Atara Biotherapeutics, Inc.
Form 10-Q
November 06, 2018

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

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 001-36548

ATARA BIOTHERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	46-0920988
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
	94080

611 Gateway Blvd., Suite 900

South San Francisco, CA
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (650) 278-8930

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

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

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

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

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

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

The number of outstanding shares of the Registrant's Common Stock as of October 31, 2018 was 45,648,266 shares.

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Atara Biotherapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except per share amounts)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$66,028	$79,223
Short-term investments	298,515	86,873
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	8,239	5,900
Total current assets	372,976	172,190
Property and equipment, net	68,279	44,129
Restricted cash - long-term	1,200	1,200
Other assets	485	260
Total assets	$442,940	$217,779
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$6,193	$14,711
Accrued compensation	9,072	5,664
Accrued research and development expenses	3,803	4,006
Other current liabilities	7,932	3,265
Total current liabilities	27,000	27,646
Long-term liabilities	12,886	12,269
Total liabilities	39,886	39,915
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock—$0.0001 par value, 500,000 shares authorized as of September 30, 2018 and December 31, 2017; 45,645 and 30,730 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	5	3
Additional paid-in capital	850,835	474,662
Accumulated other comprehensive loss	(449)	(151)
Accumulated deficit	(447,337)	(296,650)
Total stockholders' equity	403,054	177,864

Total liabilities and stockholders' equity	$442,940	$217,779

See accompanying notes.

Atara Biotherapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 43,355	$ 20,598	$ 105,202	$ 56,435
General and administrative	16,865	11,062	50,093	29,295
Total operating expenses	60,220	31,660	155,295	85,730
Loss from operations	(60,220)	(31,660)	(155,295)	(85,730)
Interest and other income, net	1,859	564	4,611	1,554
Loss before provision for income taxes	(58,361)	(31,096)	(150,684)	(84,176)
Provision for income taxes	—	—	3	2
Net loss	$ (58,361)	$ (31,096)	$ (150,687)	$ (84,178)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	56	26	(298)	95
Comprehensive loss	$ (58,305)	$ (31,070)	$ (150,985)	$ (84,083)
Net loss per common share:				
Basic and diluted net loss per common share	$ (1.29)	$ (1.02)	$ (3.49)	$ (2.84)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	45,406	30,474	43,148	29,597

See accompanying notes.

Atara Biotherapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine months ended September 30,	
	2018	2017
Operating activities		
Net loss	$(150,687)	$(84,178)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	24,264	17,003
Amortization (accretion) of investment premiums (discounts)	(1,339)	607
Depreciation and amortization expense	2,254	678
Non-cash interest expense	211	—
Asset retirement obligation accretion expense	32	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,339)	(1,125)
Other assets	(225)	2
Accounts payable	116	(1)
Accrued compensation	3,408	1,574
Accrued research and development expenses	(203)	1,402
Other current liabilities	2,063	1,104
Long-term liabilities	92	370
Net cash used in operating activities	(122,353)	(62,564)
Investing activities		
Purchases of short-term investments	(402,621)	(152,837)
Maturities of short-term investments	131,983	162,094
Sales of short-term investments	60,037	58,217
Purchases of property and equipment	(31,756)	(10,535)
Net cash (used in) provided by investing activities	(242,357)	56,939
Financing activities		
Proceeds from sale of common stock in underwritten offerings, net	293,290	—
Proceeds from issuance of common stock from "at-the-market" facility, net	47,586	19,206
Proceeds from employee stock awards	18,528	495
Taxes paid related to net share settlement of restricted stock units	(7,493)	(351)
Principal payments on capital lease obligations	(396)	—
Net cash provided by financing activities	351,515	19,350
(Decrease) increase in cash, cash equivalents and restricted cash	(13,195)	13,725
Cash, cash equivalents and restricted cash at beginning of period	80,617	48,162
Cash, cash equivalents and restricted cash at end of period	$67,422	$61,887
Non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and other accrued	$3,973	$3,064

liabilities		
Facility lease financing obligations	$441	$6,215
Property & equipment acquired under capital leases	$191	$—
Asset retirement cost	$88	$—
Interest capitalized during construction period for build-to-suit lease transaction	$77	$133
Supplemental cash flow disclosure		
Cash paid for interest	$110	$—

See accompanying notes.

Atara Biotherapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Description of Business

Atara Biotherapeutics, Inc. ("Atara", "we", "our" or "the Company") was incorporated in August 2012 in Delaware. Atara is a T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. The Company's "off-the-shelf", allogeneic T-cells are bioengineered from donors with healthy immune function and allow for rapid delivery from inventory to patients without a requirement for pretreatment. Atara's T-cell immunotherapies are designed to precisely recognize and eliminate cancerous or diseased cells without affecting normal, healthy cells.

We licensed rights to T-cell product candidates from Memorial Sloan Kettering Cancer Center ("MSK") in June 2015 and entered into agreements related to our next-generation CAR T programs with MSK in May 2018 and with Moffitt Cancer Center in August 2018. Additionally, we licensed rights to know-how and technology from QIMR Berghofer Medical Research Institute ("QIMR Berghofer") in October 2015, September 2016 and June 2018. See Note 6 for further information.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and follow the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, except that the presentation of total cash, cash equivalents and restricted cash has been conformed to current period presentation. In the opinion of management, the condensed consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company's consolidated financial information. The results of operations for the nine-month period ended September 30, 2018 are not necessarily indicative of the results to be expected for the full year or any other future period. The condensed consolidated balance sheet as of December 31, 2017 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete consolidated financial statements.

