreement pertaining to certain patent rights. The Company also granted FHCRC rights to certain share-based success payments. In December 2015, the Company entered into an agreement with FHCRC to support the establishment of a clinical immunotherapy trial unit.

Excluding the expense or gain related to success payment obligations, the Company recognized \$3.6 million and \$3.2 million of research and development expenses in connection with its collaboration and funding agreements with FHCRC for the three months ended September 30, 2017 and 2016, respectively, and \$11.3 million and \$11.9 million for the nine months ended September 30, 2017 and 2016, respectively.

The estimated fair value of the total success payment obligation to FHCRC, after giving effect to the success payments achieved and paid in December 2015, was approximately \$69.0 million and \$22.9 million as of September 30, 2017 and December 31, 2016, respectively. With respect to the FHCRC success payment obligations, the Company recognized an expense of \$23.0 million compared to a gain of \$10.5 million in the three months ended September 30, 2017 and 2016, respectively. The Company recognized an expense of \$37.8 million compared to a gain of \$13.3 million in the nine months ended September 30, 2017 and 2016, respectively. The expense and gain are recorded in research and development expense in the condensed consolidated statements of operations, and represent the change in the FHCRC success payment liability during such periods and the respective months of accrued expenses. The FHCRC success payment liabilities on the condensed consolidated balance sheets as of September 30, 2017 and December 31, 2016 were \$51.0 million and \$13.3 million, respectively.

The Company's liability for share-based success payments under the FHCRC collaboration is carried at fair value and recognized as expense over the term of the six-year collaboration agreement. To determine the estimated fair value of the success payment liability, the Company uses a Monte Carlo simulation methodology which models the future movement of stock prices based on several key variables. The following variables were incorporated in the calculation of the estimated fair value of the success payment liability as of the following balance sheet dates:

<u>Assumptions</u>	<u>September 30, 2017</u>	<u>December 31, 2016</u>
Fair value of common stock	\$ 44.86	\$ 18.85
Risk free interest rate	1.78% - 2.16%	1.88% - 2.30%
Expected volatility	75%	75%
Expected term (years)	4.04 - 7.04	4.79 - 7.79

The computation of expected volatility was estimated using a combination of available information about the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term assumption and the Company's historical and implied volatility. The risk free interest rate and expected term assumptions depend on the estimated timing of U.S. Food & Drug Administration ("FDA") approval. In addition, the Company incorporated the estimated number and timing of valuation measurement dates in the calculation of the success payment liability.

Memorial Sloan Kettering Cancer Center

In November 2013, the Company entered into a sponsored research agreement with Memorial Sloan Kettering Cancer Center ("MSK") focused on research and development relating to CAR T cell technology and a license agreement pertaining to certain patent rights and intellectual property rights related to certain know-how. The Company also granted MSK rights to certain share-based success payments. The Company is also party to clinical study agreements with MSK.

Excluding the expense or gain related to success payment obligations, the Company recognized \$1.6 million and \$0.9 million of research and development expenses in connection with its research and clinical agreements with MSK for the three months ended September 30, 2017 and 2016, respectively, and \$5.1 million and \$1.7 million for the nine months ended September 30, 2017 and 2016, respectively.

The estimated fair value of the total success payment obligation to MSK, after giving effect to the success payment achieved in December 2015 and paid in March 2016, was approximately \$41.6 million and \$14.1 million as of September 30, 2017 and December 31, 2016, respectively. With respect to the MSK success payment obligations, the Company recognized an expense of \$14.2 million compared to a gain of \$7.2 million in the three months ended September 30, 2017 and 2016, respectively. The Company recognized an expense of \$24.0 million compared to a gain of \$7.5 million in the nine months ended September 30, 2017 and 2016, respectively. The expense and gain are recorded in research and development expense in the condensed consolidated statements of operations, and represent the change in the MSK success payment liability during such periods and the respective months of accrued expense. The MSK success payment liabilities on the condensed consolidated balance sheets as of September 30, 2017 and December 31, 2016 were \$33.6 million and \$9.5 million, respectively.

The Company's liability for share-based success payments under the MSK collaboration is carried at fair value and recognized as expense over the term of the five-year collaboration agreement. To determine the estimated fair value of the success payment liability, the Company uses a Monte Carlo simulation methodology which models the future movement of stock prices based on several key variables. The following variables were incorporated in the calculation of the estimated fair value of the success payment liability as of the following balance sheet dates:

<u>Assumptions</u>	<u>September 30, 2017</u>	<u>December 31, 2016</u>
Fair value of common stock	\$ 44.86	\$ 18.85
Risk free interest rate	1.79% – 2.17%	1.90% – 2.31%
Expected volatility	75%	75%
Expected term (years)	4.14 – 7.14	4.89 – 7.89

The computation of expected volatility was estimated using a combination of available information about the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term assumption and the Company's historical and implied volatility. The risk free interest rate and expected term assumptions depend on the estimated timing of FDA approval. In addition, the Company incorporated the estimated number and timing of valuation measurement dates in the calculation of the success payment liability.

St. Jude Children's Research Hospital/Novartis

The Company is party to a license agreement with St. Jude ("St. Jude License Agreement") pertaining to certain patent rights owned by St. Jude. In connection with the April 2015 settlement of Trustees of the University of Pennsylvania v. St. Jude Children's Research Hospital, Civil Action No. 2:13-cv-01502-SD (E.D. Penn.), in which the Company was a party (the "Penn Litigation"), the Company entered into a sublicense agreement (the "Penn/Novartis Sublicense Agreement") with the Trustees of the University of Pennsylvania ("Penn") and an affiliate of Novartis Pharmaceuticals Corporation ("Novartis") pursuant to which the Company granted to Novartis a sublicense pertaining to patent rights licensed to the Company under the St. Jude License Agreement.

In August 2017, a regulatory milestone was met under both the Penn/Novartis Sublicense Agreement and the St. Jude License Agreement, pursuant to which the Company recognized milestone revenue of \$25.0 million from Novartis, and a corresponding research and development expense to St. Jude of \$6.8 million. Additionally, we are obligated to repay Novartis 50% of a milestone payment amount where Novartis achieves a milestone and we subsequently achieve the same milestone. In September 2017, we achieved two clinical milestones that had previously been achieved by Novartis and recorded research and development expense of \$7.1 million associated with the milestone repayment owed to Novartis.

3. Cash Equivalents and Marketable Securities

All marketable securities are available for use and therefore classified as available-for-sale. The following tables summarize the estimated fair value of cash equivalents and marketable securities and gross unrealized holding gains and losses (in thousands):

	September 30, 2017			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	\$ 318,402	\$ —	\$ —	\$ 318,402
U.S. government and agency securities	98,692	2	—	98,694
Corporate debt securities	3,658	—	—	3,658
Total cash equivalents	\$ 420,752	\$ 2	\$ —	\$ 420,754
Marketable securities:				
U.S. government and agency securities	\$ 304,515	\$ 3	\$ (291)	\$ 304,227
Corporate debt securities	173,633	1	(164)	173,470
Total marketable securities	\$ 478,148	\$ 4	\$ (455)	\$ 477,697
Long-term marketable securities:				
U.S. government and agency securities	\$ 94,868	\$ 1	\$ (164)	\$ 94,705
Corporate debt securities	29,561	—	(31)	29,530
Equity securities	1,700	2,260	—	3,960
Total long-term marketable securities	\$ 126,129	\$ 2,261	\$ (195)	\$ 128,195

	December 31, 2016			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	\$ 173,746	\$ —	\$ —	\$ 173,746
U.S. government and agency securities	4,712	—	—	4,712
Corporate debt securities	6,334	—	(6)	6,328
Total cash equivalents	\$ 184,792	\$ —	\$ (6)	\$ 184,786
Marketable securities:				
Commercial paper	\$ 64,260	\$ —	\$ —	\$ 64,260
U.S. government and agency securities	320,224	51	(68)	320,207
Corporate debt securities	160,379	18	(180)	160,217
Total marketable securities	\$ 544,863	\$ 69	\$ (248)	\$ 544,684
Long-term marketable securities:				
U.S. government and agency securities	\$ 132,622	\$ 4	\$ (364)	\$ 132,262
Corporate debt securities	55,920	1	(177)	55,744
Equity securities	1,700	—	—	1,700
Total long-term marketable securities	\$ 190,242	\$ 5	\$ (541)	\$ 189,706

[Table of Contents](#)

The following tables summarize the gross unrealized holding losses and fair value for investments in an unrealized loss position, and the length of time that individual securities have been in a continuous loss position (in thousands):

	September 30, 2017					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Marketable securities:						
U.S. government and agency securities	\$ 213,253	\$ (269)	\$ 17,982	\$ (22)	\$ 231,235	\$ (291)
Corporate debt securities	148,459	(130)	16,982	(34)	165,441	(164)
Total marketable securities	\$ 361,712	\$ (399)	\$ 34,964	\$ (56)	\$ 396,676	\$ (455)
Long-term marketable securities:						
U.S. government and agency securities	\$ 92,215	\$ (164)	\$ —	\$ —	\$ 92,215	\$ (164)
Corporate debt securities	29,530	(31)	—	—	29,530	(31)
Total long-term marketable securities	\$ 121,745	\$ (195)	\$ —	\$ —	\$ 121,745	\$ (195)

	December 31, 2016					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Marketable securities:						
U.S. government and agency securities	\$ 143,480	\$ (56)	\$ 9,988	\$ (12)	\$ 153,468	\$ (68)
Corporate debt securities	128,013	(180)	—	—	128,013	(180)
Total marketable securities	\$ 271,493	\$ (236)	\$ 9,988	\$ (12)	\$ 281,481	\$ (248)
Long-term marketable securities:						
U.S. government and agency securities	\$ 129,163	\$ (364)	\$ —	\$ —	\$ 129,163	\$ (364)
Corporate debt securities	53,643	(177)	—	—	53,643	(177)
Total long-term marketable securities	\$ 182,806	\$ (541)	\$ —	\$ —	\$ 182,806	\$ (541)

The Company evaluated its securities for other-than-temporary impairment and considers the decline in market value for the securities to be primarily attributable to current economic and market conditions. For the debt securities, it is not more-likely-than-not that the Company will be required to sell the securities, and the Company does not intend to do so prior to the recovery of the amortized cost basis.

All debt securities have an effective maturity date of three years or less.

4. Fair Value Measurements

The following tables set forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

	September 30, 2017			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	\$ 318,402	\$ —	\$ —	\$ 318,402
U.S. government and agency securities	—	497,626	—	497,626
Corporate debt securities	—	206,658	—	206,658
Equity securities	3,960	—	—	3,960
Total financial assets	\$ 322,362	\$ 704,284	\$ —	\$ 1,026,646
Financial liabilities:				
Success payment liabilities	\$ —	\$ —	\$ 84,603	\$ 84,603
Contingent consideration	—	—	24,901	24,901
Total financial liabilities	\$ —	\$ —	\$ 109,504	\$ 109,504

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	\$ 173,746	\$ —	\$ —	\$ 173,746
Commercial paper	—	64,260	—	64,260
U.S. government and agency securities	—	457,181	—	457,181
Corporate debt securities	—	222,289	—	222,289
Equity securities	1,700	—	—	1,700
Total financial assets	\$ 175,446	\$ 743,730	\$ —	\$ 919,176
Financial liabilities:				
Success payment liabilities	\$ —	\$ —	\$ 22,786	\$ 22,786
Contingent consideration	—	—	20,896	20,896
Total financial liabilities	\$ —	\$ —	\$ 43,682	\$ 43,682

The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets or liabilities. The Level 2 marketable securities include U.S. government and agency securities, corporate debt securities, and commercial paper and are valued either based on recent trades of securities in inactive markets or based on quoted market prices of similar instruments and other significant inputs derived from or corroborated by observable market data.

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

	Success Payment Liabilities	Contingent Consideration	Total
Balance as of December 31, 2016	\$ 22,786	\$ 20,896	\$ 43,682
Changes in fair value (1)	61,817	4,005	65,822
Balance as of September 30, 2017	\$ 84,603	\$ 24,901	\$ 109,504

- (1) The amount of success payment and contingent consideration milestones achieved, as well as the changes in fair value for success payment liabilities and contingent consideration, are recorded in research and development expense in the condensed consolidated statements of operations.

As of September 30, 2017 and December 31, 2016, the estimated fair value of the success payment obligations, after giving effect to the success payments achieved by FHCRC and MSK, was approximately \$110.6 million and \$37.0 million, respectively. Included in research and development expense for the three months ended September 30, 2017 and 2016 was an expense of \$37.2 million and a gain of \$17.7 million, respectively, related to the change in fair value of the success payment obligations. Included in research and development expense for the nine months ended September 30, 2017 and 2016 was an expense of \$61.8 million and a gain of \$20.8 million, respectively, related to the change in fair value of the success payment obligations. See Note 2, Collaboration and License Agreements, to these condensed consolidated financial statements, as well as Note 5 to the financial statements included in the 2016 Annual Report, for additional discussion of estimated fair value of the success payment obligations.

The Company utilizes significant estimates and assumptions in determining the estimated success payment liability and associated expense at each balance sheet date. The assumptions used to calculate the fair value of the success payments are subject to a significant amount of judgment including the expected volatility, estimated term, and estimated number and timing of valuation measurement dates. A small change in the assumptions and other inputs, such as the fair value of the Company's common stock, may have a relatively large change in the estimated valuation and associated liability and expense. For example, keeping all other variables constant, a hypothetical 10% increase in the stock price at September 30, 2017 from \$44.86 per share to \$49.35 per share would have increased the expense recorded in the third quarter of 2017 associated with the success payment liability by \$11.5 million. A hypothetical 10% decrease in the stock price from \$44.86 per share to \$40.37 per share would have decreased the expense recorded in the third quarter of 2017 associated with the success payment liability by \$10.6 million. Further, keeping all other variables constant, a hypothetical 35% increase in the stock price at September 30, 2017 from \$44.86 per share to \$60.56 per share would have increased the expense recorded in the third quarter of 2017 associated with the success payment liability by \$37.8 million. A hypothetical 35% decrease in the stock price from \$44.86 per share to \$29.16 per share would have decreased the expense recorded in the third quarter of 2017 associated with the success payment liability to zero, resulting in a gain of \$0.3 million.

[Table of Contents](#)

In connection with the acquisitions of Stage Cell Therapeutics GmbH ("Stage") and X-Body, Inc. ("X-Body") in the second quarter of 2015, the Company agreed to pay additional amounts based on the achievement of certain technical, clinical, regulatory, and commercialization milestones. This contingent consideration is measured at fair value and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained.

Contingent consideration may change significantly as development progresses and additional data are obtained, impacting the Company's assumptions regarding probabilities of successful achievement of related milestones used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value information, judgment is required to interpret the data used to develop the estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates.

The significant unobservable inputs used in the measurement of fair value of the Company's contingent consideration are probabilities of successful achievement of the milestones, the period in which these milestones are expected to be achieved ranging from 2017 to 2043, and a discount rate of 16%. Significant increases or decreases in any of the probabilities of success and other inputs would result in a significantly higher or lower fair value measurement, respectively.

As of September 30, 2017, the estimated fair values of the contingent consideration associated with the Stage and X-Body acquisitions, after giving effect to the milestone achieved in 2016, were \$21.3 million and \$3.6 million, respectively. The Company recognized an expense of \$0.8 million and \$0.3 million related to the change in fair value of the contingent consideration for the three months ended September 30, 2017 and 2016, respectively. The Company recognized an expense of \$4.0 million and a gain of \$5.2 million related to the change in fair value of the contingent consideration in the nine months ended September 30, 2017 and 2016, respectively. The expense and gain are recorded in research and development expense in the condensed consolidated statement of operations.

5. Intangible Assets

Intangible assets consist of developed technology and in-process research and development ("IPR&D") obtained from the 2016 AbViro, Inc. ("AbViro") acquisition and the 2015 Stage and X-Body acquisitions. IPR&D assets are required to be classified as indefinite-lived assets until they become finite-lived assets upon the successful completion of the associated research and development effort.

Beginning in the second quarter of 2017, the intangible asset recognized in connection with the AbViro acquisition completed development and reached technological feasibility, and the Company began amortizing the asset over an estimated life of three years.

Identifiable intangible assets consisted of the following (in thousands):

	September 30, 2017		
	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Finite-lived intangible assets:			
Developed technology	\$ 29,017	\$ (4,836)	\$ 24,181
Indefinite-lived intangible assets:			
In-process research and development	52,981	—	52,981
Total identifiable intangible assets	<u>\$ 81,998</u>	<u>\$ (4,836)</u>	<u>\$ 77,162</u>

Amortization expense recognized related to intangible assets was \$2.4 million and \$4.8 million for the three and nine months ended September 30, 2017, respectively. There was no amortization expense recognized related to intangible assets for the three and nine months ended September 30, 2016 as all intangibles were deemed to be indefinite-lived at that time.

[Table of Contents](#)

Estimated future amortization expense related to finite-lived intangible assets as of September 30, 2017 is as follows (in thousands):

Year ending December 31:	
2017	\$ 2,418
2018	9,672
2019	9,672
2020	2,419
Total future amortization expense	<u>\$ 24,181</u>

There was no impairment of intangible assets as of September 30, 2017 and December 31, 2016.

6. Long-term Debt

In April 2017, the Company entered into a debt agreement for a principal amount of \$11.0 million which was used to fund the purchase of the Juno-owned and -operated manufacturing facility in Bothell, Washington. The terms of the agreement include a 4.55% annual fixed interest rate and provide for 120 monthly payments beginning June 1, 2017, with the final payment of all outstanding interest and principal due May 1, 2027.