Liquidity Risk

We have incurred significant operating losses since inception and have relied on public and private equity financings to fund our operations. As of September 30, 2018, we had an accumulated deficit of $447.3 million. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization

of product candidates and on the achievement of sufficient revenues to support our cost structure. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital. Management expects that our cash, cash equivalents and short-term investments will be sufficient to fund our planned operations to mid-2020.

Concentration of Credit Risk and Other Uncertainties

We place cash and cash equivalents in the custody of financial institutions that management believes are of high credit quality, the amount of which at times, may be in excess of the amount insured by the Federal Deposit Insurance Corporation. We also have short-term investments in money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities, which can be subject to certain credit risk. However, we mitigate the risks by investing in high-grade instruments, limiting our exposure to any one issuer, and monitoring the ongoing creditworthiness of the financial institutions and issuers.

We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: our ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, our product candidates, if approved by applicable regulatory authorities; performance of third-party clinical research organizations and manufacturers upon which we rely; development of sales channels; protection of our intellectual property; litigation or claims against us based on intellectual property, patent, product, regulatory or other factors; and our ability to attract and retain employees necessary to support our growth.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgments that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relied upon in preparing these financial statements include estimates related to clinical trial and other accruals, stock-based compensation expense, construction costs and income taxes. Actual results could differ materially from those estimates.

Leases

We lease office space in multiple locations. In addition, we recently constructed a manufacturing facility in Thousand Oaks, California under a non-cancelable lease agreement. The leases are reviewed for classification as operating or capital leases. For operating leases, rent is recognized on a straight-line basis over the lease period. For capital leases, we record the leased asset with a corresponding liability for principal and interest. Payments are recorded as reductions to these liabilities with interest being charged to interest expense in our statements of operations and comprehensive loss.

We analyzed the nature of the renovations and our involvement during the construction period of our manufacturing facility and determined that we are the deemed “owner” of the construction project during the construction period. As a result, we are required to capitalize the fair value of the building as well as the construction costs incurred on our condensed consolidated balance sheet along with a corresponding financing liability for landlord-paid construction costs (i.e. “build-to-suit” accounting).

Once construction is complete, the Company considers the requirements for sale-leaseback accounting treatment, including evaluating whether all risks of ownership have been transferred back to the landlord, as evidenced by a lack of continuing involvement in the leased property. If the arrangement does not qualify for sale-leaseback accounting treatment, the building asset remains on the Company’s consolidated balance sheets at its historical cost, and such asset is depreciated over its estimated useful life. The Company bifurcates its lease payments into a portion allocated to the building and a portion allocated to the parcel of land on which the building has been built. The portion of the lease payments allocated to the land is treated for accounting purposes as operating lease payments, and therefore is recorded as rent expense in the consolidated statements of operations. The portion of the lease payments allocated to the building is further bifurcated into a portion allocated to interest expense and a portion allocated to reduce the build-to-suit lease obligation. The initial recording of these assets and liabilities is classified as non-cash investing and financing items, respectively, for purposes of the consolidated statements of cash flows.

Asset Retirement Obligations (“ARO”)

ARO are legal obligations associated with the retirement of long-lived assets pertaining to leasehold improvements. These liabilities are initially recorded at fair value and the related asset retirement costs are capitalized by increasing the carrying amount of the related assets by the same amount as the liability. Asset retirement costs are subsequently depreciated over the useful lives of the related assets. Subsequent to initial recognition, the Company records period-to-period changes in the ARO liability resulting from the passage of time and revisions to either the timing or the amount of the original estimate of undiscounted cash flows. The Company derecognizes ARO liabilities when the related obligations are settled.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, Leases (Topic 842), which is intended to increase the transparency and comparability in the reporting of

leasing arrangements by generally requiring leased assets and liabilities to be recorded on the balance sheet. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018, with early adoption permitted.

In July 2018, the FASB issued ASU No. 2018-10, “Codification Improvements to Topic 842, Leases” to clarify the implementation guidance and ASU No. 2018-11, “Leases (Topic 842) Targeted Improvements.” This updated guidance provides an optional transition method, which allows for the initial application of the new accounting standard at the adoption date and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the period of adoption. The Company will adopt the new standard on January 1, 2019 and intends to elect certain practical expedients, including the optional transition method that allows for the application of the new standard at its adoption date with no restatement of prior period amounts. We have identified our significant lease contracts and are in the process of finalizing our assessment of the impact of the new standard on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective for us on January 1, 2020. Early adoption will be available on January 1, 2019. We have not yet determined the potential effect the new standard will have on our consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, which allows a reclassification from accumulated other comprehensive income to retained earnings for adjustments to tax effects that were originally recorded in other comprehensive income due to changes in the U.S. federal corporate income tax rate resulting from the enactment of the U.S. tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018, with early adoption permitted. We have not yet determined the potential effect the new standard will have on our consolidated financial statements.

In March 2018, the FASB issued ASU 2018-05, Income Taxes (Topic 740) Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, to insert the SEC's interpretive guidance from Staff Accounting Bulletin No. 118 into the income tax accounting codification related to the Tax Act under U.S. GAAP. The ASU permits companies to use provisional amounts for certain income tax effects of the Tax Act during a one-year measurement period. During the nine months ended September 30, 2018, we did not make any adjustments to the provisional amounts included in the consolidated financial statements for the year ended December 31, 2017 and will continue to assess future guidance issued by the U.S. Treasury Department, Internal Revenue Service, FASB, and other standard-setting and regulatory bodies. The provisional accounting impacts for the Company may change in future reporting periods until the accounting analysis is finalized, which we expect to complete within the one-year measurement period in accordance with SAB 118.