The following table summarizes future principal payments on long-term debt as of September 30, 2017 (in thousands):

Year ending December 31:	
2017	\$ 69
2018	286
2019	299
2020	313
2021	328
Thereafter	9,613
Total future principal payments	<u>\$ 10,908</u>

As of September 30, 2017, the fair value of the Company's long-term debt approximates carrying value based on the borrowing rates currently available to the Company for loans with similar terms using Level 2 inputs.

7. Stock-Based Compensation

Stock-Based Compensation

Stock-based compensation expense was recognized in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development (1)	\$ 11,977	\$ 8,751	\$ 33,345	\$ 29,109
General and administrative	6,873	5,436	19,920	15,863
Total stock-based compensation expense (2)	<u>\$ 18,850</u>	<u>\$ 14,187</u>	<u>\$ 53,265</u>	<u>\$ 44,972</u>

- (1) Included in research and development stock-based compensation expense for the nine months ended September 30, 2016, was \$2.2 million related to the payout of employee stock options in connection with the AbVitro acquisition.
- (2) Included in stock-based compensation expense recognized for the three months ended September 30, 2017 and 2016, is \$1.9 million and \$1.4 million, respectively, related to service providers other than employees, scientific founders, and directors, including \$1.4 million and \$0.9 million, respectively, for a former cofounding director who became a consultant upon his departure from the board of directors. Included in stock-based compensation expense recognized for the nine months ended September 30, 2017 and 2016, is \$4.3 million and \$5.7 million, respectively, related to service providers other than employees, scientific founders, and directors, including \$3.0 million and \$3.3 million, respectively, for a former cofounding director who became a consultant upon his departure from the board of directors.

[Table of Contents](#)

Total stock-based compensation cost related to unvested awards not yet recognized and the weighted average periods over which the awards are expected to be recognized as of September 30, 2017 for all employees are as follows:

	Stock Options	Restricted Stock and RSUs
Unrecognized stock-based compensation cost (in thousands)	\$ 122,685	\$ 35,876
Expected weighted average period compensation costs to be recognized (years)	2.63	2.56

Restricted Stock and RSUs

A summary of the Company's restricted stock and RSU activity is as follows (in thousands, except per share data):

	Restricted Stock and RSUs	Weighted Average Fair Value at Date of Grant per Share
Unvested shares as of December 31, 2016	3,055	\$ 7.10
Granted	1,391	21.79
Vested	(1,757)	3.09
Forfeited	(562)	6.55
Unvested shares as of September 30, 2017	2,127	\$ 20.12

Stock Options

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

	Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2016	8,521	\$ 30.28		
Granted	3,800	24.15		
Exercised	(364)	15.90		
Forfeited/Cancelled	(898)	34.55		
Outstanding as of September 30, 2017	11,059	\$ 28.28	8.34	\$ 191,950
Exercisable as of September 30, 2017	3,847	\$ 29.76	7.47	\$ 64,538

The fair value of each stock option granted has been determined using the Black-Scholes option pricing model. The material factors incorporated in the Black-Scholes model in estimating the fair value of the options granted to employees, directors, and consultants included the following:

<u>Assumptions</u>	<u>Nine Months Ended September 30, 2017</u>
Risk free interest rate	1.62% – 2.40%
Expected volatility	75
Expected life (years)	3.22 - 9.96
Expected dividend yield	0

For employees, scientific founders, and directors, the expected life was calculated based on the simplified method as permitted by the SEC Staff Accounting Bulletin No. 110, *Share-Based Payment*. For other service providers, the expected life was calculated using the contractual term of the award. Management's estimate of expected volatility was based on available information about the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term assumption and its own historical and implied future volatility. The risk-free interest rate is based on a U.S. Treasury instrument whose term is consistent with the expected life of the stock options.

8. Comprehensive Income (Loss)

The components of accumulated other comprehensive income (loss) and the adjustments to other comprehensive income (loss) are as follows (in thousands):

	Foreign Currency Translation Adjustments	Net Unrealized Gain (Loss) on Marketable Securities	Accumulated Other Comprehensive Income (Loss)
Balance as of December 31, 2016	\$ (1,791)	\$ (1,051)	\$ (2,842)
Other comprehensive income	3,834	1,512	5,346
Balance as of September 30, 2017	\$ 2,043	\$ 461	\$ 2,504

9. Income Taxes

The Company recorded an income tax benefit of \$4.2 million on a pre-tax loss of \$305.3 million for the nine months ended September 30, 2017. The income tax benefit primarily relates to the benefit associated with the net loss incurred by the Company's German subsidiary in the nine months ended September 30, 2017.

The Company recorded an income tax benefit of \$9.1 million on a pre-tax loss of \$201.9 million for the nine months ended September 30, 2016. Of the total tax benefit, \$6.7 million relates to the release of valuation allowance on the U.S. deferred tax assets as a result of the deferred tax liabilities established for intangible assets from the acquisition of AbVitro, net of tax attributes, and \$2.0 million relates to the benefit associated with the net loss incurred by the Company's German subsidiary in the nine months ended September 30, 2016.

The Company maintains a full valuation allowance on its net U.S. deferred tax assets. The assessment regarding whether a valuation allowance is required considers both positive and negative evidence when determining whether it is more-likely-than-not that deferred tax assets are recoverable. In making this assessment, significant weight is given to evidence that can be objectively verified. In its evaluation, the Company considered its cumulative loss in recent years and its forecasted losses in the near term as significant negative evidence. Based upon a review of the four sources of income identified within Accounting Standard Codification ("ASC") 740, *Accounting for Income Taxes*, the Company determined that the negative evidence outweighed the positive evidence and a full valuation allowance on its U.S. net deferred tax assets will be maintained. The Company will continue to assess the realizability of its deferred tax assets going forward and will adjust the valuation allowance as needed. The Company has determined that it is more-likely-than-not that it will realize the benefit of the losses for its German subsidiary and has not recorded a valuation allowance against the German deferred tax assets.

The Company is generally subject to examination by the U.S. federal and local income tax authorities for all tax years in which a loss carryforward is available and is subject to examination in Germany for four years. The Company's German subsidiary is currently under examination by the German tax authorities for the years ended December 31, 2013 through December 31, 2015.

The Company applies judgment in the determination of the consolidated financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. As of September 30, 2017 and December 31, 2016, the Company's uncertain tax positions were immaterial.

10. Net Loss per Share

Basic and diluted net loss per share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. The Company's potentially dilutive shares, which include unvested restricted stock, unvested RSUs, options to purchase common stock, and potential shares issued for success payments, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The share amounts in the table below were excluded from the calculation of diluted net loss per share for the periods indicated due to their anti-dilutive effect (in thousands):

	Nine Months Ended September 30,	
	2017	2016
Unvested restricted stock and RSUs	2,127	3,580
Options to purchase common stock	11,059	8,007
Total	13,186	11,587

11. Commitments and Contingencies

Leases

The Company has entered into various lease agreements for its office, laboratory, and manufacturing spaces with original lease periods expiring between 2019 and 2026. In addition to minimum rent, certain leases require payment of real estate taxes, insurance, common area maintenance charges and other executory costs. These executory costs are not included in the table below. Certain of these arrangements have free or escalating rent payment provisions. The Company recognizes rent expense under such arrangements on a straight-line basis over the effective term of each lease.

The following table summarizes the Company's future minimum lease commitments as of September 30, 2017 (in thousands):

Year ending December 31:		
2017	\$	757
2018		13,221
2019		15,222
2020		14,866
2021		14,342
Thereafter		37,108
Total future minimum lease payments	\$	95,516

Rent expense for the three months ended September 30, 2017 and 2016 was \$2.8 million and \$0.9 million, respectively. Rent expense for the nine months ended September 30, 2017 and 2016 was \$8.0 million and \$3.3 million, respectively.

Litigation

From time to time, the Company may become involved in litigation or proceedings relating to claims arising from the ordinary course of business.

Beginning on July 12, 2016, three putative securities class action complaints were filed against the Company and several of its officers. On October 7, 2016, these complaints were consolidated into a single action titled "In re Juno Therapeutics, Inc." On October 19, 2016, the Court appointed a lead plaintiff. On December 12, 2016, the lead plaintiff filed an amended complaint.

The putative class in the amended complaint is composed of all purchasers of the Company's securities between May 9, 2016 and November 22, 2016, inclusive. The amended complaint names as defendants the Company, its chief executive officer, its chief financial officer, and its chief medical officer and generally alleges material misrepresentations and omissions in public statements regarding patient deaths in the Company's Phase II clinical trial of JCAR015 and the safety of JCAR015, violations by all named defendants of Section 10(b) of the Exchange Act, and Rule 10b-5 thereunder, as well as violations of Section 20(a) of the Exchange Act by the individual defendants. The amended complaint seeks compensatory damages of an undisclosed amount. On February 2, 2017, the Company and the individual defendants filed a motion to dismiss the complaint. On June 14, 2017, the defendants' motion to dismiss was denied. On September 15, 2017, plaintiffs filed a motion to certify the proposed class. On October 20, 2017, the Company and the individual defendants filed a non-opposition to the motion for class certification. On October 24, 2017, the Court issued an order granting the lead plaintiff's motion for class certification. On October 24, 2017, the Court also entered a scheduling order providing deadlines, including that discovery must be completed by March 18, 2019; all dispositive motions must be filed by April 16, 2019; and mediation, if requested by the parties, must be held by May 31, 2019. The Court scheduled a 2-3 week trial to commence on July 15, 2019.

In addition, on September 8, 2017, a stockholder filed a purported derivative action on behalf of the Company against two of the Company's executive officers and certain members of our board of directors in the federal district court for the Western District of Washington. The complaint alleges claims for breaches of fiduciary duties arising out of the same issues that are the subject of the securities class action, as well as claims for breaches of fiduciary duties and under the federal securities laws related to the Company's compensation for non-employee directors. The Company has not yet responded to the complaint.

On August 22, 2017, City of Hope filed a lawsuit against the Company, *City of Hope v. Juno Therapeutics, Inc.*, Case No. 2:17-cv-06201-RGK, in the federal district court for the Central District of California. The complaint alleges that the Company has materially breached its exclusive license agreement with City of Hope by failing to seek consent for an alleged sublicense of the Company's rights under such license to Celgene, and by failing to pay fees owed in connection with that alleged sublicense. The City of Hope license requires the Company to pay City of Hope 15% of sublicense revenues, defined as "all consideration received by [the Company] in return for the grant of rights to manufacture, use, offer for sell, or sell a Licensed Product, other

[Table of Contents](#)

than consideration in the form of: (i) running royalties calculated as a function of Net Sales and payment, (ii) payment or reimbursement to [the Company] of costs actually incurred by [the Company] in conducting clinical trials of a Licensed Product, and (iii) reimbursement for actual Patent Expenses due pursuant to this Agreement.” In its request for relief, City of Hope seeks compensatory damages in an amount “no less than 15% of all consideration received by the Company pursuant to the [Celgene] Collaboration Agreement, [Celgene] Share Purchase Agreement, and Celgene Option Exercise [i.e., the Celgene CD19 License].” The complaint also seeks a declaratory judgment that the Company materially breached the City of Hope license. On August 31, 2017, the Company filed an answer and counterclaim in the lawsuit, denying City of Hope’s allegations of breach of contract, asserting several affirmative defenses, and bringing various counterclaims, including claims for breach of contract and breach of the covenant of good faith and fair dealing, and seeking, among other things, a declaratory judgment that City of Hope has no grounds to terminate the City of Hope license. City of Hope filed an amended complaint on September 21, 2017, which Juno answered on October 5, 2017.

The Company has not recorded a liability as of September 30, 2017 because a potential loss is not probable or reasonably estimable given the preliminary nature of the proceedings.

12. Related-Party Transactions

The Company is party to the Celgene Collaboration Agreement, the Celgene CD19 License, the Celgene Share Purchase Agreement, a voting agreement, and a registration rights agreement with Celgene, who is a holder of more than 5% of the Company’s common stock. See Note 2, Collaboration and License Agreements, to these condensed consolidated financial statements, as well as Note 5 to the financial statements included in the 2016 Annual Report.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion in conjunction with our condensed consolidated financial statements (unaudited) and related notes included elsewhere in this report. This Quarterly Report on Form 10-Q contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "aim," "potential," "continue," "ongoing," "goal," or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

These forward-looking statements, include, but are not limited to, statements regarding: the success, cost and timing of our product development activities and clinical trials; our ability and the potential to successfully advance and leverage our technology platform to improve the safety and effectiveness of our existing product candidates; the potential costs and benefits for our identified research priorities to advance our CAR and TCR technologies; the potential of our collaboration with Celgene and the ability and willingness of Celgene to be our commercialization partner outside of North America, including with respect to our CD19 license agreement with Celgene and the exercise by Celgene of its opt-in right to the CD19 program; our anticipated expenses with respect to the development of our CD19 product candidates; the ability of JW Therapeutics (Shanghai) Co., Ltd to develop and commercialize product candidates in China; the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates; the potential of our other research and development and strategic collaborations, including our collaborations with Editas Medicine, Inc., Fate Therapeutics, Inc., and MedImmune Limited; our ability to obtain orphan drug designation or breakthrough status for our CD19 product candidates and any other product candidates, or to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; our ability to license additional intellectual property relating to our product candidates; our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; our ability to commercialize our products in light of the intellectual property rights of others; our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates, and the potential terms of such funding; our plans to research, develop, and commercialize our product candidates; the potential of the technologies we have acquired through license agreements or strategic transactions, such as the acquisition of Stage, X-Body, AbVitro, and RedoxTherapies; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; regulatory developments in the United States and foreign countries; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; our plans to develop our own manufacturing facilities, including our manufacturing facility in Bothell, Washington and our ability to scale our manufacturing operations; the potential benefits of our efforts to optimize our process development and manufacturing; the success of competing therapies that are or may become available; our ability to attract and retain key scientific, quality assurance/control, manufacturing, or management personnel; the accuracy of our estimates regarding expenses, success payments, future revenue, capital requirements, profitability, and needs for additional financing; fluctuations in the trading price of our common stock; the anticipated benefits of our litigation settlement with Penn and Novartis; our plans regarding our corporate headquarters; and our use of the proceeds from our initial public offering and proceeds received from Celgene.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" in this Quarterly Report on Form 10-Q. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Unless the context requires otherwise, in this Quarterly Report on Form 10-Q, the terms "Juno," "Company," "we," "us" and "our" refer to Juno Therapeutics, Inc., a Delaware corporation, and its wholly-owned subsidiaries on a consolidated basis.

Overview

We are building a fully-integrated biopharmaceutical company focused on developing innovative cellular immunotherapies for the treatment of cancer. Founded on the vision that the use of human cells as therapeutic entities will drive one of the next important phases in medicine, we are developing cell-based cancer immunotherapies based on our CAR and high-affinity TCR technologies to genetically engineer T cells to recognize and kill cancer cells. We have shown compelling clinical responses in clinical trials using multiple cell-based product candidates to address refractory B cell lymphomas and leukemias, and we also have a number of ongoing trials exploring our platform in solid-organ cancers and multiple myeloma, and in combination with various strategies to overcome the immune-suppressive effects of cancer. Over time, we aim to improve and leverage our cell-

[Table of Contents](#)

based platform to develop additional product candidates to address a broad range of cancers and human diseases, including moving forward our preclinical product candidates that target additional hematologic and solid-organ cancers.

We are conducting a Phase I trial with JCAR017 in adult r/r aggressive non-Hodgkin lymphoma ("NHL"), including relapsed or refractory ("r/r") diffuse large B cell lymphoma ("DLBCL"), and are currently enrolling the cohort we believe may support registration. We are also planning to begin a Phase I/II trial with JCAR017 in r/r chronic lymphocytic leukemia ("CLL") in the fourth quarter of 2017. If the results of these trials are favorable, we believe we may obtain U.S. regulatory approval in r/r DLBCL as early as 2018 and in r/r CLL as early as 2019. Key variables impacting the timing of approval will be the time it takes to complete enrollment of our pivotal cohort, the timing of our FDA submission, which we expect to be completed for JCAR017 in r/r DLBCL in the second half of 2018, and the duration of FDA review. Additionally, we have begun a Phase Ib clinical trial of JCAR017 in combination with durvalumab in adult r/r aggressive NHL. We also intend to develop JCAR017 or a next generation product candidate in both pediatric r/r acute lymphoblastic leukemia ("ALL") and adult r/r ALL.

We are continuing to enroll patients in an ongoing Phase I/II trial for JCAR014 in B cell malignancies, and although we do not plan to move JCAR014 into registration trials, we plan to use this trial to explore important questions that may improve our platform overall, including testing the combination of JCAR014 and ibrutinib in r/r CLL patients. We are enrolling patients in a combination Phase Ib clinical trial combining JCAR014 with durvalumab for the treatment of r/r NHL. Additionally, we are conducting a Phase I trial in adult patients with certain B cell malignancies using a CD19-directed product candidate that incorporates a fully human binding domain. Additionally, we have commenced a Phase I trial through our collaborator MSK of a CD19/4-1BBL "armored" CAR in r/r CLL patients.

Beyond CD19, we are conducting Phase I trials for additional product candidates that target seven different cancer-associated proteins in hematological and solid organ cancers, including two Phase I trials for CAR T cell product candidates targeting B-cell maturation antigen ("BCMA") in patients with multiple myeloma. We have a number of other preclinical programs against other targets that we expect to move into human testing over the next several years.

We have assembled a talented group of scientists, engineers, clinicians, directors, and other advisors who develop and consolidate technologies and intellectual property from some of the world's leading research institutions, including FHCRC, MSK, Seattle Children's Research Institute ("SCRI"), the University of California, San Francisco, and the National Cancer Institute ("NCI"). We have also entered into a number of strategic collaborations with commercial companies that we believe will help us manufacture and commercialize our product candidates around the world or develop additional or improved product candidates, including Celgene, Editas Medicine, Inc. ("Editas"), Fate Therapeutics, Inc. ("Fate Therapeutics"), and MedImmune Limited ("MedImmune").

We have established a Juno-owned and -operated manufacturing facility in Bothell, Washington. We began manufacturing clinical trial material from this facility beginning in the first quarter of 2016, and plan to manufacture commercial products, subject to the required regulatory approvals, beginning as early as 2018.

Revenue for the three months ended September 30, 2017 and 2016 was \$44.8 million and \$20.8 million, and revenue for the nine months ended September 30, 2017 and 2016 was \$85.4 million and \$58.2 million, respectively. In the future, we may generate revenue from the Celgene collaboration, strategic alliances, licensing arrangements, product sales, and royalties, or a combination of these. We expect that any revenue we generate will fluctuate from quarter to quarter and year to year as a result of the timing and amount of opt-in payments from Celgene, license fees, milestones, reimbursement of costs incurred, other payments, and product sales, to the extent any product candidates are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval of them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

As described in Note 5 of the financial statements included in the 2016 Annual Report, in April 2016 we entered into a license agreement with Celgene pertaining to our CD19 program. As a result, we expect the development activities around the CD19 program to continue to grow as Celgene leads development of our CD19 product candidates in the Celgene Territory. Under the license agreement, we and Celgene will generally share worldwide development expenses for certain CD19 product candidates, although either party may opt out of funding specific studies being led by the other. We will also receive royalties from Celgene for CAR product candidates arising from the CD19 program at a percentage in the mid-teens of net sales of such product candidates in the Celgene Territory.

We have agreed to make success payments to each of FHCRC and MSK pursuant to the terms of our collaboration agreements with each of those entities. In December 2015, success payment obligations to FHCRC were triggered in the amount of \$75.0 million less indirect cost offsets of \$3.3 million and to MSK of \$10.0 million less indirect cost offsets of \$1.0 million. We elected to make the payments to FHCRC and MSK in shares of our common stock, and thereby issued 1,601,085 and 240,381 shares of our common stock to FHCRC in December 2015, and to MSK in March 2016, respectively. In April 2016, we repurchased the 240,381 shares of our common stock issued to MSK at a repurchase price of \$41.90 per share.

[Table of Contents](#)

As of September 30, 2017, we had cash, cash equivalents, and marketable securities of \$1.06 billion compared with \$922.3 million as of December 31, 2016. Cash used in operations for the nine months ended September 30, 2017 was \$132.2 million and is net of a cash inflow of \$37.7 million received in connection with a tenant allowance for our new headquarters facility and \$30.8 million from the partial reimbursement by Celgene of research and development costs incurred by us in the fourth quarter of 2016 and the first half of 2017. Cash provided by investing activities for the nine months ended September 30, 2017 was \$70.9 million and is net of a cash outflow of \$56.9 million for the purchase of property and equipment, the majority of which related to the build-out of our new headquarters facility. Cash provided by financing activities in the nine months ended September 30, 2017 was \$323.2 million and includes net cash proceeds from the September 2017 follow-on public offering of \$272.4 million, cash proceeds from Celgene of \$32.8 million, \$31.1 million of which related to the concurrent private placement and the remaining \$1.7 million was for the purchase of 75,568 shares of our common stock in the first quarter of 2017, as well as \$10.8 million in net cash proceeds related to a long-term debt agreement entered into in April.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies from those described in Part II—Item 7— "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2016 Annual Report.

Components of Operating Results

Revenue

Our revenues have been primarily derived from collaboration and license agreements.

Ongoing collaboration revenue is generated from our collaboration with Celgene. The terms of this arrangement contain multiple deliverables, which include (1) access to certain of our technology through a non-exclusive, worldwide, royalty-free right and license to conduct certain activities under the collaboration and (2) participation on various collaboration committees. We recognize revenue from the \$150.2 million upfront payment under the Celgene Collaboration Agreement ratably over the term of our estimated period of performance under the arrangement, which we estimate to be through June 2025. In addition to receiving upfront payments, we may also be entitled to option exercise fees. In April 2016, Celgene exercised its right to opt-in to our CD19 program, and as a result, we entered into the Celgene CD19 License and received an option exercise fee of \$50.0 million. The license agreement contains the following deliverables: (1) an exclusive license with respect to intellectual property, (2) transfer of certain clinical and manufacturing knowledge and related support, and (3) participation on various collaboration committees during the technology transfer period. The \$50.0 million option exercise fee is being recognized ratably over the period we expect to fulfill these performance obligations, which we estimate to be approximately two years.

Additionally, we and Celgene will generally share worldwide research and development costs for certain CD19 product candidates. To the extent our research and development costs for certain product candidates in the CD19 program exceed Celgene's research and development costs for the CD19 program for a given quarter, Celgene is required to provide us partial reimbursement for such costs. Either party may opt out from the cost sharing arrangement for specific studies being led by the other party, with the possibility to opt back in to the study in the future at a premium in exchange for the right to use data from that study in such party's territory. We recognize the reimbursement by Celgene as revenue in the period in which the costs are incurred. To the extent Celgene's eligible research and development costs for the CD19 program exceed our eligible research and development costs for the CD19 program for a given quarter, we are required to provide Celgene partial reimbursement for such costs. We recognize any reimbursements owed to Celgene as research and development expense in the period in which the costs are incurred. As a result, our revenues and research and development expenses may fluctuate depending on which party in the collaboration is incurring the majority of the development costs in any particular quarterly period, and as a result of the timing and amount of option exercise fees and other payments from our collaboration and license agreements.

We have also recognized upfront and milestone revenue under our sublicense agreement with Novartis. For the nine months ended September 30, 2017 and 2016 we recognized milestone revenue of \$25.0 million and \$14.3 million, respectively. In the future we may recognize revenue upon the achievement of specified clinical, regulatory, and commercialization milestones for licensed products under the Novartis agreement. Each of these milestones will be reduced by 50% if we achieve the milestone

before Novartis achieves the same milestone. Additionally, we are obligated to repay Novartis 50% of a milestone payment amount where Novartis achieves a milestone and we subsequently achieve the same milestone. Novartis is also required to pay us royalties on the U.S. net sales of licensed products.

Research and Development Expenses

Research and development expenses represent costs incurred by us for the discovery, development, and manufacture of our product candidates and include costs to acquire technology complimentary to our own, external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), collaboration partners, academic and non-profit institutions and consultants, salaries and personnel-related costs, including non-cash stock-based compensation, changes in the estimated fair value of our success payment liabilities to FHCRC and MSK, changes in the estimated fair value of our contingent consideration liabilities, intangible asset amortization, milestones, and other expenses, which include direct and allocated expenses for laboratory, facilities, overhead and other costs.

We use our employee and infrastructure resources across multiple research and development programs directed toward developing our cell-based platform and for identifying and developing product candidates. We manage certain activities such as contract research, clinical trial operations, and manufacture of product candidates through our partner institutions or other third-party vendors. We track our significant external costs by product candidate. Although we began in the second quarter of 2016 to calculate, at a high level, our internal personnel costs by project, we do not have such data for all of 2016, so we are not at this time disclosing the allocation of internal personnel costs by product candidate. Due to the number of ongoing projects and our ability to use resources across several projects, we do not record or maintain information regarding the other indirect operating costs incurred for our research and development programs on a program-specific basis.

[Table of Contents](#)

Our research and development expenses by project were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Project-specific external costs:				
JCAR017 (1)	\$ 16,587	\$ 4,155	\$ 33,741	\$ 9,602
JCAR015	283	5,226	2,802	15,689
JCAR014	1,684	1,147	5,134	4,143
CD19 general (2)	8,052	425	10,261	16,676
JCAR018 (3)	—	74	—	23,433
JCARH125	2,153	—	7,445	—
Early development	6,280	5,750	18,837	20,910
Success payment expense (gain) related to FHCRC collaboration agreement	22,989	(10,455)	37,788	(13,287)
Success payment expense (gain) related to MSK collaboration agreement	14,260	(7,184)	24,029	(7,471)
Change in estimated fair value of contingent consideration	806	336	4,005	(5,175)
Upfront fees to acquire technology	—	15,000	—	15,000
Intangible asset amortization	2,418	—	4,836	—
Unallocated internal and external research and development costs (4)	64,760	46,380	175,410	127,367
Total research and development expenses	\$ 140,272	\$ 60,854	\$ 324,288	\$ 206,887

- (1) JCAR017 expenses for the three and nine months ended September 30, 2017 include milestone expense of \$9.1 million.
- (2) CD19 general expenses for the three and nine months ended September 30, 2017 and for the nine months ended September 30, 2016 include milestone expense of \$6.8 million and \$12.5 million, respectively.
- (3) JCAR018 expenses for the nine months ended September 30, 2016 include milestone expense of \$23.2 million.
- (4) Unallocated internal and external research and development costs include salaries and personnel-related costs, including non-cash stock-based compensation, for our personnel in research, clinical development, process development and manufacturing, regulatory, and other research and development functions; allocated facilities and other overhead costs; lab supplies; depreciation; and other research and development costs not specific to a project.

Research and development activities account for a significant portion of our operating expenses. Excluding amounts attributable to changes in the estimated fair value of the success payment and contingent consideration liabilities and upfront fees to acquire technology, we expect our research and development expenses to increase over the next several years as we implement our business strategy which includes conducting existing and new clinical trials, manufacturing clinical trial and preclinical study materials, expanding our research and development and process development efforts, seeking regulatory approval for product candidates that successfully complete clinical trials, and hiring additional personnel to support our research and development efforts. As a result of our decision to cease further development of JCAR015, we expect that expense associated with JCAR015 will significantly decrease in 2017 and future years, but these decreases will be offset in whole or in part by increased expenses for the development of other CD19 product candidates. Research and development expense related to our success payments is unpredictable and may vary significantly from quarter to quarter and year to year due to changes in our stock price or other assumptions used in the calculation. A significant decline in the estimated value of the success payment liability may result in a gain and possibly net income during the period. Amounts associated with the change in the estimated fair value of the contingent consideration liabilities also may vary significantly from quarter to quarter and year to year due to changes in our assumptions used in the calculation. In addition, we may incur research and development expense for acquisition of technology in the future, but the timing and amount of those expenses cannot be estimated with reliability and may also fluctuate from quarter to quarter and year to year.

General and Administrative Expenses

General and administrative expenses consist of salaries and personnel-related costs, including non-cash stock-based compensation, for our personnel in executive, legal, finance and accounting, human resources, commercial, and other

[Table of Contents](#)

administrative functions, legal costs, transaction costs associated with acquisitions and collaboration and licensing agreements, as well as fees paid for accounting and tax services, consulting fees, including costs to support commercial readiness, and facility costs not otherwise included in research and development expenses. Legal costs include general corporate legal fees, patent costs, and litigation expenses.

We anticipate that our general and administrative expenses will increase in the future to support potential commercialization of our product candidates, our continued research and development activities, and future business development opportunities. These increases will likely include costs related to outside consultants, attorneys, and accountants, among other expenses.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2017 and 2016

The following table summarizes our results of operations for the three and nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	\$ 44,816	\$ 20,826	\$ 85,411	\$ 58,203
Operating expenses:				
Research and development	140,272	60,854	324,288	206,887
General and administrative	26,347	18,441	70,689	51,210
Total operating expenses	166,619	79,295	394,977	258,097
Loss from operations	(121,803)	(58,469)	(309,566)	(199,894)
Other-than-temporary impairment loss	—	—	—	(5,490)
Interest income, net	1,968	1,485	5,445	4,322
Other expenses, net	(83)	(507)	(1,187)	(871)
Loss before income taxes	(119,918)	(57,491)	(305,308)	(201,933)
Benefit for income taxes	1,785	594	4,238	9,131
Net loss	\$ (118,133)	\$ (56,897)	\$ (301,070)	\$ (192,802)
Net loss per share, basic and diluted	\$ (1.12)	\$ (0.56)	\$ (2.88)	\$ (1.91)

Revenue

The following table summarizes our revenue for the three and nine months ended September 30, 2017 and 2016, the majority of which is related to the amortization of upfront and option exercise fees, milestone payments, and reimbursement of certain research and development expenses under our Celgene Collaboration Agreement (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Celgene:				
Recognition of upfront and option exercise fees	\$ 10,340	\$ 10,341	\$ 31,020	\$ 23,775
Reimbursement revenue	9,328	10,407	28,994	19,600
Celgene total	19,668	20,748	60,014	43,375
Novartis milestone revenue	25,000	—	25,000	14,250
Other	148	78	397	578
Total revenue	\$ 44,816	\$ 20,826	\$ 85,411	\$ 58,203

Revenue. Revenue was \$44.8 million and \$85.4 million for the three and nine months ended September 30, 2017, compared to \$20.8 million and \$58.2 million for the three and nine months ended September 30, 2016, respectively. The increase in the three months ended September 30, 2017 compared to the three months ended September 30, 2016 was due to milestone revenue recognized in the third quarter of 2017 in connection with the Novartis sublicense agreement. The increase in the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was primarily due to an increase in revenue recognized under our Celgene Collaboration Agreement and Celgene CD19 License for the upfront license fee and partial reimbursement by Celgene of research and development costs incurred by us, and an increase in milestone revenue recognized in connection with the Novartis sublicense agreement.

[Table of Contents](#)

Operating Expenses

Research and Development Expenses. Research and development expenses were \$140.3 million and \$324.3 million for the three and nine months ended September 30, 2017, compared to \$60.9 million and \$206.9 million for the three and nine months ended September 30, 2016, respectively.

The increase of \$79.4 million in the three months ended September 30, 2017 was primarily due to:

- a \$54.9 million increase in expense related to changes in the estimated fair value of our success payment obligations,
- a \$17.9 million increase in milestone expense,
- a \$15.2 million increase in costs to manufacture our product candidates, execute our clinical development strategy, and expand our overall research and development capabilities, and
- a \$3.2 million increase in non-cash stock-based compensation expense.

These increases were offset by a decrease in costs to acquire technology of \$14.7 million.

The increase of \$117.4 million in the nine months ended September 30, 2017 was primarily due to:

- an \$82.6 million increase in expense related to changes in the estimated fair value of our success payment obligations,
- a \$46.7 million increase in costs to manufacture our product candidates, execute our clinical development strategy, and expand our overall research and development capabilities,
- a \$9.2 million increase in expense related to changes in the estimated fair value of our contingent consideration obligations,
- a \$4.8 million expense for the amortization of the intangible asset recorded in connection with the AbVitro acquisition, and
- a \$4.2 million increase in non-cash stock-based compensation expense.

These increases were offset by a decrease in milestone expense of \$19.2 million and a decrease in costs to acquire technology of \$10.9 million.

General and Administrative Expenses. General and administrative expenses were \$26.3 million and \$70.7 million for the three and nine months ended September 30, 2017, compared to \$18.4 million and \$51.2 million for the three and nine months ended September 30, 2016, respectively.

The increase of \$7.9 million in the three months ended September 30, 2017 was primarily due to a \$2.4 million increase in consulting and other expenses to support the growing organization including costs related to commercial readiness, a \$2.4 million increase in personnel expenses primarily related to increased headcount to support the business, a \$1.7 million increase in legal fees, and a \$1.4 million increase in stock-based compensation expense.

The increase of \$19.5 million for the nine months ended September 30, 2017 was primarily due to a \$6.6 million increase in consulting and other expenses to support the growing organization including costs related to commercial readiness, a \$6.0 million increase in personnel expenses related to increased headcount to support the business, a \$4.1 million increase in stock-based compensation expense, and a \$2.8 million increase in legal fees.

Other-Than-Temporary Impairment Loss. The other-than-temporary impairment loss in the nine months ended September 30, 2016 of \$5.5 million was related to the decline in value of our investment in Fate Therapeutics.

Interest Income, Net. Interest income, net was \$2.0 million and \$5.4 million for the three and nine months ended September 30, 2017, compared to \$1.5 million and \$4.3 million for the three and nine months ended September 30, 2016, respectively. Interest income, net consisted primarily of interest income earned on our marketable securities.

Benefit for Income Taxes. We recorded an income tax benefit of \$1.8 million and \$4.2 million for the three and nine months ended September 30, 2017, compared to \$0.6 million and \$9.1 million for the three and nine months ended September 30, 2016, respectively. The income tax benefit for the three and nine months ended September 30, 2017 primarily related to the net loss incurred by our Germany subsidiary. Of the total tax benefit recognized in the nine months ended September 30, 2016, \$6.7 million related to the release of valuation allowance on the U.S. deferred tax assets as a result of the acquisition of

[Table of Contents](#)

AbViro, and the remaining amount was primarily related to the net loss incurred by our German subsidiary. We have determined that it is more-likely-than-not that we will realize the benefit of the German losses.

Net Loss Per Share, Basic and Diluted. Upon the closing of the September 2017 follow-on public offering and the concurrent Celgene private placement, the Company sold 7,773,327 shares of common stock. The issuance of these shares will result in a significant increase in the Company's weighted-average shares outstanding when compared to the comparable prior year period and is expected to continue to impact the year-over-year comparability of the Company's net loss per share calculations for the next twelve months.