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (ASU 2018-15), which clarifies the accounting for implementation costs in cloud computing arrangements. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019, with early adoption permitted. We have not yet determined the potential effect the new standard will have on our consolidated financial statements.

Adoption of New Accounting Pronouncements

On January 1, 2018, the Company adopted two new accounting standards issued by the FASB that clarify presentation and classification in the statement of cash flows on a retrospective basis. As a result of adoption, amounts generally described as restricted cash and restricted cash equivalents are now presented with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. As a result of adoption, cash, cash equivalents and restricted cash reported on the condensed consolidated statements of cash flows now includes restricted cash of $1.4 million, $1.4 million, and $0.2 million as of December 31, 2017, September 30, 2017, and December 31, 2016, respectively, as well as previously reported cash and cash equivalents.

3. Net Loss per Common Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of common share equivalents. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock and common share equivalents outstanding for the period. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Potential dilutive securities, which include, unvested restricted stock units ("RSUs"), vested and unvested options to purchase common stock and shares to be issued under our employee stock purchase plan ("ESPP") have been excluded from the computation of diluted net loss per share as the effect is antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following table represents the potential common shares issuable pursuant to outstanding securities as of the related period end dates that were excluded from the computation of diluted net loss per common share as their inclusion would have an antidilutive effect:

	As of September 30,	
	2018	2017
Unvested RSUs	1,431,891	1,735,999
Vested and unvested options	6,332,199	4,910,449
ESPP share purchase rights	23,509	32,205
Total	7,787,599	6,678,653

4.Financial Instruments

Our financial assets are measured at fair value on a recurring basis using the following hierarchy to prioritize valuation inputs, in accordance with applicable GAAP:

Level 1: Quoted prices in active markets for identical assets or liabilities that we have the ability to access
Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data such as quoted prices, interest rates and yield curves
Level 3: Inputs that are unobservable data points that are not corroborated by market data

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs. There have been no transfers between Level 1, Level 2 and Level 3 in any periods presented.

Financial assets and liabilities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities are valued primarily using market prices of comparable securities, bid/ask quotes, interest rate yields and prepayment spreads and are included in Level 2.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. We have no Level 3 financial assets or liabilities.

The following tables summarize the estimated fair value and related valuation input hierarchy of our available-for-sale securities as of each period end:

As of September 30, 2018:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
		(in thousands)			
Money market funds	Level 1	$40,424	$ —	$ —	$40,424
U.S. Treasury obligations	Level 2	138,332	—	(180)	138,152
Government agency obligations	Level 2	18,990	—	(39)	18,951
Corporate debt obligations	Level 2	137,678	5	(206)	137,477
Commercial paper	Level 2	15,488	—	—	15,488
Asset-backed securities	Level 2	12,809	1	(31)	12,779
Total available-for-sale securities		363,721	6	(456)	363,271
Less amounts classified as cash equivalents		(64,761)	—	5	(64,756)
Amounts classified as short-term investments		$298,960	$ 6	$ (451)	$298,515

As of December 31, 2017:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
		(in thousands)			
Money market funds	Level 1	$68,730	$ —	$ —	$68,730
U.S. Treasury obligations	Level 2	39,068	—	(28)	39,040
Government agency obligations	Level 2	4,749	—	(21)	4,728
Corporate debt obligations	Level 2	46,532	2	(98)	46,436
Commercial paper	Level 2	1,592	—	—	1,592
Asset-backed securities	Level 2	4,122	—	(6)	4,116
Total available-for-sale securities		164,793	2	(153)	164,642
Less amounts classified as cash equivalents		(77,769)	—	—	(77,769)
Amounts classified as short-term investments		$87,024	$ 2	$ (153)	$86,873

The amortized cost and fair value of our available-for-sale securities by contractual maturity were as follows:

	As of September 30, 2018		As of December 31, 2017	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(in thousands)		(in thousands)	
Maturing within one year	$324,519	$324,204	$151,938	$151,852
Maturing in one to five years	39,202	39,067	12,855	12,790
Total available-for-sale securities	$363,721	$363,271	$164,793	$164,642

As of September 30, 2018, certain available-for-sale securities had been in a continuous unrealized loss position, each for less than twelve months. As of this date, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the respective issuers, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. During the three and nine months ended September 30, 2018 and 2017, we did not recognize any other-than-temporary impairment losses.

In addition, restricted cash collateralized by money market funds is a financial asset measured at fair value and is a Level 1 financial instrument under the fair value hierarchy. As of September 30, 2018 and December 31, 2017, restricted cash totaled $1.4 million and $1.4 million, respectively.

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the condensed consolidated balance sheets that sum to the total of the same such amounts in the condensed consolidated statement of cash flows:

	September 30, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	66,028	79,223
Restricted cash - short term	194	194
Restricted cash - long term	1,200	1,200
Total cash, cash equivalents and restricted cash	$67,422	$ 80,617

5. Property and Equipment

Property and equipment consisted of the following as of each period end:

	September 30, 2018	December 31, 2017
	(in thousands)	
Leasehold improvements	$40,390	$ 623
Construction in progress	14,136	40,797
Build-to-suit asset (see Note 7)	10,686	—
Lab equipment	2,830	2,156
Machinery equipment	1,410	885
Furniture and fixtures	1,628	536
Computer equipment and software	798	477
	71,878	45,474
Less accumulated depreciation and amortization	(3,599)	(1,345)
Property and equipment, net	$68,279	$ 44,129

Construction in progress represents capitalized costs for our manufacturing facility in Thousand Oaks, California and capitalizable costs incurred for development of internal use software. Depreciation and amortization expense was $1.2 million and $0.3 million for the three months ended September 30, 2018 and 2017, respectively and $2.3 million and $0.7 million for the nine months ended September 30, 2018 and 2017, respectively.