Liquidity and Capital Resources

Sources and Uses of Liquidity

As of September 30, 2017, we had \$1.06 billion in cash, cash equivalents and marketable securities. Prior to our entry into the Celgene collaboration, we raised an aggregate of approximately \$618.0 million in gross proceeds, through our initial public offering and private placements of our convertible preferred stock which we used to fund our operations. As a result of our entry into the collaboration with Celgene and our initial sale of stock to Celgene, we received \$1.0 billion in cash from Celgene in August 2015. Celgene also has the right to purchase additional shares of our common stock, including annual "top-up" rights as described under "Licenses and Third-Party Collaborations" in Part I—Item 1—"Business" of our 2016 Annual Report. If exercised, these purchases will provide us with additional funding for our operations. We received \$1.7 million and \$47.0 million in the nine months ended September 30, 2017 and 2016, respectively, from Celgene in connection with the sale of our stock pursuant to the exercise by Celgene of its annual top-up right under the Celgene Share Purchase Agreement. In April 2016 we received an opt-in payment of \$50.0 million from Celgene upon Celgene's election to opt-in to our CD19 program. We and Celgene now generally share worldwide development costs for certain CD19 product candidates, which can lead to reimbursements to us from Celgene for certain of our expenses. As of September 30, 2017, we have received an aggregate of \$50.2 million in such reimbursements from Celgene. In September 2017, we received \$272.4 million in net proceeds from the September 2017 follow-on public offering and \$31.1 million in proceeds from Celgene from the concurrent private placement. We also may receive funding from Celgene in the form of option exercise fees or reimbursements for qualified expenses related to the development and commercialization of product candidates in programs that Celgene opts into in the future under the Celgene Collaboration Agreement.

The funding from Celgene and the September 2017 follow-on public offering decreases our need for additional near-term funding, although we may still need to raise additional capital in the future. We believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operations for at least the next 12 months.

We expect to continue to incur substantial additional losses in the future as we expand our research and development activities and build our commercial infrastructure. Until such time, if ever, as we can generate substantial product revenue, and if funding from Celgene is not sufficient for our operations, we may be required to finance our cash needs through a combination of equity or debt financings.

Cash Flows

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

	Nine Months Ended September 30,	
	2017	2016
Net cash provided by (used in):		
Operating activities	\$ (132,169)	\$ (120,367)
Investing activities	70,906	51,534
Financing activities	323,243	39,907
Effect of exchange rate changes on cash and cash equivalents	(34)	(52)
Net increase (decrease) in cash and cash equivalents	\$ 261,946	\$ (28,978)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2017 was \$132.2 million compared to \$120.4 million for the nine months ended September 30, 2016. The increase of \$11.8 million was primarily due to increased costs incurred to manufacture our product candidates, execute our clinical development strategy, and expand our overall research and development capabilities. For the nine months ended September 30, 2017, we received cash of \$30.8 million in connection with

[Table of Contents](#)

the Celgene Collaboration Agreement for the partial reimbursement by Celgene of research and development costs incurred by us and \$37.7 million related to a tenant improvement allowance for our new headquarters facility. For the nine months ended September 30, 2016, we received a \$50.0 million upfront payment in connection with the CD19 opt-in, \$9.2 million in connection with the Celgene Collaboration Agreement for the partial reimbursement by Celgene of research and development costs incurred by us, and \$14.3 million in milestone payments from Novartis.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2017 was \$70.9 million compared to \$51.5 million for the nine months ended September 30, 2016. The increase of \$19.4 million was primarily due to a decline in cash outflows for acquisitions offset by an increase in property and equipment purchases. Included in investing activities for the nine months ended September 30, 2017 was a \$56.9 million cash outflow for the purchase of property and equipment, the majority of which related to the build-out of our new headquarters facility. Included in investing activities for the nine months ended September 30, 2016 was net cash paid to acquire AbVitro of \$74.6 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2017 was \$323.2 million compared to \$39.9 million for the nine months ended September 30, 2016. The increase of \$283.3 million was primarily due to net proceeds of \$272.4 million received from the September 2017 follow-on public offering and proceeds of \$31.1 million received from the concurrent private placement with Celgene. The increase was offset by lower proceeds received from Celgene's exercise of its annual right to purchase shares of our common stock to "top-up" its ownership in Juno. In the nine months ended September 30, 2017 and 2016 we received proceeds from Celgene of \$1.7 million and \$47.0 million, respectively, for the exercise of its annual right to purchase shares of our common stock.

Off-Balance Sheet Arrangements

As of September 30, 2017, we did not have any off-balance sheet arrangements or holdings in variable interest entities that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources that is material to investors.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business, primarily related to interest rate sensitivities, the volatility of our stock price, and foreign exchange rates.

Interest Rate Sensitivity

As of September 30, 2017, we had \$605.9 million in marketable securities, largely composed of investment grade short- to intermediate-term fixed income securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality.

Our marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Stock Price Sensitivity

We agreed to make success payments to FHCRC and MSK based on increases in the per share fair market value of our common stock during the term of the agreements payable in cash or publicly-traded equity at our discretion.

As of September 30, 2017, the estimated fair value of the total success payment obligations was approximately \$110.6 million. We recognized an expense of \$37.2 million and \$61.8 million for the three and nine months ended September 30, 2017, respectively, with respect to the success payment obligations. The success payment liabilities on the condensed consolidated balance sheet as of September 30, 2017 were \$84.6 million.

Changes in the fair value of our common stock as of each balance date may have a relatively large change in the estimated valuation of the success payment obligations and associated liability and resulting expense or gain. See Note 4 to our condensed consolidated financial statements included herein for a sensitivity analysis showing the impact that a hypothetical change in the value of our common stock would have had on our results for the three months ended September 30, 2017.

Foreign Currency Sensitivity

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions and future potential milestones including potential contingent consideration payments pursuant to the terms of our Stage acquisition, that are denominated in currencies other than the U.S. dollar, primarily the Euro, and we therefore are subject to foreign exchange risk. Additionally, our German subsidiary operates with the Euro as its functional currency. The fluctuation in the value of the U.S. dollar against the Euro affects the reported amounts of revenues, expenses, assets and liabilities. As we expand our international operations, our exposure to exchange rate fluctuations will increase. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2017, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2017, the design and operation of our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, our 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. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business.

USPTO Proceedings

In August 2015, Kite Pharma, Inc. ("Kite") filed a petition with the U.S. Patent & Trademark Office (the "USPTO") for inter partes review of U.S. Patent No. 7,446,190 (the "'190 Patent"), a patent that we have exclusively licensed from MSK. In February 2016, the USPTO determined to initiate the inter partes review proceedings, in Kite Pharma, Inc. v. Sloan Kettering Institute for Cancer Research, Case IPR2015-01719. As the exclusive licensor, we opted to exercise our right to control the defense of the patent in the proceedings. A hearing was held before the USPTO Patent Trial and Appeal Board on October 20, 2016. On December 16, 2016, the USPTO Patent Trial and Appeal Board issued a final written decision upholding all the claims of this patent. On February 16, 2017, Kite appealed the USPTO Patent Trial and Appeal Board's final written decision to the U.S. Court of Appeals for the Federal Circuit. Kite filed its opening brief on June 29, 2017. Our opening brief was filed on October 10, 2017, and Kite's Reply Brief is due on December 15, 2017. We will incur expenses associated with the appeal, which expenses may be substantial. If we are unsuccessful in the appeal and the USPTO's decision is reversed, one or more of the patent's claims could be narrowed or invalidated, but we do not expect that this would have a material adverse effect on our business.

Intellectual Property Litigation

On December 19, 2016, we filed a complaint for declaratory judgment of infringement of U.S. Patent No. 7,446,190 against Kite. The lawsuit was filed in federal district court in Delaware. The complaint alleges that Kite's axicabtagene ciloleucel (KTE-C19) product does or will infringe claims 1-3, 5, 7-9, and 11 of the '190 Patent. We sought, among other things, a declaratory judgment that axicabtagene ciloleucel does or will infringe these claims of the '190 Patent. On February 23, 2017, Kite filed a motion to dismiss the complaint. On March 23, 2017, we filed an opposition to Kite's motion to dismiss. On April 6, 2017, Kite filed a reply in support of its motion to dismiss. The district court granted Kite's motion to dismiss on June 13, 2017, reasoning that the court lacked subject matter jurisdiction due to the "speculative" nature of FDA approval for Kite's axicabtagene ciloleucel product.

On September 1, 2017, we filed a complaint against Kite in the federal district court for the Central District of California for infringement and declaratory judgment of infringement of U.S. Patent No. 7,446,190. The complaint alleges that KTE-C19 infringes claims 1-3, 5, 7-9, and 11 of the '190 Patent, based in part on Kite's manufacturing and stockpiling of KTE-C19 retroviral vector intended for commercial use. We are seeking, among other things, both a judgment that Kite has infringed these claims of the '190 Patent, and a declaratory judgment that Kite does or will infringe the '190 Patent.

On October 18, 2017, the same day the FDA approved Kite's Yescarta KTE-C19 product, we filed a second complaint against Kite in the federal district court for the Central District of California. The complaint alleges that Yescarta infringes claims 1-3, 5, 7-9, and 11 of the '190 Patent. We are seeking, among other things, a judgment that Kite has infringed these claims of the '190 Patent based on its commercialization of Yescarta.

Contract Litigation

See Note 11 to our condensed consolidated financial statements included in this report for a description of our contract litigation with City of Hope.

Securities and Derivative Litigation

See Note 11 to our condensed consolidated financial statements included in this report for a description of a putative class action and a purported derivative action involving Juno.

ITEM 1A. RISK FACTORS

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this report, including our financial statements and the related notes and Part I—Item 2 —“Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business and Industry

We are a clinical-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical-stage biopharmaceutical company that was formed in August 2013. We have no cell-therapy products approved for commercial sale and as of September 30, 2017, had not generated any revenue from such products. We are focused on developing products that use human cells as therapeutic entities and, although there have been significant advances in cell-based immunotherapy, our T cell technologies are new and largely unproven. Our limited operating history, particularly in light of the rapidly evolving cancer immunotherapy field, may make it difficult to evaluate our current business and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses in the future.

We are not profitable and have incurred losses in each period since our inception. For the nine months ended September 30, 2017, we reported a net loss of \$301.1 million. As of September 30, 2017, we had an accumulated deficit of \$1.13 billion, which includes \$51.1 million related to non-cash deemed dividends, \$174.4 million in upfront fees to acquire technology, of which \$100.5 million was paid in cash and \$73.9 million was paid through the issuance of common stock, non-cash expense of \$165.8 million associated with the change in the estimated fair value and elapsed service period for our potential and actual success payment liability to FHCRC and MSK, expense of \$23.2 million associated with non-cash milestones, non-cash gain of \$5.6 million associated with the change in the estimated value of our contingent consideration liabilities, and \$10.7 million of expense associated with our convertible preferred stock options. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our product candidates, scale-up manufacturing capabilities and hire additional personnel to support the development of our product candidates and to enhance our operational, financial and information management systems.

A critical aspect of our strategy is to invest significantly in our technology platform to improve the efficacy and safety of our product candidates. Even if we succeed in commercializing one or more of these product candidates, we will continue to incur losses for the foreseeable future relating to our substantial research and development expenditures to develop our technologies. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders’ equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period to period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant losses for the foreseeable future. We expect these losses and our cash utilization to increase in the near term as we continue to conduct clinical trials, file additional IND filings for additional product candidates, and conduct research and development of our other product candidates.

We are collaborating with Celgene pursuant to the Celgene Collaboration Agreement, under which we and Celgene will research, develop, and commercialize novel cellular therapy product candidates and other immuno-oncology and immunology therapeutics, including, in particular, CAR and TCR product candidates. Contingent upon the payment of certain upfront payments, Celgene may exercise options to acquire exclusive licenses in territories outside North America and China to certain therapeutics we develop and each party may exercise certain options to co-develop and co-commercialize product candidates developed, or acquired or in-licensed, by the other party. If Celgene does not exercise its options, or if Celgene exercises an option for a program (as it has for our CD19 program) but later the license agreement with Celgene for such program is

[Table of Contents](#)

terminated, we will be responsible for the full costs of funding further worldwide development of the relevant product candidates, which would cause our expenses to increase, unless we choose not to pursue further development of such product candidates or we enter into another collaboration for such product candidates, which may not be possible within an acceptable timeframe or on suitable terms. Additionally, either we or Celgene may opt not to fund a study led by the other under an active license agreement, such as the Celgene CD19 License, and if Celgene opts not to fund a Juno-led study, then we would be responsible for the full cost of that study until such time, if ever, that Celgene determines to opt back in to the study at a premium to obtain the right to use data from that study in Celgene's territories. Similarly, our expenses would increase if we exercise an option to co-develop and co-commercialize any product candidate developed, or in-licensed or acquired, by Celgene.

We have never generated any revenue from sales of cell-therapy products and our ability to generate revenue from cell-therapy product sales and become profitable depends significantly on our success in a number of factors.

We have no cell-therapy products approved for commercial sale, have not generated any revenue from cell-therapy product sales, and do not anticipate generating any revenue from cell-therapy product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options, and obtaining adequate coverage, reimbursement, and pricing by third-party payors, integrated delivery networks, and government authorities;
- addressing any competing technological and market developments;
- Celgene's efforts in its territories to further develop and commercialize the product candidates for which Celgene exercises an option under the Celgene Collaboration Agreement, such as the product candidates in our CD19 program;
- Celgene exercising any other of its options under our Celgene Collaboration Agreement;
- JW Therapeutics (Shanghai) Co., Ltd's ability to develop and commercialize product candidates in China;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is 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, or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

Our technology platform, including our CAR and high-affinity TCR technologies are new approaches to cancer treatment that present significant challenges.

We have concentrated our research and development efforts on T cell immunotherapy technology, and our future success is highly dependent on the successful development of T cell immunotherapies in general and our CAR and TCR technologies and product candidates in particular. Our approach to cancer treatment aims to alter T cells *ex vivo* through genetic modification using certain viruses designed to reengineer the T cells to recognize specific proteins on the surface or inside cancer cells. Because this is a new approach to cancer immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities that have very limited experience with the commercial development of genetically modified T cell therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient's T cells *ex vivo* and infusing the engineered T cells back into the patient;
- conditioning patients with chemotherapy or other non-Juno product treatments in conjunction with delivering each of our products, which may increase the risk of adverse side effects;
- educating medical personnel regarding the potential side effect profile of each of our products, such as the potential adverse side effects related to cytokine release or neurotoxicity;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive our product candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement, and pricing by third-party payors and government authorities; and
- developing therapies for types of cancers beyond those addressed by our current product candidates.

We cannot be sure that our T cell immunotherapy technologies will yield satisfactory products that are safe and effective, scalable, or profitable.

Additionally, because our technology involves the genetic modification of patient cells *ex vivo* using a virus, we are subject to many of the challenges and risks that gene therapies face, including:

- Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. To date, only three products that involve the genetic modification of patient cells has been approved in the United States and only one has been approved in the European Union ("EU").
- Genetically modified products in the event of improper insertion of a gene sequence into a patient's chromosome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells.
- Although our viral vectors are not able to replicate, there is a risk with the use of retroviral or lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases.
- The FDA recommends a 15 year follow-up observation period for all patients who receive treatment using gene therapies, and we may need to adopt such an observation period for our product candidates.
- Clinical trials using genetically modified cells conducted at institutions that receive funding for recombinant DNA research from the NIH, are subject to review by the Recombinant DNA Advisory Committee ("RAC"). Although the FDA decides whether individual protocols may proceed, the RAC review process can impede the initiation of a clinical trial, even if the FDA has reviewed the study and approved its initiation.

Moreover, public perception of therapy safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies

and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Our near-term ability to generate product revenue is dependent on the success of one or more of our CD19 product candidates, each of which are in clinical development and will require significant additional clinical testing before we can seek regulatory approval and begin commercial sales.

Our near-term ability to generate product revenue is highly dependent on our ability to obtain regulatory approval of and successfully commercialize one or more of our CD19 product candidates. Our lead product candidate, JCAR017, is in clinical development, has been tested in a relatively small number of patients, and will require additional clinical and nonclinical development, regulatory review and approval in each jurisdiction in which we intend to market the product, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety, purity, and potency of the product candidates in humans. We cannot be certain that any of our product candidates will be successful in clinical studies and they may not receive regulatory approval even if they are successful in clinical studies.

In addition, because our product candidates are based on similar technology, if any of our product candidates encounter safety or efficacy problems, developmental delays, regulatory issues, reagent supply issues, or other problems, our development plans for the affected product candidate and some or all of our other product candidates could be significantly harmed, which would have a material adverse effect on our business. Because JCAR017 is the backbone of our development strategy, a setback for JCAR017 could have a relatively large impact on our plans and business. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business.

Prior to the Juno-sponsored Phase I trial of JCAR017 and Phase II clinical trial of JCAR015 that began in 2015, third parties had sponsored and conducted all clinical trials of our CD19 product candidates and other product candidates, and our ability to influence the design and conduct of such trials has been limited. We have assumed control over the future clinical and regulatory development of JCAR017 in NHL, and may do so for additional indications or other product candidates, which will entail additional expenses and may be subject to delay. Any failure by a third party to meet its obligations with respect to the clinical and regulatory development of our product candidates may delay or impair our ability to obtain regulatory approval for our products and result in liability for our company.

Prior to the Juno-sponsored Phase I clinical trial of JCAR017 and the Phase II clinical trial of JCAR015, both of which began in 2015, we had not sponsored any clinical trials relating to our CD19 product candidates or other product candidates. Instead, faculty members at our third-party research institution collaborators, or those institutions themselves, sponsored all clinical trials relating to these product candidates, in each case under their own INDs. We have now assumed control of the U.S. clinical and regulatory development of JCAR017 in NHL for future clinical trials. We may assume control over the clinical and regulatory development of other product candidates in the future, in which case we will need to obtain sponsorship of the INDs or file new Juno-sponsored INDs. Failure to obtain, or delays in obtaining, sponsorship of INDs or in filing new Juno-sponsored INDs for these or any other product candidates we determine to advance could negatively affect the timing of our potential future clinical trials. Any such impacts on timing could increase research and development costs and could delay or prevent obtaining regulatory approval for our product candidates, either of which could have a material adverse effect on our business.

Further, even in the event that the IND sponsorship is or has been obtained for existing and new INDs, we did not control the design or conduct of the previous trials. It is possible that the FDA will not accept these previous trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any of one or more reasons, including the safety, purity, and potency of the product candidate, the degree of product characterization, elements of the design or execution of the previous trials or safety concerns, or other trial results. We may also be subject to liabilities arising from any treatment-related injuries or adverse effects in patients enrolled in these previous trials. As a result, we may be subject to unforeseen third-party claims and delays in our potential future clinical trials. We may also be required to repeat in whole or in part clinical trials previously conducted by our third-party research institution collaborators, which will be expensive and delay the submission and licensure or other regulatory approvals with respect to any of our product candidates. Any such delay or liability could have a material adverse effect on our business.

Although we have assumed control of the overall clinical and regulatory development JCAR017 in NHL going forward, we expect to be dependent on our contractual arrangements with collaborators for certain of our JCAR017 trials and for ongoing

[Table of Contents](#)

and planned trials for our other product candidates until we determine to assume control of the clinical and regulatory development of those candidates. Such arrangements provide us certain information rights with respect to certain previous, planned, or ongoing trials of our product candidates, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from such trials. Even after we assume control of the overall clinical and regulatory development of a product candidate, including JCAR017, we will still remain dependent on such contractual data rights for use in our clinical and regulatory development activities. If these obligations are breached by our collaborators, or if the data, or our data rights, prove to be inadequate compared to the first-hand knowledge we might have gained had the completed trials been Juno-sponsored trials, then our ability to design and conduct our Juno-sponsored clinical trials may be adversely affected. Additionally, the FDA may disagree with the sufficiency of the preclinical, manufacturing, or clinical data generated by these prior collaborator-sponsored trials, or our interpretation of preclinical, manufacturing, or clinical data from these clinical trials. If so, the FDA may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may begin our planned trials and/or may not accept such additional data as adequate to begin our planned trials.

Additionally, we may remain dependent on our third-party research institution collaborators for other support services in connection with our Juno-sponsored clinical trials.

We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. We expect that the early clinical work performed by our third-party research institution collaborators will help support the filing with the FDA of multiple INDs for our product candidates in the next five years. However, we cannot be sure that we will be able to submit INDs at this rate, and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in sufficiently developing, characterizing, or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching a consensus with regulatory agencies on study design;
- the FDA may not allow us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical studies;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required institutional review board ("IRB") approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical study requirements;

[Table of Contents](#)

- failure to perform in accordance with the FDA’s good clinical practice ("GCP") requirements, or applicable regulatory guidelines in other countries;
- transfer of manufacturing processes to Celgene or any other commercialization partner for the manufacture of product candidates in trials outside of the United States;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- transfer of manufacturing processes from our academic collaborators to larger-scale facilities operated by either a CMO or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- delays or failure to secure supply agreements with suitable reagent suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary reagents; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We have entered into collaborations, including our Celgene collaboration, and strategic alliances, and may enter into additional arrangements like these in the future, and we may not realize the anticipated benefits of such collaborations or alliances.

Research and development collaborations, including those we have entered into with Celgene, Fate Therapeutics, Editas, and MedImmune, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and may not commit sufficient efforts and resources, or may misapply those efforts and resources;
- collaborators may not pursue development and commercialization of collaboration product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results or changes in their strategic focus;
- collaborators may delay, provide insufficient resources to, or modify or stop clinical trials for collaboration product candidates;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our products or product candidates (for instance, Celgene and bluebird bio are collaborating on an anti-BCMA CAR T product candidate);
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

[Table of Contents](#)

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital and personnel to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

In particular, for product candidates in our CD19 program and product candidates from any other programs for which Celgene opts to exercise its options under the Celgene Collaboration Agreement, we may have limited influence or control over their approaches to development and commercialization in the territories in which they lead development and commercialization, including the choice of which product candidates Celgene determines to advance in those territories. Although we will still lead development and commercialization activities in North America and China for our product candidates arising from our CD19 program and any other program for which Celgene exercises an option, Celgene's development and commercialization activities in the territories where it is the lead party may adversely impact our own efforts in North America and China and lead to changes to clinical and regulatory development strategy for associated product candidates that may impact development timelines. Celgene may also assist us with conducting some of our clinical trials in North America, which will cause us to be dependent in part on Celgene's efforts for our development activities in North America. Celgene will also require some level of assistance from us with respect to product candidates from the CD19 program and product candidates from any other programs it opts into, and this assistance could be burdensome on our organization and resources and disrupt our own development and commercialization activities. Celgene will also be subject to many of the same risks that are set forth in this "Risk Factors" section pertaining to operations and government regulation, which may adversely affect Celgene's ability to develop and commercialize collaboration products.

In early 2016, we and WuXi AppTec formed a new company, JW Therapeutics (Shanghai) Co., Ltd, to develop and commercialize cell-based immunotherapies for patients with hematologic and solid organ cancers in China. We have limited control over JW Therapeutics (Shanghai) Co., Ltd and its affiliated companies and so we will be subject to many of the same risks set forth above with respect to collaborations. JW Therapeutics (Shanghai) Co., Ltd and its affiliated companies will also be subject to many of the same risks that are set forth in this "Risk Factors" section pertaining to operations, government regulation, and intellectual property, which may adversely affect JW Therapeutics (Shanghai) Co., Ltd and its affiliated companies' ability to develop and commercialize products.

We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Such alliances will be subject to many of the risks set forth above. Moreover, any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex.

As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies, which could harm our business prospects, financial condition, and results of operations.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans, including our plans to seek accelerated approval, and we may fail to obtain regulatory approval of our product candidates.

We are conducting a Phase I trial in adult r/r NHL with JCAR017, which we refer to as the TRANSCEND trial, and are currently enrolling the cohort that we believe may support registration, and we plan to conduct additional clinical trials in other B cell malignancies, including r/r CLL, adult r/r ALL, and pediatric r/r ALL, using this product candidate or a next generation product candidate. If the results of these trials are sufficiently compelling, we intend to discuss with the FDA the potential for filing biologics license applications ("BLAs") for accelerated approval of the associated product candidates as treatments for patients who are refractory to currently approved treatments in these indications.

The FDA generally requires a BLA to be supported by two adequate and well-controlled Phase III studies or one large and robust, well-controlled Phase III study in the patient population being studied that provides substantial evidence that a biologic is safe, pure and potent. Phase III clinical studies typically involve hundreds of patients, have significant costs and take years to complete. However, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses

[Table of Contents](#)

and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. We believe our accelerated approval strategy is warranted given the currently limited alternative therapies for patients with r/r NHL, r/r CLL, r/r ALL, and r/r multiple myeloma but the FDA may not agree or competing or alternative therapies may enter the market that cause the FDA to determine that the accelerated approval framework is no longer appropriate in those indications. The FDA may ultimately require one or multiple Phase III clinical trials prior to approval, particularly because our product candidates are novel and personalized treatments.

As part of its marketing authorization process, the European Medicines Agency ("EMA") may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use ("CHMP") to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete nonclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats.

Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

The granting of a conditional marketing authorization will allow medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product are generated, submitted, assessed and acted upon. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied. Even if conditional marketing authorization is granted, we cannot guarantee that the EMA or CHMP will renew the authorization annually. Celgene may seek conditional marketing approval in the EU for our CD19 product candidates.

Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or standard approval procedures. The results of preclinical and clinical studies may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;

[Table of Contents](#)

- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third-party manufacturer's facilities with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Further, failure to obtain approval for any of the above reasons may be made more likely by the fact that the FDA and other regulatory authorities have very limited experience with commercial development of genetically engineered T cell therapies for cancer. Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects.

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

The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival, and an acceptable safety profile. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Similarly, the final results from a clinical trial may not be as good as interim results reported earlier in the same clinical trial. Additionally, the results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. We expect there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our product candidates, than for "off-the-shelf" products, like many other drugs. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Data from studies conducted by the third-party research institutions that are our collaboration partners, such as FHCRC, MSK, SCRI, and the NCI, should not be relied upon as evidence that later or larger-scale clinical trials will succeed. Some future trials may have different patient populations than current studies and will test our product candidates in different indications, among other differences. In addition, our manufacturing processes for our CD19 product candidates include what we believe to be process improvements that are not part of the production processes that have been used in the clinical trials conducted by the

[Table of Contents](#)

research institutions. Accordingly, our results with our CD19 product candidates may not be consistent with the results of the clinical trials conducted by our research institute collaborators.

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

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

As with most biological drug products, use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. It is not uncommon for there to be treatment-related deaths in clinical trials in advanced cancer patients, and even some standard of care treatments, such as HSCT, are associated with a level of treatment-related mortality. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials. As of a data cutoff date of August 11, 2017 for JCAR015 and August 10, 2017 for JCAR017, treatment-emergent adverse events, whether or not treatment related, occurring in at least 25% of patients across trials conducted under a Juno-sponsored IND include cytokine release syndrome ("CRS"), nausea, diarrhea, vomiting, decreased appetite, fatigue, headache, hypokalemia, neutropenia, anemia, thrombocytopenia, and events of neurotoxicity, including confusional state, aphasia, encephalopathy, tremor, muscular weakness, and somnolence. Similar adverse events have been observed in trials conducted by our collaborators. Characteristic symptoms of CRS include fever, low blood pressure, nausea, difficulty breathing, and oxygen deficiency. Some of these treatment-emergent adverse events from our or our collaborators' clinical trials have required admission to the intensive care unit and, in some severe cases, have resulted in death. Fatal events of cerebral edema have also been observed.

Undesirable side effects or deaths in clinical trials with our product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical trials, to require additional studies, or otherwise to delay or deny approval of our product candidates for any or all targeted indications. For instance, in July 2016, the FDA placed our JCAR015 Phase II trial in r/r ALL on clinical hold after we observed an increased incidence of severe neurotoxicity, including two patients who died in late June 2016 from cerebral edema. After a protocol amendment, the clinical hold was removed a few days later and the trial resumed. However, in November 2016, the FDA again placed our trial on clinical hold after the occurrence of two more deaths from cerebral edema in the trial. Following the November 2016 events, we conducted an investigation into the toxicity and identified multiple factors that may have contributed to this increased risk, including patient specific factors, the conditioning chemotherapy patients received, and factors related to the product, but we cannot know that we have identified the root causes of the toxicity to sufficiently prevent its occurrence in the future. We subsequently determined to discontinue Juno development of JCAR015. We cannot provide any assurances that there will not be further treatment-related severe adverse events or deaths with other product candidates, from cerebral edema or otherwise, that the trials for those other product candidates will not be placed on clinical hold in the future, or that patient recruitment for trials with our other product candidates will not be adversely impacted by the events with JCAR015, any of which could materially and adversely affect our business and prospects.

Negative side effects could also result in a more restrictive label, or a boxed warning on the label, for any product that is approved. We may also be required by the FDA to create a risk evaluation and mitigation strategy ("REMS") plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use, such as restricted distribution methods and patient registries.

Treatment-related side effects or clinical holds could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the research institutions that collaborate with us, as toxicities resulting from personalized T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand their side effect profiles, both for our planned clinical trials and upon any commercialization of any product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in adverse effects to patients, including death. Any of these occurrences may materially and adversely harm our business, financial condition and prospects.

[Table of Contents](#)

Undesirable side effects or deaths in clinical trials conducted by others in the engineered T cell therapy field may also adversely impact our own prospects with the FDA or comparable foreign regulatory authorities and may adversely impact our own patient recruitment activities if enthusiasm for the prospects of engineered T cell therapy generally is diminished.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product or we may voluntarily halt the sale of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required by the FDA to create a new REMS plan;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving T cell based immunotherapy;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

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

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

[Table of Contents](#)

Clinical trials are expensive, time-consuming and difficult to design and implement, and our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies and manufactured on a patient-by-patient basis, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients with r/r cancer and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from, Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and we may be required by those trial sites to pay such costs. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. Depending on the number of patients we ultimately enroll in our trials, and the number of trials we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments.

Research and development of biopharmaceutical products is inherently risky. We may not be successful in our efforts to use and enhance our technology platform and CAR and TCR technologies to create a pipeline of product candidates and develop commercially successful products, or we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited.

We and our collaborators are simultaneously pursuing clinical development of multiple product candidates developed employing our CAR and TCR technologies. We are at an early stage of development and our technology platform has not yet led, and may never lead, to approved or commercially successful products.

Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates may require substantial additional funding and are prone to the risks of failure inherent in medical product development.

Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

[Table of Contents](#)

Even if we receive FDA approval to market our product candidates, whether for the treatment of cancers or other diseases, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Further, because of our limited financial and managerial resources, we are required to focus our research programs on certain product candidates and on specific diseases. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forgo or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. For additional information regarding the factors that will affect our ability to achieve revenue from product sales, see the risk factor above "*We have never generated any revenue from sales of cell-therapy products and our ability to generate revenue from cell-therapy product sales and become profitable depends significantly on our success in a number of factors.*"

Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we, Celgene, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our product candidates are biologics and the process of manufacturing our products is complex, highly-regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including harvesting T cells from patients, genetically modifying the T cells *ex vivo*, multiplying the T cells to obtain the desired dose, and ultimately infusing the T cells back into a patient's body. As a result of the complexities, the cost to manufacture biologics in general, and our genetically modified cell product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure, or product variation that may adversely impact patient outcomes, due to logistical issues associated with the collection of white blood cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues or different product characteristics resulting from the differences in patient 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. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's starting material or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market, if licensed.

Historically, our product candidates have been manufactured using unoptimized processes by our third-party research institution collaborators that we do not intend to use for more advanced clinical trials or commercialization. Although we are working to develop commercially viable processes, including for JCAR017, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We will also need to build out and implement electronic systems to support scale and reduce human error, which may be difficult to do in a timely manner. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

We also may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. During the course of the TRANSCEND trial, we have made changes to the JCAR017 manufacturing process to support commercialization. Changes to our manufacturing process carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials, future clinical trials, or the performance of the product once commercialized. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in

[Table of Contents](#)

our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. We may also make further changes to our manufacturing process before or after commercialization, and such changes may require us to show the comparability of the resulting product to the product used in the clinical trials using earlier processes. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate.

We expect our manufacturing strategy will involve the use of our manufacturing facility in Bothell, Washington, and potentially additional Juno-operated manufacturing facilities or one or more CMOs, to manufacture our product candidates. We also plan to manufacture certain of the reagents used for making our product candidates ourselves. We expect that development of our own manufacturing capabilities, as well as manufacturing some of our own reagents, will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have limited experience as a company manufacturing product candidates for use in the clinic and no experience as a company manufacturing product candidates for commercial supply, and we have only limited experience (through our German subsidiary) in manufacturing reagents. We may never be successful in manufacturing product candidates or reagents in sufficient quantities or with sufficient quality for clinical or commercial use. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly.

Even if we are successful in developing our manufacturing capabilities sufficient for clinical and commercial supply, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, operator error, natural disasters, availability of qualified personnel, difficulties with logistics and shipping, problems regarding yields or stability of product, contamination or other quality control issues, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

Furthermore, if contaminants are discovered in our supply of our product candidates or in our manufacturing facilities or those of our CMOs, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, we and our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we or our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval process, and we will need to meet, and our CMOs will need to meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

We also will need to assist Celgene with the transfer of our manufacturing processes for our CD19 product candidates, and product candidates for any other programs for which they exercise an option, to geographies outside of North America and China. The transfer of process to Celgene, or to CMOs selected by Celgene, and the actual manufacture of our product candidates by Celgene or its selected CMOs, will be subject to the same types of risk as set forth above and may not ultimately be successful or may take longer to succeed than expected, which could delay or impair development and commercialization activities in those geographies, which would have an adverse effect on our business. Such transfer activities will also require a significant amount of attention from our personnel, which may disrupt our other development and commercialization activities, which in turn may have an adverse effect on our business. Additionally, in the interim we expect we will need to manufacture product candidates out of our existing facilities for use in clinical trials in the Celgene territories, which may disrupt our own clinical activities and, to the extent we are not able to produce product candidate in the volumes required by Celgene or experience difficulties coordinating manufacturing in the United States with patient material collection and treatment centers in the Celgene territories, may also lead to delays in development plans in such Celgene territories. To the extent product

[Table of Contents](#)

candidates need to be shipped across international borders for use in clinical trials in the Celgene territories, there may be shipping, customs, or other import/export related delays that could lead to a loss of a patient's manufactured product, which could prevent patients from being treated or require a new batch to be manufactured from the patient's starting material. Losses of this sort could cause delays in the associated clinical trials, which could delay or prevent the clinical development and commercialization of our product candidates in the Celgene territories.