6. License, Collaboration and Manufacturing Agreements

MSK Agreements – In September 2014, the Company entered into an exclusive option agreement with MSK under which it had the right to acquire the exclusive worldwide license rights to three clinical stage T-cell therapies from MSK. In June 2015, we exercised an option to enter into an exclusive license agreement with MSK for three clinical stage T-cell therapies. In connection with the execution of the license agreement, the Company paid $4.5 million in cash to MSK, which was recorded as research and development expense in our condensed consolidated statement of operations and comprehensive loss.

We are required to make additional payments of up to $33.0 million to MSK based on achievement of specified regulatory and sales-related milestones, as well as mid-single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any. In addition, under certain circumstances, we are required to make certain minimum annual royalty payments to MSK, which are creditable against earned royalties owed for the same annual period. We are also required to pay a low double-digit percentage of any consideration we receive for sublicensing the licensed rights. The license agreement expires on a product-by-product and country-by-country basis on the later of: (i) expiration of the last licensed patent rights related to each licensed product, (ii) expiration of any market exclusivity period granted by law with respect to each licensed product, and (iii) a specified number of years after the first commercial sale of the licensed product in each country. Upon expiration of the license agreement, Atara will retain non-exclusive rights to the licensed products.

QIMR Berghofer Agreements – In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer.

Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic cytotoxic T-lymphocyte (“CTL”) therapy programs utilizing technology and know-how developed by QIMR Berghofer. In

consideration for the exclusive license, we paid $3.0 million in cash to QIMR Berghofer, which was recorded as research and development expense in our statement of operations and comprehensive loss in the fourth quarter of 2015. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional CTL programs as well as the option to license additional technology in exchange for $3.3 million in cash, which was recorded as research and development expense in our statement of operations and comprehensive loss in the third quarter of 2016. We exercised this option in June 2018. The amended and restated license agreement also provides for various milestone and royalty payments to QIMR Berghofer based on future product sales, if any.

Under the terms of the amended and restated research and development collaboration agreement, we are also required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. These payments are expensed on a straight-line basis over the related development periods. The agreement also provides for various milestone payments to QIMR Berghofer based on achievement of certain developmental and regulatory milestones.

Milestones and royalties under each of the above agreements are contingent upon future events and will be recorded as expense when it is probable that the milestones will be achieved or royalties are due. As of September 30, 2018 and December 31, 2017, there were no outstanding obligations for milestones and royalties to MSK and QIMR Berghofer.

From time to time, we have entered into other license and collaboration agreements with other parties. For example we entered into agreements related to our next-generation CAR T programs with MSK in May 2018 and with Moffitt Cancer Center in August 2018.

Cognate Agreement - In August 2015, Atara entered into a Development and Manufacturing Services Agreement (the “Manufacturing Agreement”) with Cognate Bioservices, Inc. (“Cognate”). The Manufacturing Agreement was amended in December 2017 to provide for additional rights for Atara in relation to the conduct of the services and amended again in May 2018 to modify certain financial provisions with respect to manufacturing services. Pursuant to the Manufacturing Agreement, Cognate provides process development and manufacturing services for certain Atara product candidates. Atara may terminate the Manufacturing Agreement for convenience on six months written notice to Cognate, or immediately if Cognate is unable to perform the Services or fails to obtain or maintain certain necessary approvals. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of Services for at least ninety days. The Manufacturing Agreement also includes standard provisions in the case of termination or cancellation of any specific manufacturing services.

7. Commitments and Contingencies

License and Collaboration Agreements

Potential payments related to our license and collaboration agreements, including milestone and royalty payments, are detailed in Note 6.

Other Research and Development Agreements

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for pre-clinical studies, clinical trials, supplies and other services for our operating purposes. These contracts generally provide for termination on notice. As of September 30, 2018 and December 31, 2017, there were no amounts accrued related to termination charges for minimum purchase volumes not being met.

Operating and Capital Leases

We lease our corporate headquarters in South San Francisco, California under a non-cancellable lease agreement that expires in April 2021. In connection with the lease, we are required to maintain a letter of credit in the amount of $0.2 million to the landlord, which expires and is renewed every 12 months, and is classified as restricted cash in our condensed consolidated balance sheet. We also lease office space in Westlake Village, California under a lease agreement that expires in April 2019. Also, in fourth quarter of 2017, we entered into multiple agreements to lease certain equipment that have been accounted for as capital leases. The terms of the lease agreements range between 2-3 years.

Rent expense was $0.6 million and $0.4 million for the three months ended September 30, 2018 and 2017, respectively and $1.6 million and $1.0 million for the nine months ended September 30, 2018 and 2017, respectively.

Facility Lease Financing Obligation

In February 2017, we entered into a lease agreement for approximately 90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California. The initial 15-year term of the lease commenced on February 15, 2018, upon the substantial completion of landlord's work as defined under the agreement. The contractual obligations during the initial term are $16.4 million in aggregate. We have the option to extend the lease for two additional periods of ten and nine years, respectively, after the initial term. In connection with the lease, we were required to issue a letter of credit in the amount of $1.2 million to the landlord, which is recorded as long-term restricted cash in our condensed consolidated balance sheet.