We rely on third parties for certain aspects of the manufacture our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We currently rely on outside vendors for certain aspects of the manufacturing process for our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. Although our manufacturing and processing approach originates with the approach undertaken by our third-party research institution collaborators, we have limited experience in managing the T cell engineering process, and our process may be more difficult or expensive than the approaches in use by others. We have made and will continue to make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will not result in significantly different T cells that may not be as safe and effective as any T cell therapy deployed by our third-party research institution collaborators.

Although we have brought a Juno-operated manufacturing facility online for clinical manufacturing, we also intend to continue to use third parties as part of our manufacturing process, including for the manufacturing of critical reagents and materials, such as viral vector. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any manufacturers. This approval would require new testing and good manufacturing practices compliance inspections by FDA. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of the reagents and materials used in the manufacturing of our products.
- Our manufacturers may have little or no experience with autologous cell products, which are products made from a patient's own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates.
- Our third-party manufacturers might be unable to timely manufacture reagents and materials used in the manufacture of our product candidates, or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Our contract manufacturers may not perform as agreed, may not devote sufficient resources us, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute the materials or reagents used in the manufacture of our product candidates.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practices ("cGMPs") and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products, or in the manufacture of the custom materials or reagents used in the manufacture thereof.
- Our third-party manufacturers could breach or terminate their agreement with us.
- Raw materials, reagents, and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects, or may introduce variability into our final products.
- Our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Celgene may similarly rely on third parties for manufacturing activities in the territories where Celgene leads development and commercialization of product candidates from programs for which it has exercised an option, and therefore Celgene's activities

[Table of Contents](#)

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

Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates requires many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for product candidate that is already in clinical testing, the change may require us to perform both *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

We do and will continue to rely in significant part on outside scientists and their third-party research institutions for research and development and early clinical testing of our product candidates. These scientists and institutions may have other commitments or conflicts of interest, which could limit our access to their expertise and harm our ability to leverage our technology platform.

We rely to a significant extent at present on our third-party research institution collaborators for research and development capabilities. Currently, SCRI is conducting a Phase I trial using JCAR023 to address refractory or recurrent pediatric neuroblastoma; FHCRC is conducting a Phase I/II clinical trial using JCAR014 to address r/r ALL, NHL, and CLL, including in combination with ibrutinib in CLL, a Phase Ib trial using JCAR014 in combination with durvalumab to address r/r NHL, a Phase I trial using a CD19-directed product candidate incorporating a fully human binding domain to address certain r/r B cell malignancies, a Phase I trial using JCAR024 to address advanced stage ROR-1 expressing cancers, a Phase I/II trial using JTCCR016 to address newly diagnosed or relapsed high risk adult myeloid leukemia, a Phase I/II trial using JTCCR016 to address advanced NSCLC and mesothelioma, and a Phase I clinical trial using a fully-human BCMA-directed CAR product candidate to address r/r multiple myeloma; MSK is conducting Phase I clinical trial using a fully-human BCMA-directed CAR product candidate to address r/r multiple myeloma, a Phase I trial with JCAR020 to address advanced stage ovarian cancer, and a Phase I trial with a CD19/4-1BBL "armored" CAR to address r/r CLL; Peter MacCallum Cancer Centre is conducting a Phase I clinical trial using a Lewis Y-directed CAR T cell product candidate to address advanced stage lung cancer and other Lewis Y-expressing advanced stage tumors; and the NCI is conducting a clinical trial of JCAR018 for the treatment of pediatric and young adult r/r ALL and r/r NHL. SCRI is also conducting the Phase II portion of a Phase I/II trial with a CD19-directed CAR in pediatric patients with r/r ALL. SCRI has used a manufacturing process for many patients in the trial's Phase II portion that

[Table of Contents](#)

is different than the process SCRI used in the Phase I portion of the trial and the process we use in the TRANSCEND trial to manufacture JCAR017. Differences in manufacturing process may contribute to meaningful product differences that could affect patient outcomes or our ability to rely on the data from these studies in support of regulatory submission for our product candidates that are manufactured differently than those evaluated in these studies.

Each of these clinical trials addresses a limited number of patients. We expect to use the results of these trials, if favorable, to help support the filing with the FDA of Juno-sponsored INDs to conduct more advanced clinical trials with the corresponding product candidates. We are conducting the TRANSCEND trial under a Juno-sponsored IND.

We also fund research and development under agreements with FHCRC, MSK, and SCRI, among other institutions. However, the research we are funding constitutes only a small portion of the overall research of each research institution. Other research being conducted by these institutions may at times receive higher priority than research on the programs we are funding. We typically have less control of the research, clinical trial protocols, and patient enrollment than we might with activity led by Juno employees.

The outside scientists who conduct the clinical testing of our current product candidates, and who conduct the research and development upon which our product candidate pipeline depends, are not our employees; rather they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. These factors could adversely affect the timing of the clinical trials, the timing of receipt and reporting of clinical data, the timing of Juno-sponsored IND filings, and our ability to conduct future planned clinical trials. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to, and have a material adverse effect on, our business.

Our existing agreements with our collaboration partners may be subject to termination by the counterparty upon the occurrence of certain circumstances as described in more detail under the caption "Licenses and Third-Party Collaborations" in Part I—Item 1—"Business" of the 2016 Annual Report. If any of our collaboration partners terminates their collaboration agreement, the research and development of the relevant product candidate would be suspended, and we may be unable to research, develop, and license future product candidates. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us. In addition, there is a natural transition period when a new third party begins work. In addition, switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

We will be highly dependent on the NCI for early clinical testing of JCAR018.

In December 2014, we entered into an exclusive license agreement with Opus Bio pursuant to which Opus Bio has granted us an exclusive, worldwide, sublicensable license under certain patent rights related to a CD22-directed CAR product candidate, JCAR018. In connection therewith, the NCI agreed to separate the activities that are exclusively related to CD22 under its agreement with Opus Bio and to enter into a separate agreement with us (the "Juno CRADA"), on the same terms as such agreement and incorporate such activities into its agreement with us.

The NCI has commenced a Phase I clinical trial of JCAR018 for the treatment of pediatric and young adult r/r ALL and r/r NHL. If the results of this trial are compelling, we expect to conduct a clinical trial of a related CD22-directed product candidate. However, we will have limited control over the nature or timing of the NCI's clinical trial and limited visibility into their day-to-day activities, including manufacturing activities. For example, the clinical trial will constitute only a small portion of the NCI's overall research and the research of the principal investigators. Other research being conducted by the principal investigators may at times receive higher priority than research on JCAR018. We will also be dependent on the NCI to provide us with data, include batch records, to support the filing of our IND. These factors could adversely affect the timing of our IND filing. Additionally, the NCI manufactures drug product and we do not control the process or facility. While JCAR018 was not impacted, certain non-Juno product candidates' development was delayed in 2016 due to contamination issues at another NCI cell manufacturing facility.

The NCI may unilaterally terminate our rights under the Juno CRADA at any time for any reason or for no reason upon at least 60 days prior written notice. If the NCI unilaterally terminates the Juno CRADA, the research and development under the Juno CRADA would be suspended and we may lose certain of our data rights, which may impair our ability to obtain regulatory approval of JCAR018.

Our results of operations and financial position could be negatively impacted if our tax positions are challenged by tax authorities or if there are adverse changes in tax laws and regulations.

We are a U.S.-based multinational company subject to tax in certain U.S. and foreign tax jurisdictions. United States federal, state and local, as well as international tax laws and regulations are extremely complex and subject to varying interpretations. Although we believe that our tax estimates and tax positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities or that we would be successful in any such challenge. If we are unsuccessful in such a challenge, the relevant tax authorities may assess additional taxes, which could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position. Presently, our German subsidiary is under examination by the German tax authorities for the years ended December 31, 2013 through December 31, 2015.

We could also be adversely affected in the future by changes in applicable tax laws, regulations, or administrative interpretations thereof. The Trump Administration and key members of Congress have made public statements indicating that U.S. corporate tax reform is a high priority, and Congress is expected to propose sweeping changes to the U.S. tax system, including changes to corporate tax rates and the taxation of income earned outside the United States (including the taxation of previously unrepatriated foreign earnings). A change to the U.S. tax system, a change to the tax system in a jurisdiction where we have significant operations, or a change in tax law in other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates, including our ongoing and planned clinical trials for our CD19 and BCMA product candidates. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of September 30, 2017, we had \$1.06 billion in cash, cash equivalents, and marketable securities. We believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operations for at least the next 12 months. However, changing circumstances or business opportunities, within or beyond our control, may lead us to use our capital faster than we currently anticipate. We may ultimately need to raise additional funds for the further development and commercialization of our product candidates or to pursue strategic transactions and other business opportunities that arise.

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 our product candidates or other research and development initiatives. Our license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek additional collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

If Celgene declines to exercise its option with respect to one or more product candidates covered by our Celgene Collaboration Agreement, or if a license agreement with Celgene for a program for which has exercised an option is terminated, we will need to secure funding to advance worldwide development of those programs on our own or secure relationships with collaborators that have the necessary capital and expertise. In addition, we may need additional funding to advance product candidates prior to Celgene's decisions regarding option exercise with respect to such product candidate if development of that program is not discontinued. Even after Celgene exercises an option for a program, we will still be responsible for a portion of worldwide development expenses for the associated product candidates and will be responsible for all commercialization expenses in the territories in which Juno leads development and commercialization activities. Additionally, either we or Celgene may opt not to fund a study led by the other under an active license agreement, and if Celgene opts not to fund a Juno-led study, then we would be responsible for the full cost of that study until such time, if ever, that Celgene determines to opt back in to the study at a premium to obtain the right to use data from that study in Celgene's territories. In addition, if we exercise our option to any of Celgene's in-licensed programs to co-develop and co-commercialize products, then we may need to secure additional funding to support our obligations to pay one-half of the acquisition costs of any such in-licensed program.

If we are unable to obtain sufficient financing when needed, it could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Any future revenue from the license agreement with Penn and Novartis is highly dependent upon milestone and contingent royalty payments generated from the efforts of Penn and Novartis, over which we have no control, and we may not realize the intended benefits of this agreement.

On April 4, 2015, the parties to *Trustees of the University of Pennsylvania v. St. Jude Children's Research Hospital*, Civil Action No. 2:13-cv-01502-SD (E.D. Penn.), agreed to settle the case, which was dismissed on April 7, 2015. In connection with this settlement we entered into a sublicense agreement with Penn and an affiliate of Novartis pursuant to which we granted Novartis a non-exclusive, royalty-bearing sublicense under certain patent rights, including U.S. Patent No. 8,399,645, to develop, make and commercialize licensed products and licensed services for all therapeutic, diagnostic, preventative and palliative uses. In exchange for this sublicense, Novartis is obligated to pay us mid-single digit royalties on the U.S. net sales of products and services related to the disputed contract and patent claims, a low double digit percentage of the royalties Novartis pays to Penn for global net sales of those products, and milestone payments upon the achievement of specified clinical, regulatory and commercialization milestones for licensed products. The sublicense agreement with Novartis and Penn is terminable by Novartis at will without notice to us and without our consent.

Our receipt of royalty and milestone payments from Novartis is subject to many risks and uncertainties. In particular, these payments are dependent upon Novartis' ability to make U.S. and global sales of its products and services, and its ability to achieve clinical, regulatory and commercialization milestones for the licensed products. We will have no control over the nature or timing of Novartis' efforts towards making these sales or achieving these milestones. Furthermore, in the course of developing and commercializing its products, Novartis and Penn will likely be subject to many risks and uncertainties similar to those faced by our company and our product candidates as described in this section, and may be subject to other risks specific to Novartis and Penn. Additionally, if Novartis or Penn breaches our sublicense agreement, we may determine to terminate the agreement, or may be required to do so by St. Jude pursuant to the terms of our license agreement with St. Jude. To the extent Novartis fails, for any of the reasons outlined above or any other reason, to remit royalty payments or milestone payments under our sublicense agreement, or fails to remit these payments in the amount anticipated, or to the extent that our sublicense agreement with Novartis and Penn is terminated, we may not realize the potential benefits of the sublicense agreement with Penn and Novartis.

We may never formalize our agreement in principle with Celgene to license Celgene a subset of the acquired AbVITRO technology or the final terms of the agreement may not be as favorable to us as expected.

We and Celgene have agreed in principle to enter into an agreement to license Celgene a subset of the technology acquired from AbVITRO and to grant Celgene options to certain related potential product rights emanating from the acquired technology. However, we may never come to agreement with Celgene on the formal terms of such an agreement, in which case we will not receive the financial benefits of such an agreement. Even if we do come to agreement with Celgene, it may not be on terms that are favorable to us as expected.

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

We depend and expect to continue depending upon independent investigators and other third parties to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners, and others. At present, we contract directly with all of our trial sites, and therefore have to negotiate budgets and contracts with each trial site, which may result in delays to our development timelines and increased costs. If we transition to a CRO to manage the conduct of our clinical trials, we will also have to negotiate budgets and contracts with such CRO, which may similarly lead to delays and increased costs.

We rely and expect to continue relying heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to how they are providing and administering T cell therapy. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, some or all of 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 nonclinical or clinical trials or to enroll additional patients before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials complies with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third

[Table of Contents](#)

parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. We have disclosed in the 2016 Annual Report and various corporate presentations certain investigator-reported interim data from some of our trials, including interim data for which we have not yet independently reviewed the source data. We also sometimes rely on such investigator-reported interim data in making business decisions. Independent review of the data by us or by an independent review board could fail to confirm the investigator-reported interim data, which may lead to revisions in disclosed clinical trial results in the future. Any such revisions that reveal more negative data than previously disclosed investigator-reported interim data could have an adverse impact on our business prospects and the trading price of our common stock. Such revisions could also reduce investor confidence in investigator-reported interim data that we disclose in the future.

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding additional trial sites or CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines and such delays could have a material adverse impact on our business, financial condition, and prospects.

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

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We expect to initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments.

Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive third line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Regulatory authorities also may establish narrower definitions around when a patient is ineligible for other treatments than we have used in our projections, and that would reduce the size of the patient population eligible for our product candidates. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, with our CD19 product candidates we expect to initially target a small patient population that suffers from certain types of aggressive NHL, r/r CLL, and r/r ALL. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy.

[Table of Contents](#)

Our market opportunities may also be limited by competitor treatments that may enter the market. See the risk factor below "*We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.*"

We plan to seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

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

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

We plan to seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. We have obtained orphan drug designation for JCAR017 for the treatment of each of DLBCL, CLL, ALL and follicular lymphoma, and for JCARH125 for the treatment of multiple myeloma. Even when we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations.

We plan to seek but may fail to obtain breakthrough therapy designation and Regenerative Medicine Advanced Therapy designation, and Celgene may seek but may fail to obtain access to PRIME, for some or all of our CD19 product candidates across various indications.

In 2012, the FDA established a breakthrough therapy designation which is intended to expedite the development and review of product candidates that treat serious or life-threatening diseases when "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase I; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Similarly, the EMA has established the PRIME scheme to expedite the development and review of product candidates that show a potential to address to a significant extent an unmet medical need, based on early clinical data.

In 2017, the FDA established a Regenerative Medicine Advanced Therapy ("RMAT") designation as part of its implementation of the 21st Century Cures Act. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue

[Table of Contents](#)

product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

We have obtained breakthrough therapy designation and RMAT designation for JCAR017 for the treatment of r/r aggressive large B cell NHL, including DLBCL, not otherwise specified (de novo or transformed from indolent lymphoma), primary mediastinal B-cell lymphoma, or follicular lymphoma grade 3B. Celgene has obtained access to PRIME for JCAR017 for the treatment of r/r DLBCL. We intend to seek breakthrough therapy designation and RMAT designation, and Celgene may seek access to PRIME, for some or all of our other product candidates that may qualify. There is no assurance that we will obtain breakthrough therapy designation or RMAT designation, or that Celgene will obtain access to PRIME, for any of our other product candidates.

Breakthrough therapy designation, RMAT designation, and PRIME eligibility do not change the standards for product approval, and there is no assurance that such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the breakthrough therapy designation, RMAT designation, or PRIME eligibility. Additionally, breakthrough therapy designation, RMAT designation, and access to PRIME can each be revoked if the criteria for eligibility cease to be met as clinical data emerges.

We currently have very limited marketing and sales organization and have no experience as a company in marketing products. If we are unable to establish marketing and sales capabilities on our own or through our collaboration with Celgene or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

Although we have begun to assemble a marketing and sales organization, the team is still very limited and we have no commercial product distribution capabilities and have no experience as a company in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources, and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel.

Under our collaboration with Celgene, for Juno-developed programs that Celgene opts into, as it has for our CD19 program, Celgene will lead development and commercialization activities outside of North America and China, but we will still be responsible for leading such activities in North America and China. If Celgene does not opt into a program for one of our product candidates that we move to commercialization, we will alone be responsible for commercialization activities worldwide, unless we find another collaborator to assist with the sales and marketing of our products.

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

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or other territories, and as a result, we may not be able to generate product revenue.

A variety of risks associated with operating our business internationally could materially adversely affect our business.

As a result of the acquisition of Stage Cell Therapeutics GmbH, we acquired a German subsidiary with employees in Germany. We also plan to seek regulatory approval of our product candidates outside of the United States. Accordingly, we expect that we, Celgene, JW Therapeutics (Shanghai) Co., Ltd, and any other potential collaborators that have operations in foreign jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

[Table of Contents](#)

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, taxes, price and exchange controls, or price and currency fluctuations;
- weak economic conditions, labor unrest, political instability, war, or terror;
- compliance with applicable tax, employment, immigration, data privacy, and labor laws for employees living or traveling abroad;
- difficulties staffing operations and managing foreign employees;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

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

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry, and the rapidly evolving market for developing genetically engineered T cells in particular, is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Specifically, genetically engineering T cells faces significant competition in both the CAR and TCR technology space from multiple companies and their collaborators, such as Novartis/Penn, Kite / Gilead Sciences, Inc. ("Gilead") / NCI, Collectis / Pfizer / Servier, Johnson & Johnson / Transposagen Biopharmaceuticals, bluebird bio, Nanjing Legend Biotech Co., Bellicum, Celyad, Cell Design Labs, NantKwest, Intrexon / Ziopharm / MD Anderson Cancer Center, Unum Therapeutics, Adaptimmune / GlaxoSmithKline, ImmunoCellular Therapeutics, Adicet Bio, and Autolus. We also face competition from non-cell based treatments offered by companies such as Amgen, Pfizer, Abbvie, AstraZeneca, Bristol-Myers, Incyte, Merck, Roche, Regeneron, Corvus, MacroGenics, Mustang Bio, Inc., and Johnson & Johnson. In particular, in August 2017 Novartis received approval from the FDA for Kymriah (tisagenlecleucel), formerly known as CTL019, for the treatment of pediatric and young adult r/r ALL. Additionally, in October 2017, Kite received approval from the FDA for Yescarta (axicabtagene ciloleucel), formerly known as KTE-C19, for treatment of patients with r/r NHL. Kite has been acquired by Gilead.

Even if we obtain regulatory approval of our product candidates, we may not be the first to market and that may affect the price or demand for our product candidates. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our product candidates, that may prevent us from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances.

For additional information regarding our competition, see the section captioned "Competition" in Part I—Item 1—"Business" located in the 2016 Annual Report.

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries and to scale our operations depends upon our ability to attract, motivate, train, and retain highly qualified managerial, scientific, medical, commercial, manufacturing, and quality control/assurance personnel. We are highly dependent on our management, particularly our chief executive officer, Hans Bishop, and our scientific, medical, commercial, manufacturing, and quality control/assurance personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements or to recruit a sufficient number of qualified personnel to scale our operations, could result in delays in product development or commercialization activities and harm our business.

We conduct most of our operations at our facilities in Seattle and Bothell, Washington, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. We also have operations in Massachusetts, California, and Germany and currently have employees in all three geographies. Competition for skilled personnel is intense in all of these geographies and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of the regions in which we currently operate, and doing so may be costly and difficult. Further expansion into additional states or countries could also increase our regulatory and legal risks.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of all of these individuals or the lives of any of our other employees.

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

As of September 30, 2017, we had 589 employees worldwide, most of whom are full time. As our development and commercialization plans and strategies develop, we must add a significant number of additional research and development, managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

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

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

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

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

[Table of Contents](#)

We have engaged in and may in the future engage in acquisitions or strategic partnerships, which could divert management's attention, increase our capital requirements, dilute our stockholders, be difficult to integrate, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We have made or entered into several acquisitions or strategic partnerships, such as our acquisitions of AbVItro and RedoxTherapies, Inc. in 2016, and we may continue to evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses.

Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities, including any earn-out milestones;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- expense or diversion of efforts related to the development of acquired technology under any diligence obligation required of us with respect to earn out milestones for an acquisition transaction, where we may not undertake such expense or efforts absent such diligence obligations;
- risk that the other party or parties to an acquisition transaction may claim that we have not satisfied any earn out diligence obligation and seek damages or other legal or equitable relief;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake additional acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our success payment obligations to FHCRC and MSK may result in dilution to our stockholders, may be a drain on our cash resources, or may cause us to incur debt obligations to satisfy the payment obligations.

We have agreed to make success payments to each of FHCRC and MSK pursuant to the terms of our agreements with each of those entities. These success payments will be based on increases in the estimated fair value of our common stock, payable in cash or publicly-traded equity at our discretion. The term of these obligations may last up to 11 years. Success payments will be owed (if applicable) after measurement of the value of our common stock in connection with the following valuation measurement dates during the term of the success payment agreement: (1) December 19, 2014, which was the date our common stock first became publicly traded; (2) the date on which we sell, lease, transfer or exclusively license all or substantially all of our assets to another company; (3) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity); (4) any date on which ARCH Venture Fund VII, L.P. or C.L. Alaska L.P. transfers a majority of its shares of company capital stock held by it on such date to a third party; (5) every second anniversary of any event described in the preceding clauses (1), (2), (3) or (4), but, in the case of FHCRC, only upon a request by FHCRC made within 20 calendar days after receiving written notice from us of such event; and (6) the last day of the 11 year period. The amount of a success payment is determined based on whether the value of our common stock meets or exceeds certain specified threshold values ascending, in the case of FHCRC, from \$20.00 per share to \$160.00 per share and, in the case of MSK, from \$40.00 per share to \$120.00 per share, in each case subject to adjustment for any stock dividend, stock split, combination of shares, or other similar events. Each threshold is associated with

[Table of Contents](#)

a success payment, ascending, in the case of FHCRC, from \$10.0 million at \$20.00 per share to \$375.0 million at \$160.00 per share and, in the case of MSK, from \$10.0 million at \$40.00 per share to \$150.0 million at \$120.00 per share, payable if such threshold is reached. The maximum aggregate amount of success payments to FHCRC is \$375.0 million and to MSK is \$150.0 million, in each case subject to cost offsets related to our cash payments for collaboration activities. In December 2015, success payments to FHCRC were triggered in the aggregate amount of \$75.0 million, less indirect cost offsets of \$3.3 million, and a success payment to MSK was triggered in the amount of \$10.0 million, less indirect cost offsets of \$1.0 million. We elected to make the payment to FHCRC and MSK in shares of our common stock, and thereby issued 1,601,085 and 240,381 shares of our common stock to FHCRC in December 2015 and to MSK in March 2016, respectively. In April 2016, we agreed to repurchase the shares issued to MSK at a price per share equal to \$41.90. See the section captioned "Licenses and Third-Party Collaborations" in Part I—Item 1—"Business" in the 2016 Annual Report for further discussion of these success payments.

The next anticipated valuation measurement date at which success payments may be triggered is December 19, 2018. Success payments will only be triggered on that date to the extent the average closing price of a share of our common stock over the consecutive 90 calendar day period preceding December 19, 2018 meets or exceeds \$60.00, subject to adjustment for any stock dividend, stock split, combination of shares, and other similar events. In order to satisfy our obligations to make these success payments, if and when they are triggered, we may issue equity securities that may cause dilution to our stockholders, or we may use our existing cash or incur debt obligations to satisfy the success payment obligation in cash, which may adversely affect our financial position.

The success payment obligations to FHCRC and MSK may cause GAAP operating results to fluctuate significantly from quarter to quarter, which may reduce the usefulness of our GAAP financial statements.

Our success payment obligations to FHCRC and MSK are recorded as a liability on our balance sheet. Under GAAP, we are required to estimate the fair value of this liability as of each quarter end and changes in estimated fair value are amortized using the accelerated attribution method over the remaining term of the corresponding collaboration agreement. Factors that may lead to increases or decreases in the estimated fair value of this liability include, among others, changes in the value of the common stock, change in volatility, changes in the applicable term of the success payments, changes in the risk free rate, and changes in the estimated indirect costs that are creditable against FHCRC and MSK success payments. A small change in the inputs and related assumptions may have a relatively large change in the estimated valuation and associated liability and resulting expense or gain. For instance, see Note 4 to our condensed consolidated financial statements included in this report for a sensitivity analysis showing the impact that a hypothetical change in the value of our common stock would have had on our results for the three months ended September 30, 2017. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and from year to year and may reduce the usefulness of our GAAP financial statements.

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

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

If we, our CROs or our CMOs use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

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

[Table of Contents](#)

and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition, or results of operations.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information or patient information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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

Our operations, and those of our third-party research institution collaborators, CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Our headquarters and our Juno-operated manufacturing facility are located less than 25 miles apart, and therefore could both be similarly affected by the same event. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers in part to produce and process our product candidates or to supply us with certain reagents or specialized equipment or materials used our manufacturing process. Our ability to obtain clinical or commercial supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development, research, or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

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

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

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;

[Table of Contents](#)

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Although we currently carry \$10.0 million of clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

As of December 31, 2016, we had U.S. federal net operating loss carryforwards of approximately \$249.4 million, which will begin to expire in 2033. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. As a result of our transactions that have occurred since our incorporation in August 2013, including our initial public offering, we have experienced such "ownership changes," but we have determined that our use of pre-change net operating loss carryforwards and other pre-change tax attributes is not subject to a material annual limitation. However, we may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which changes are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to further limitation.

Risks Related to Government Regulation

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure, and potent for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of genetically modified T cell therapies for cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained. In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory approval to begin a trial, if applicable;
- the availability of financial resources to begin and complete the trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol, not complying with GCPs, or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMPs for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. See the risk factor above "*If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected*" for additional information on risks related to patient enrollment.

Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, or the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate adequate benefit from using a product candidate, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Some studies, including our TRANSCEND trial for JCAR017, include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides a recommendation for whether or not a study should move forward at designated check points based on access to certain data from the study and may recommend the suspension of the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy, insufficient pace of enrollment, or lack of adherence to protocol. The recommendations of the data safety monitoring board are then considered by us, the trial site IRBs, and the FDA or other regulatory agencies, and may impact our or their decisions regarding the continuation, suspension, or termination of a clinical trial.

If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition,

[Table of Contents](#)

any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Our third-party research institution collaborators may also experience similar difficulties in completing ongoing clinical trials and conducting future clinical trials of product candidates. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases Good Tissue Practices regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or holds on clinical trials;

[Table of Contents](#)

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order directing all executive agencies, including the FDA, that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. On February 24, 2017, President Trump issued another Executive Order obligating agencies to designate regulatory reform officers to oversee implementation of regulatory reform initiatives, including the two-for-one provisions described in the January 30, 2017 Executive Order. On September 8, 2017, the FDA published notices in the Federal Register soliciting broad public comment to identify regulations that could be modified, repealed, or replaced in furtherance of these Executive Orders. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we were able to obtain accelerated approval of any of our CD19 product candidates or any of our other product candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

Our product candidates are regulated as biologic products, which may face competition from biosimilars, potentially sooner than anticipated.

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. This new pathway could allow competitors to reference data from innovative biological products 12 years after the time of approval of the innovative biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data, and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

[Table of Contents](#)

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to get it on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

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

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. We expect physicians in the large bone marrow transplant centers to be particularly influential, and we may not be able to convince them to use our product candidates for many reasons. For example, certain of the product candidates that we will be developing target a cell surface marker that may be present on cancer cells as well as non-cancerous cells. It is possible that our product candidates may kill these non-cancerous cells, which may result in unacceptable side effects, including death. Additional factors will influence whether our product candidates are accepted in the market, including:

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

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit

[Table of Contents](#)

market acceptance our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

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

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

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

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

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, and integrated delivery networks decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage will be obtained or that payors will permit open access to our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our genetically modified products. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

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

Healthcare legislative reform measures, or public focus on product pricing, may have a material adverse effect on our business and results of operations.

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

[Table of Contents](#)

particular, in 2010, the Affordable Care Act was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future, particularly in light of the new presidential administration and Congress. In addition, Congress will likely continue to seek to modify, repeal, or otherwise invalidate all of, or certain provisions of, the Affordable Care Act. At this time, the full effect that the Affordable Care Act and any subsequent legislation or executive action would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, the 21st Century Cures Act changed the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain drugs.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. For instance, there have recently been public hearings in the Congress concerning pharmaceutical product pricing and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Additionally, at the state-level, individual states in the U.S. have increasingly been active in passing legislation and implementing 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. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

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

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

There has also been, and may in the future be, public attention on product pricing, and that may result in political, interest group, or media criticism of companies whose pricing or potential pricing is perceived by the public as high. If we were to become subject to such criticism, it could harm our reputation, create adverse publicity, and impact our relationships with our suppliers, collaborators, medical providers, and patients, each which could adversely affect our business and results of operations.

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that

[Table of Contents](#)

fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices.

These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our current activities with clinical study investigators and research subjects, as well as proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Health Insurance Portability and Accountability Act of 1996, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

[Table of Contents](#)

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as (1) state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers, (2) state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources, (3) state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities, and (4) state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to Intellectual Property

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

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. See the section captioned "Licenses and Third-Party Collaborations" in Part I—Item 1—"Business" of the 2016 Annual Report for additional information regarding our license agreements.

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

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. For an example of the risks relating to such disputes, see the risk factor below "—We are involved in litigation that may be expensive and time consuming, and if resolved adversely, could harm our business, financial condition, or results of operations."

We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce patents and patent applications that are material to our business.

Patents relating to our product candidates are controlled by certain of our licensors. Each of our licensors generally has rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor. We generally have the first right to enforce our patent rights, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such 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 or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control.

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

We own or license from third parties certain intellectual property rights necessary to develop our product candidates. The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights. For

[Table of Contents](#)

example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

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

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We are dependent on intellectual property sublicensed to us by Opus Bio from the NIH for development of JCAR018. Failure to meet our own obligations to Opus Bio and the NIH may result in the loss of our rights to such intellectual property, which could harm our business.

Under our license agreement with Opus Bio, we are obligated to make certain pass-through payments to the NIH as well as to meet certain development benchmarks within certain time periods. We may be unable to make these payments or meet these benchmarks or may breach our other obligations under this license agreement, which could lead to the termination of the license agreement.

In addition, the NIH has the right to require us to grant mandatory sublicenses to the intellectual property licensed from the NIH under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations. Any required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products.

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our products or product candidates.

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

- if and when any patents will issue;
- the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products such as CAR or TCR product candidates are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent

[Table of Contents](#)

applications covering the composition of matter of our product candidates will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field can be uncertain, and evaluating the scope of such patents involves complex legal and scientific analyses. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. For example, in 2015, Kite filed a petition with the USPTO for inter partes review of U.S. Patent No. 7,446,190, a patent that we have exclusively licensed from MSK. Although the USPTO upheld all the claims of this patent in December 2016, Kite has appealed this decision. If Kite is successful in its appeal, one or more of the patent's claims could be narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

[Table of Contents](#)

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents, or that we are otherwise employing their proprietary technology without authorization, and may sue us. For instance, Novartis has asserted in writing its belief that we infringe the following patents controlled by Novartis: U.S. Patent Nos. 7,408,053, 7,205,101, 7,527,925, and 7,442,525. There may be third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture, or methods of use or treatment that cover our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that 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 or the manufacture, use, or sale of our product candidates infringes upon these patents. If any such third-party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Third parties asserting their patent rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may 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. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

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

We have limited intellectual property rights outside the United States, and, in particular, some of our patents directed to CAR constructs do not extend outside of the United States. Filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. In addition, the laws of some foreign countries, such as China, Brazil, Russia, and India, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, such as China, Brazil, Russia, and India, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Competitors may infringe our patents or the patents of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming. For instance, in September 2017,

[Table of Contents](#)

we filed a complaint against Kite in the federal district court for the Central District of California for infringement and declaratory judgment of infringement of U.S. Patent No. 7,446,190. In addition, in an infringement proceeding or a declaratory judgment action, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, or derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

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

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves, both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. Our patents issued as of December 31, 2016 will expire on dates ranging from 2019 to 2033, subject to any patent extensions that may be available for such patents. If patents are issued on our patent applications pending as of December 31, 2016, the resulting patents are projected to expire on dates ranging from 2021 to 2037. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to Our Common Stock

We expect that our stock price will fluctuate significantly.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- adverse results, clinical holds, or delays in the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any disruption in our ability to manufacture drug product that impacts our clinical trial enrollment, regulatory approval timelines, or commercial supply;
- 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;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products, including clinical trial requirements for approvals;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- any failure to commercialize our product candidates or if the size and growth of the markets we intend to target fail to meet expectations;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to cancer immunology or the use of our product candidates;
- introductions or announcements of new products offered by us or significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our collaborators or our competitors and the timing of such introductions or announcements;
- announcements relating to future collaborations or our existing collaboration with Celgene, including decisions regarding the exercise by Celgene or us of any of our or their options thereunder, or any exercise or non-exercise by Celgene of a right to purchase shares of our common stock;
- our ability to effectively manage our growth;
- our ability to successfully treat additional types of cancers or at different stages;
- changes in the structure of healthcare payment systems;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- market conditions in the pharmaceutical and biotechnology sectors or the economy generally;
- our ability or inability to raise additional capital through the issuance of equity or debt or collaboration arrangements and the terms on which we raise it;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- rumors and market speculation involving us or other companies in our industry, regardless of the accuracy of such rumors or speculation;

[Table of Contents](#)

- clinical trial, regulatory, or commercial setbacks to other companies in our field, which may impact perceptions of value or risk to our business; and
- significant lawsuits, including patent or stockholder litigation.

The stock market in general, and market prices for the securities of biopharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. The defense and disposition of any such lawsuits could be costly and divert the time and attention of our management and harm our operating results, regardless of the merits of such a claim.