Based on the terms of the lease agreement and due to our involvement in certain aspects of the construction, we were deemed the owner of the building (for accounting purposes only) during the construction period in accordance with U.S. GAAP. Under this build-to-suit lease arrangement, we recognized construction in progress based on all construction costs incurred by both us and the landlord. We also recognized a financing obligation equal to all costs funded by the landlord.

As of September 30, 2018, due to completion of the construction by the landlord and not having met the criteria for sale-lease back accounting, we transferred the $10.3 million of landlord's construction costs previously capitalized as construction in progress to a build-to-suit asset, and have recognized a corresponding long-term financing obligation for the same amount in long-term liabilities in our consolidated balance sheets.

A portion of the monthly lease payment is allocated to land rent and recorded as an operating lease expense and the non-interest portion of the amortized lease payments to the landlord related to rent of the building is applied to the lease financing liability.

Asset Retirement Obligation

The Company's ARO consists of a contractual requirement to remove the tenant improvements at our manufacturing facility in Thousand Oaks, California and restore the facility to a condition specified in the lease agreement. The Company records an estimate of the fair value of its ARO in long-term liabilities in the period incurred. The fair value of the ARO is also capitalized as construction in progress. The fair value of our ARO was estimated by discounting projected cash flows over the estimated life of the related assets using our credit adjusted risk-free rate.

The following table presents the activity for our ARO liabilities:

	ARO Liability (in thousands)
Balance as of December 31, 2017	$ 580
Liabilities incurred during the period	88
Accretion expense	32
Balance as of September 30, 2018	$ 700

Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record liabilities for these agreements as of September 30, 2018 and December 31, 2017.

Contingencies

From time to time, we may be involved in legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business or otherwise. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on our results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on us because of the defense costs, diversion of management resources and other factors. We are not currently involved in any material legal proceedings.

8. Stockholders' Equity

Equity Offerings

In January 2018, we completed an underwritten public offering of 7,675,072 shares of common stock at an offering price of $18.25 per share and received net proceeds of $131.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us. Further, in March 2018, we completed an underwritten public offering of 4,928,571 shares of common stock at an offering price of $35.00 per share and received net proceeds of $161.9 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

ATM Facility

In March 2017, we entered into a sales agreement (the "ATM Facility") with Cowen and Company, LLC ("Cowen") for the sale, in our sole discretion, of shares of our common stock, having an aggregate offering price of up to $75.0 million through Cowen, as our sales agent. We pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold under the ATM Facility. The issuance and sale of these shares by us pursuant to the ATM Facility are deemed "at the market" offerings and are registered under the Securities Act of 1933, as amended.

During the nine months ended September 30, 2018, we sold an aggregate of 1,007,806 shares of common stock under the ATM Facility, at an average price of approximately $48.52 per share, for gross proceeds of $48.9 million and net proceeds of $47.6 million, after deducting commissions and other offering expenses. No shares were sold under the ATM Facility in the third quarter of 2018. As of September 30, 2018, $6.1 million of common stock remained available to be sold under this facility, subject to certain conditions as specified in the agreement.

Equity Incentive Plans

Under the terms of the 2014 Equity Incentive Plan ("2014 EIP"), we may grant stock options, restricted stock awards ("RSAs") and RSUs to employees, directors, consultants and other service providers. As of September 30, 2018, a total of 10,540,933 shares of common stock were reserved for issuance under the 2014 EIP, of which 3,457,163 shares were available for future grant and 7,083,770 shares were subject to outstanding options and RSUs.

In February 2018, we adopted the 2018 Inducement Plan ("2018 IP"), under which we may grant options, stock appreciation rights, RSAs and RSUs to new employees. As of September 30, 2018, 1,250,000 shares of common stock were reserved for issuance under the 2018 IP, of which 720,000 shares were available for future grant and 530,000

shares were subject to outstanding options and RSUs.

Restricted Stock Units

The following is a summary of RSU activity under our 2014 EIP and 2018 IP:

	RSUs	
	Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2017	1,685,000	$ 16.90
Granted	836,487	$ 34.61
Forfeited	(469,613)	$ 20.93
Vested	(619,983)	$ 17.33
Unvested as of September 30, 2018	1,431,891	$ 31.86
Vested and unreleased	2,617	
Outstanding as of September 30, 2018	1,434,508	

The fair value of RSUs is determined as the closing stock price on the date of grant. The weighted average grant date fair value of RSUs granted was $34.61 and $15.07 for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, there was $33.0 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.7 years. The aggregate intrinsic value of the RSUs outstanding as of September 30, 2018 was $59.3 million.

Under our RSU net settlement procedures, for most of our employees, we withhold shares at settlement to cover the minimum payroll withholding tax obligations. During the nine months ended September 30, 2018, we settled 634,851 RSUs, of which 439,986 RSUs were net settled by withholding 189,951 shares. The value of the RSUs withheld was $7.5 million, based on the closing price of our common stock on the settlement date. During the nine months ended September 30, 2017, we settled 290,534 RSUs, of which 51,592 RSUs were net settled by withholding 21,895 shares. The value of the RSUs withheld was $0.4 million, based on the closing price of our common stock on the settlement date. The value of RSUs withheld in each period was remitted to the appropriate taxing authorities and has been reflected as a financing activity in our condensed consolidated statements of cash flows.

Stock Options

The following is a summary of stock option activity under our 2014 EIP and 2018 IP. The table below also includes 275,000 stock options which were issued in 2017 outside of these plans:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2017	5,229,648	$ 21.06		
Granted	2,633,950	38.55		
Exercised	(781,191)	22.53		
Forfeited or expired	(750,208)	30.00		
Outstanding as of September 30, 2018	6,332,199	$ 27.10	5.4	$ 92,326
Vested and expected to vest as of September 30, 2018	6,332,199	$ 27.10	5.4	$ 92,326
Exercisable as of September 30, 2018	2,258,774	$ 21.26	4.0	$ 45,458

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on September 30, 2018 and the exercise price of outstanding, in-the-money options. As of September 30, 2018, there was $67.9 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized

over a weighted average period of 3.1 years.

Options for 781,191 shares of our common stock were exercised during the nine months ended September 30, 2018, with an intrinsic value of $13.9 million. No options were exercised during the nine months ended September 30, 2017. As we believe it is more likely than not that no stock option related tax benefits will be realized, we do not record any net tax benefits related to exercised options.

The fair value of each option issued was estimated at the date of grant using the Black-Scholes valuation model. The following table summarizes the weighted-average assumptions used as inputs to the Black-Scholes model, and resulting weighted-average grant date fair values of stock options granted to employees during the periods indicated:

	Nine months ended September 30, 2018		Nine months ended September 30, 2017	
Assumptions:				
Expected term (years)	4.6		4.5	
Expected volatility	73.4	%	69.1	%
Risk-free interest rate	2.7	%	1.8	%
Expected dividend yield	0.0	%	0.0	%
Fair Value:				
Weighted-average estimated grant date fair value per share	$ 22.86		$ 8.88	
Options granted	2,633,950		1,155,900	
Total estimated grant date fair value	$ 60,212,000		$ 10,264,000	

The estimated fair value of stock options that vested in the nine months ended September 30, 2018 and 2017 was $12.7 million and $10.9 million, respectively.

Employee Stock Purchase Plan

As of September 30, 2018, there were 943,338 shares available for purchase under the 2014 Employee Stock Purchase Plan (“2014 ESPP”). The Company recorded $0.5 million and $0.4 million of expense related to the 2014 ESPP in the nine months ended September 30, 2018 and 2017, respectively. 77,100 and 43,962 shares were purchased under the 2014 ESPP during the nine months ended September 30, 2018 and 2017, respectively.

Reserved Shares

The following shares of common stock were reserved for future issuance as of September 30, 2018:

	Total Shares Reserved
2014 Equity Incentive Plan	10,540,933

2018 Inducement Plan	1,250,000
2014 Employee Stock Purchase Plan	943,338
Options granted outside the equity plans	258,666
Total reserved shares of common stock	12,992,937

Stock-based Compensation Expense

Total stock-based compensation expense related to all employee and non-employee stock awards was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
Research and development	$ 4,682	$ 2,136	$ 10,997	$ 6,260
General and administrative	4,570	3,864	13,267	10,743
Total stock-based compensation expense	$ 9,252	$ 6,000	$ 24,264	$ 17,003

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Atara Biotherapeutics is a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. The Company's T cells are bioengineered from donors with healthy immune function and are being developed to allow for rapid delivery from inventory to patients without a requirement for pretreatment. Atara's T-cell immunotherapies are designed to precisely recognize and eliminate cancerous or diseased cells without affecting normal, healthy cells. Atara’s most advanced T-cell immunotherapy, tab-cel® (tabelecleucel), is in Phase 3 development for patients with Epstein-Barr virus, or EBV, associated post-transplant lymphoproliferative disorder, or “EBV+ PTLD”, as well as other EBV-associated hematologic and solid tumors, including nasopharyngeal carcinoma, or NPC. Atara is also developing T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis, or MS. Atara's pipeline also includes next generation chimeric antigen receptor T-cell, or CAR T immunotherapies for patients with hematologic and solid tumors, autoimmune and viral diseases as well as ATA621 directed against the BK and JC viruses, ATA520 targeting Wilms Tumor 1, or WT1 and ATA230 directed against cytomegalovirus, or CMV.

Our off-the-shelf, allogeneic technology allows for rapid delivery of a T-cell immunotherapy product that has been manufactured in advance and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient’s own cells must be extracted, modified outside the body and then delivered back to the patient. We utilize a proprietary cell selection algorithm to select the appropriate set of cells for use based on a patient’s unique immune profile, and, unlike many other T-cell programs, there is neither a requirement for pre-treatment before our cells are administered nor is there extended monitoring following administration. For example, in our ongoing trials, patients are monitored for one to two hours following receipt of tabelecleucel. Our T-cell immunotherapy platform is applicable to a broad array of targets and diseases. With more than 200 patients treated across the platform, we have observed clinical proof of concept across both viral and non-viral targets in conditions ranging from hematological malignancies and solid tumors to infectious and autoimmune diseases. We have also observed a safety profile characterized by few treatment-related serious adverse events, or SAEs, positive long-term outcomes including durable remissions, and no evidence of cytokine release syndrome to date.

Our allogeneic T-cell immunotherapy product candidates are bioengineered from cells donated by healthy individuals with normal immune function. Once cells are collected from a donor, they are bioengineered to recognize the antigens of interest and then expanded in number. The resulting expanded T-cells are then characterized and held as inventory. From inventory, these cells can be selected, distributed and prepared for infusion in a partially human leukocyte antigen, or HLA, matched patient in approximately 3-5 days. Following administration, our T-cells home to their target, undergo target-dependent proliferation, eliminate diseased cells and eventually recede. Target-dependent proliferation means that our T-cells expand in number when they encounter diseased cells in a patient’s body that express the antigen the cells are designed to recognize.