We are involved in litigation that may be expensive and time consuming, and if resolved adversely, could harm our business, financial condition, or results of operations.

As described in Note 11 to our condensed consolidated financial statements included in this report, a consolidated securities class action is pending against Juno and two of our executive officers, a purported derivative action is pending on behalf of Juno against two of our executive officers and certain members of our board of directors, and City of Hope has filed a lawsuit against Juno alleging breach of contract. Defending against these lawsuits will be costly and may significantly divert management's time and attention from our business. There can be no assurance that a favorable outcome will be obtained. A negative outcome, whether by final judgment or an unfavorable settlement, could result in payments of significant monetary damages or fines and, in the case of the City of Hope litigation could potentially lead to the termination of the City of Hope license, and could adversely affect our business, financial condition, or results of operations.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on The NASDAQ Global Select Market, the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active trading market may not be sustained in the future. The lack of an active market may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the market value of their shares and may impair our ability to raise capital.

If securities or industry analysts do not continue to publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Future sales of our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. 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.

As of September 30, 2017, we had 113,950,383 shares of common stock outstanding, including 505,410 shares of restricted stock that remained subject to vesting requirements. All 11,109,160 shares acquired by Celgene from us to date under the Celgene Share Purchase Agreement and the private placement that occurred concurrent with the September 2017 follow-on public offering are subject to a market standoff agreement through September 25, 2018, which is 364 days from the date of Celgene's most recent acquisition of stock from us. Any subsequent acquisitions of shares of our common stock by Celgene will commence another 364 day market standoff period for all Juno shares held by Celgene, subject to certain exceptions.

We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, including upon the exercise of stock options. These shares can be freely sold in the public market upon issuance.

In connection with the September 2017 follow-on public offering, subject to certain exceptions, we and all of our directors and executive officers have agreed not to offer, sell or agree to sell, directly or indirectly, any shares of common stock without the permission of Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC, through December 20, 2017. When the lock-up period expires, subject to the applicable securities laws, we and our directors and executive officers subject to such lock-up agreements will be able to sell shares in the public market.

[Table of Contents](#)

As of September 30, 2017, the holders of as many as 19.8 million shares, or 17.4% of our common stock outstanding, have rights, subject to some conditions, under the investor rights agreement with such holders to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Additionally, any shares of common stock issued in the future upon payment of success payments with FHCRC and MSK or upon achievement of the remaining milestone payable in equity under the license with Opus Bio will also be entitled to registration rights under the investor rights agreement. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market. In connection with the Celgene Share Purchase Agreement, we have also entered into a registration rights agreement with Celgene, pursuant to which upon the written request of Celgene at certain times and subject to the satisfaction of certain conditions, we have agreed to prepare and file with the SEC a registration statement on Form S-3 for purposes of registering the resale of the shares specified in Celgene's written request or, if we are not at such time eligible for the use of Form S-3, use commercially reasonable efforts to prepare and file a registration statement on a Form S-1 or alternative form that permits the resale of the shares.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise, including up to 30% of shares of our outstanding common stock to Celgene. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Additionally, sales of our common stock by our executive officers or directors, even when done during an open trading window under Juno's policies with respect to insider sales or done under a trading plan adopted in accordance with the guidelines set forth by Rule 10b5-1, may adversely impact the trading price of our common stock. Although we do not expect that the relatively small volume of such sales will itself significantly impact the trading price of our common stock, the market could react negatively to the announcement of such sales, which could in turn affect the trading price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over matters subject to stockholder approval.

Our executive officers, directors and our 10% or greater stockholders as of September 30, 2017, together with their respective affiliates, beneficially owned approximately 22.9% of our capital stock as of September 30, 2017, excluding shares underlying outstanding options and restricted stock units. Accordingly, such persons and entities, if they acted together, may be able to significantly influence the composition of the board of directors and the outcome of the vote on many matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. In addition, other than in connection with a change of control, in any vote or action by written consent of our stockholders, including, without limitation, with respect to the election of directors, Celgene has agreed to vote or execute a written consent with respect to all of our voting securities held by Celgene in accordance with the recommendation of our board of directors, limiting the ability of Celgene to vote contrary to our board of directors that you otherwise may believe is in your best interest as our stockholder. This concentration of ownership amongst our significant holders, including Celgene, could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as one of our stockholders. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

Celgene has acquired an aggregate of 11,109,160 shares of our common stock to date under the Celgene Share Purchase Agreement and the private placement that occurred concurrent with the September 2017 follow-on public offering and, subject to certain conditions, may purchase additional shares annually to obtain and maintain a 9.76% ownership percentage through June 29, 2020. Furthermore, between June 29, 2019 and June 29, 2025 and between June 29, 2024 and the expiration of the Celgene Collaboration Agreement, subject to certain conditions, Celgene has the option to acquire and maintain an ownership of up to 19.99% and up to 30%, respectively, of our then outstanding shares of common stock. We have also entered into a voting and standstill agreement with Celgene, pursuant to which we have agreed to give Celgene certain board designation rights until at least June 29, 2020, and thereafter for as long as Celgene and its affiliates beneficially own at least 7.5% of the voting power of our outstanding shares. As a result of the concentration of ownership, Celgene could have the ability to delay or prevent a change in our control or otherwise discourage a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as our stockholder.

Anti-takeover provisions in our charter documents and under Delaware or Washington law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price.

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a

[Table of Contents](#)

premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws will:

- permit the board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide the board of directors into three classes;
- provide that a director may only be removed from the board of directors by the stockholders for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice;
- prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- require that, to the fullest extent permitted by law, a stockholder reimburse us for all fees, costs and expenses incurred by us in connection with a proceeding initiated by such stockholder in which such stockholder does not obtain a judgment on the merits that substantially achieves the full remedy sought;
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer (or president, in the absence of a chief executive officer) or by the board of directors; and
- provide that stockholders will be permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

Furthermore, pursuant to the voting and standstill agreement with Celgene, until the later of the fifth anniversary of the date of such agreement and the expiration or earlier termination of our Celgene Collaboration Agreement, it will be bound by certain "standstill" provisions which generally will prevent it from purchasing outstanding shares of our common stock, making a tender offer or encouraging or supporting a third-party tender offer, nominating a director whose nomination has not been approved by our board of directors, soliciting proxies in opposition to the recommendation of our board of directors or assisting a third party in taking such actions, entering into discussions with a third party as to such actions, or requesting or proposing in writing to our board of directors or any member thereof that we amend or waive any of these limitations. As a result, the ability of Celgene to act in contrary to our board of directors is severely limited and any attempts by Celgene to acquire us or encourage a third party to acquire us are prohibited by this voting and standstill agreement. In addition, subject to certain exceptions—including a vote in connection with a change in control of our company—Celgene has agreed to vote or execute a written consent with respect to all of our voting securities held by Celgene in accordance with the recommendation of our board of directors, limiting the ability of Celgene to contrary to our board of directors that you otherwise may believe is in your best interest as our stockholder.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person."

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, 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 any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Complying with the laws and regulations affecting public companies has increased and will increase our costs and the demands on management and could harm our operating results.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC and NASDAQ. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

For example, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. Section 404 of the Sarbanes-Oxley Act ("Section 404") requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. Our compliance with applicable provisions of Section 404, including the requirement that our independent registered public accounting firm undertake an assessment of our internal control over financial reporting, will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

Our management team has broad discretion to use the net proceeds from the September 2017 follow-on offering, the initial payments to us under our Celgene Collaboration Agreement, and the sale of our shares to Celgene, and our investment of these proceeds may not yield a favorable return. We may invest the proceeds of the September 2017 follow-on offering or the Celgene transactions in ways with which investors disagree.

Our management has broad discretion over the use of proceeds from the September 2017 follow-on offering, the initial payments to us under our Celgene Collaboration Agreement, and the sale of our shares to Celgene, and we could spend the proceeds from these transactions in ways our stockholders may not agree with or that do not yield a favorable return, if at all. In addition, until the proceeds are used, they may be placed in investments that do not produce significant income or that may lose value. If we do not invest or apply the proceeds in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a)

Not applicable.

(b)

In September 2017, we completed a follow-on public offering, in which we sold an aggregate of 7,015,000 shares of common stock at a price to the public of \$41.00 per share. The aggregate offering price to the public for shares sold in the offering was \$287.6 million. The shares sold in the follow-on public offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333-220537), which became effective immediately upon filing with the SEC on September 20, 2017 (the "Registration Statement"), and a registration statement on Form S-3 (File No. 333-220560), which became effective immediately upon filing with the SEC on September 22, 2017. No additional shares were registered. The joint book-running managers for the follow-on offering were Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC. After deducting underwriting discounts, commissions and offering expenses paid or payable by us of approximately \$15.2 million, the net proceeds from the offering were approximately \$272.4 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the planned use of the net proceeds from the follow-on public offering as described in the Registration Statement. We invested the funds received in short-term, interest-bearing investment-grade securities and government securities.

(c)

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

(a)

Not applicable.

(b)

Not applicable.

10b5-1 Plans

Most of our executive officers (including our Chief Executive Officer and Chief Financial Officer) and one of our directors have adopted prearranged trading plans in accordance with guidelines specified by Rule 10b5-1 under the Securities and Exchange Act of 1934, and Juno's policies with respect to insider sales. Rule 10b5-1 plans permit insiders to sell a specified portion of their holdings at a specified time or over a specified period of time, at prevailing market prices often subject to certain minimum price thresholds, pursuant to a plan established at a time when the insider is not in possession of material non-public information. After adopting such a plan, the insider no longer controls the decision to exercise or sell the securities in the plan. Using these plans, officers and directors can prudently and gradually diversify their asset portfolios for estate, retirement, tax, or other financial planning reasons, can spread stock trades out over an extended period of time to reduce any market impact, can satisfy tax obligations upon the vesting of restricted stock units, and can avoid concerns about initiating stock transactions at a time when they might be in possession of material, non-public information. These plans may also serve to reduce the risk that investors will view routine portfolio diversification stock sales by executive officers as a signal of negative expectations with respect of the future value of Juno's common stock. Any trading plan, or modification thereof, must be submitted for review and approval by the Company and must comply with Juno's written guidelines for such plans.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
2.1#†‡	Share Purchase Agreement, dated May 11, 2015, by and among Dr. Herbert Stadler, Dr. Lothar Germeroth, Prof. Dr. Dirk Busch, and the registrant	8-K	5/11/2015	2.1	
2.2#†‡	Agreement and Plan of Merger, dated June 1, 2015, by and among X Acquisition Corporation, X-Body, Inc., Brant Binder as stockholder representative, certain principal stockholders of X-Body, Inc., and the registrant	8-K	6/5/2015	2.1	
2.3(A)#†‡	Agreement and Plan of Reorganization, dated January 11, 2016, by and among registrant, P Acquisition Corporation, P Acquisition LLC, AbViro, Inc., Fortis Advisors LLC, as securityholders' representative, and those AbViro stockholders made party thereto by joinder	8-K	1/11/2016	2.1	
2.3(B)	Amendment, dated May 23, 2016, to Agreement and Plan of Reorganization, dated January 11, 2016	10-Q	8/5/2016	2.3(B)	
3.1	Amended and Restated Certificate of Incorporation	8-K	12/29/2014	3.1	
3.2	Amended and Restated Bylaws, as amended	8-K	4/1/2016	3.1	
4.1	Fourth Amended and Restated Investors' Rights Agreement, dated December 5, 2014, by and among the registrant and the investors named therein	S-1/A	12/9/2014	4.1	
4.2	Amendment and Waiver of Fourth Amended and Restated Investors' Rights Agreement, dated July 27, 2015	10-Q	8/14/2015	4.2	
4.3	Second Amendment to Fourth Amended and Restated Investors' Rights Agreement, dated January 29, 2016	10-K	2/29/2016	4.3	
4.4	Amendment No. 3 and Waiver of Fourth Amended and Restated Investors' Rights Agreement, dated September 21, 2017				X
4.5	Form of Common Stock Certificate	S-1/A	12/9/2014	4.2	
10.1	Share Purchase Agreement and Omnibus Amendment by and between Juno Therapeutics, Inc., Celgene Corporation and certain of its affiliates, dated September 21, 2017	8-K	9/22/2017	10.1	
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
32.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, formatted in eXtensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at September 30, 2017 (unaudited) and December 31, 2016, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2017 and 2016, (iii) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2017 and 2016, and (iv) Notes to the Condensed Consolidated Financial Statements.				X

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Juno

[Table of Contents](#)

Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

- # Confidential treatment has been granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.
- † The representations and warranties contained in this agreement were made only for purposes of the transactions contemplated by the agreement as of specific dates and may have been qualified by certain disclosures between the parties and a contractual standard of materiality different from those generally applicable under securities laws, among other limitations. The representations and warranties were made for purposes of allocating contractual risk between the parties to the agreement and should not be relied upon as a disclosure of factual information about the registrant or the transactions contemplated thereby.
- ‡ The exhibits and schedules to this agreement have been omitted in reliance on Item 601(b)(2) of Regulation S-K promulgated by the Securities and Exchange Commission, and a copy thereof will be furnished supplementally to the Securities and Exchange Commission upon its request.

**AMENDMENT NO. 3 AND WAIVER OF
FOURTH AMENDED AND RESTATED
INVESTORS' RIGHTS AGREEMENT
OF JUNO THERAPEUTICS, INC.**

This Amendment No. 3 and Waiver dated as of September 21, 2017 (the "*Amendment and Waiver*") amends and waives certain provisions of that certain Fourth Amended and Restated Investors' Rights Agreement dated as of December 5, 2014 (the "*Agreement*"), as amended, between Juno Therapeutics, Inc., a Delaware corporation (the "*Company*"), and the Investors named therein. Capitalized terms used herein without definition shall have the meanings given in the Agreement.

RECITALS

A. The Agreement provides, among other things, for certain registration rights granted by the Company to the Investors.

B. On June 29, 2015, the Company entered into a Registration Rights Agreement (the "*Celgene Agreement*") with Celgene Corporation and Celgene RIVOT Ltd (together, along with Celgene Switzerland LLC as assignee of Celgene RIVOT Ltd, "*Celgene*") granting certain registration rights to Celgene.

C. The Company anticipates issuing additional shares to Celgene on or about September 26, 2017 (the "*Additional Celgene Shares*") and the Additional Celgene Shares will also be subject to the terms of the Celgene Agreement.

D. Under Section 6.1 of the Agreement, the Company and the holders of at least a majority of the Registrable Securities issued upon conversion of the Company's preferred stock, voting together as a single class, may amend or waive any term of the Agreement.

E. The Company and the Investors party hereto desire to amend and waive the Agreement to allow Celgene to exercise its registration rights under the Celgene Agreement without being subject to the rights of the Investors under the Agreement.

AMENDMENT AND WAIVER

For good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Investors party hereto, voting together as a single class in accordance with Section 6.1 of the Agreement, hereby amend and waive the Agreement on behalf of all Investors thereunder as follows:

1. The registration rights granted to Celgene under the Celgene Agreement (including with respect to the Additional Celgene Shares) shall not be subject to the rights of the Investors under Section 2.2 of the Agreement, except that Celgene's rights under Section 6(f) of the Celgene Agreement shall remain subject to the rights of the Investors under the Agreement such that Celgene's exercise of its rights under Section 6(f) of the Celgene Agreement shall not reduce the amount of securities to be registered on the associated registration statement by the Investors pursuant to registration rights provided under the Agreement.

2. Without limiting the generality of the foregoing, Celgene and its permitted transferees and assigns may exercise its registration rights under the Celgene Agreement (other than those in Section 6(f) of the Celgene

Agreement), including with respect to the Additional Celgene Shares, without being subject to the notice or inclusion requirements under Section 2.2(a) of the Agreement or the underwriters' cutback provision under Section 2.2(b) of the Agreement.

3. The application of Section 2.12 of the Agreement is hereby waived with respect to the Celgene Agreement and the rights granted thereunder (including with respect to the Additional Celgene Shares).

4. Nothing herein shall derogate from any rights of the Investors under the Agreement, including without limitation their right to request registration of their Registrable Securities under the Agreement, except to the extent set forth in the limited amendment and waiver above. The Agreement as amended hereby shall continue in full force and effect from and after the date hereof.

(signature page follows)

The parties are signing this Amendment No. 3 and Waiver as of the date stated in the introductory clause.

INVESTOR:

ARCH Venture Fund VII, L.P.

By: ARCH Venture Partners VII, L.P.

Its: General Partner

By: ARCH Venture Partners VII, LLC

Its: General Partner

By: /s/ Robert Nelsen

Name: Robert Nelsen

Title: Managing Director

CERTIFICATIONS

I, Hans E. Bishop, certify that:

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

Date: November 1, 2017

/s/ Hans E. Bishop

Hans E. Bishop

*President and Chief Executive Officer
(Principal Executive Officer)*

CERTIFICATIONS

I, Steven D. Harr, certify that:

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

Date: November 1, 2017

/s/ Steven D. Harr

Steven D. Harr
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report of Juno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Hans E. Bishop, President and Chief Executive Officer (*Principal Executive Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Hans E. Bishop

Hans E. Bishop

*President and Chief Executive Officer
(Principal Executive Officer)*

Date: November 1, 2017

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Juno Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

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

In connection with the Quarterly Report of Juno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven D. Harr, Chief Financial Officer (*Principal Financial and Accounting Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Steven D. Harr

Steven D. Harr

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: November 1, 2017

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Juno Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