We licensed rights to certain know-how and T-cell product candidates from Memorial Sloan Kettering Cancer Center, or MSK, in June 2015. In May 2018, we entered into an agreement to expand our collaboration with MSK to the development of CAR T immunotherapies. Our most advanced product candidate, tabelecleucel, targets EBV. Tabelecleucel received Breakthrough Therapy Designation, or BTD, from the U.S. Food and Drug Administration, or FDA, and Priority Medicines, or PRIME, designation from the European Medicines Agency, or EMA, and is currently being evaluated as monotherapy in two Phase 3 trials for the treatment of patients with EBV+ PTLD. We believe that tabelecleucel has the potential to be the first commercially available off-the-shelf T-cell immunotherapy and the first FDA- and EMA-approved therapy for EBV+ PTLD, with regulatory submissions based on data from our ongoing Phase 3 trials as well as earlier studies conducted at MSK. We are currently developing the infrastructure to commercialize tabelecleucel globally for EBV+ PTLD. We are also evaluating the potential utility of tabelecleucel in patients with other EBV-associated cancers, such as NPC, to continue its development in both solid tumors and other hematological malignancies. Additional product candidates derived from the collaboration with MSK are being developed to treat various cancers and severe viral infections.

In October 2015 and September 2016, we licensed rights to certain know-how and technology from QIMR Berghofer that are complementary to those we licensed from MSK. This know-how and technology uses targeted antigen recognition to create off-the-shelf T-cell immunotherapy product candidates applicable to a variety of diseases, including autoimmune conditions such as MS. We are also working with QIMR Berghofer on the development of EBV-targeted and other virally targeted T-cells. Through this technology, we are expanding the role of T-cell-based immunotherapy beyond oncology and viral infections to autoimmune disease. Our most advanced off-the-shelf T-cell product candidate utilizing this technology, ATA188, targets select antigens of EBV and is currently being evaluated in a Phase 1 trial in an initial cohort for the treatment of patients with progressive MS. In connection with the initial license from QIMR Berghofer, we received an option to exclusively license an autologous version of ATA188, which is known as ATA190, which recently demonstrated clinical activity in a Phase 1 trial in progressive MS. We exercised this option in June 2018. We expect to broadly explore the utility of our targeted antigen recognition technology in EBV-related and other virally driven diseases, and additional product candidates derived from our collaboration with QIMR Berghofer are being developed.

In September 2018, we entered into a strategic collaboration with Moffitt Cancer Center, or Moffitt, to develop multi-targeted CAR T immunotherapies for patients with acute myeloid leukemia, or AML, and B cell malignancies. As part of this relationship, we expect to collaborate with Moffitt to develop multi-targeted CAR T immunotherapies designed to address cancers with diverse cell types that often become resistant to treatment such as AML and B-cell malignancies. In addition, the collaboration includes the use of novel CAR T intracellular co-stimulatory domains based on CD28 and 4-1BB that may improve CAR T proliferation when responding to an appropriate antigen and enhance CAR T persistence by reducing T-cell exhaustion.

In August 2015, we entered into a Development and Manufacturing Services Agreement, or Manufacturing Agreement, with Cognate Bioservices, Inc., or Cognate. The Manufacturing Agreement was amended in December 2017 to provide us with additional rights in relation to the conduct of the services and amended again in May 2018 to modify certain financial terms related to manufacturing services. Pursuant to the Manufacturing Agreement, Cognate provides process development and manufacturing services for certain of our product candidates. We may terminate the Manufacturing Agreement for convenience on six months written notice to Cognate, or immediately if Cognate is unable to perform the Services or fails to obtain or maintain certain necessary approvals. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of Services for at least ninety days. The Manufacturing Agreement also includes standard provisions in the case of termination or cancellation of any specific manufacturing services.

Tabelecleucel for EBV+ PTLD following HCT or SOT

Since its discovery as the first human oncovirus, EBV has been implicated in the development of a wide range of diseases, including lymphomas and other cancers. EBV is widespread in human populations and persists as a lifelong, asymptomatic infection. In healthy individuals, a small percentage of T cells are devoted to keeping EBV in check. In contrast, immunocompromised patients, such as those undergoing hematopoietic cell transplants, or HCT, or solid organ transplants, or SOT, have a reduced ability to control EBV. Left without appropriate immune surveillance, EBV transformed cells can, in some patients, proliferate and cause an aggressive, life-threatening cancer called EBV+ PTLD.

Our most advanced T-cell immunotherapy product candidate, tabelecleucel, is an allogeneic EBV-specific T-cell immunotherapy that is currently being investigated for the treatment of patients with EBV+ PTLD who have failed rituximab. In February 2015, the FDA granted tabelecleucel BTD for the treatment of patients with EBV+ PTLD after HCT who have failed rituximab. BTD is an FDA process designed to accelerate the development and review of drugs intended to treat a serious condition when early trials show that the drug may be substantially better than current treatment. In October 2016, tabelecleucel was accepted into the EMA PRIME regulatory pathway for the same

indication, providing enhanced regulatory support. In addition, tabelecleucel has received orphan designation in the United States and European Union for the treatment of patients with EBV+ PTLD following HCT or SOT. In December 2016, we announced that we had reached agreement with the FDA on the designs of two Phase 3 trials for tabelecleucel intended to support approval in two separate indications, the treatment of EBV+ PTLD following HCT (which we refer to as the MATCH trial) and SOT in patients who have failed rituximab (which we refer to as the ALLELE trial). In December 2017, following discussion with the FDA of manufacturing and comparability data generated on material manufactured by our contract manufacturing organization, we initiated these trials in the United States. We expect to expand these trials geographically to include clinical sites outside the United States.

The Phase 3 MATCH trial is a multicenter, open label, single arm trial designed to enroll approximately 35 patients with EBV+ PTLD following HCT who have failed rituximab. The Phase 3 ALLELE trial is a multicenter, open label trial with two non-comparative cohorts. Each cohort is designed to enroll approximately 35 patients. The first cohort will include patients who previously received rituximab monotherapy, and the second cohort will include patients who previously received rituximab plus chemotherapy. Both cohorts are enrolling concurrently. The primary endpoint of both the MATCH and ALLELE trials is confirmed best objective response rate, or ORR, defined as the percent of patients achieving either a complete or partial response to treatment with tabelecleucel confirmed after the initial tumor assessment showing a response. Secondary endpoints for both trials include duration of response, overall survival, safety, quality of life metrics, and other measures to evaluate its health economic impact. A safety committee will meet periodically to monitor for safety.

We are also pursuing marketing approval of tabelecleucel in the European Union. In March 2016, the EMA issued a positive opinion for orphan drug designation for tabelecleucel for the treatment of patients with EBV+ PTLD. In October 2016, the EMA Committee for Medicinal Products for Human Use and the Committee for Advanced Therapies granted tabelecleucel access to the EMA's recently established PRIME regulatory initiative for the treatment of patients with EBV+ PTLD following HCT who have failed rituximab. PRIME provides early enhanced regulatory support to facilitate regulatory applications and accelerate the review of medicines that address a high unmet need. In January 2017, we received parallel scientific advice from the EMA's Scientific Advice Working Group and several national Health Technology Assessment agencies in the EU, including those in the United Kingdom, Germany and France. We are in on-going discussions with both the EMA and the FDA regarding the development and regulatory paths for tabelecleucel in patients with EBV+ PTLD. We plan to share initial Phase 3 clinical results as well as observed EBV+ PTLD incidence with these agencies. The outcomes of these regulatory discussions are expected in the first half of 2019, and we plan to submit an application for EU Conditional Marketing Authorization, or CMA, of tabelecleucel in the treatment of patients with EBV+ PTLD who have failed rituximab in the second half of 2019.

Tabelecleucel for nasopharyngeal carcinoma, or NPC

NPC is a type of head and neck cancer that is primarily EBV-associated. Standard treatment for NPC typically includes radiation therapy, platinum-based chemotherapy or a combination of both. Surgical intervention is only rarely employed and is usually only utilized in select early stage cases. There are no approved therapeutic agents available to treat relapsed/refractory NPC, although there are multiple agents in development for this patient population. In April 2017, we entered into an agreement with Merck (known as MSD outside of the United States and Canada) to provide drug supply for a trial to be sponsored and conducted by us to evaluate tabelecleucel in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated NPC. This Phase 1/2 trial will evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the combination and was initiated in the fourth quarter of 2018.

ATA188 and ATA190 for multiple sclerosis

MS is a chronic disorder of the central nervous system, or CNS, that disrupts the myelination and normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss. The evolution of MS results in an increasing loss of both physical and cognitive (e.g., memory) function. This has a substantial negative impact on the more-than two million people worldwide affected by MS.

There are two categories of MS: progressive MS, or PMS, and relapsing-remitting MS, or RRMS. PMS is a severe form of MS with few therapeutic options. Within PMS there are two types of MS: secondary progressive MS, or SPMS, and primary progressive MS, or PPMS. According to the National Multiple Sclerosis Society, there are approximately one million people affected by PMS. Both types of PMS are characterized by persistent progression and worsening of MS symptoms and physical disability over time. PPMS occurs when the patient has a disease course characterized by steady and progressive worsening after disease onset. SPMS initially begins as RRMS, but once patients have continuous progression of their disease, they have developed SPMS. This is distinct from RRMS, where patients have flares of the disease that are followed by periods of recovery and quiescence during which the disease does not progress.

Scientific and clinical findings support a strong biologic connection between EBV and MS. EBV is present in nearly all patients with MS. For example, in an international study of patients with clinically isolated syndrome, or CIS, a CNS demyelinating event isolated in time that is compatible with the possible future development of MS, only one

patient out of 1,407 was seronegative for, or not infected with, EBV. In addition, in separate studies, clear differences in location and frequency of EBV-infected B cells and plasma cells were evident between the brains of MS patients and the brains of patients without MS. In these studies, the EBV-infected B cells and plasma cells were in close proximity to areas of active demyelination. Studies suggest that EBV-positive B cells and plasma cells in the CNS have the potential to catalyze an autoimmune response and the MS pathophysiology. In patients with MS, their T-cells may be unable to control EBV-positive B cells and plasma cells so that B cells and plasma cells could then accumulate in the brain and generate antibodies that attack and destroy myelin, the protective layer that insulates nerves in the brain and spinal cord. This loss of myelin ultimately leads to MS symptoms. MS disease course has also been shown to correlate with measures of EBV activity. The role of B cells in MS is supported by the recent approval by the FDA of ocrelizumab for PPMS which broadly targets B cells through their expression of a cell surface marker known as CD20. Low vitamin D also suppresses T-cells and is associated with MS.

Our T-cell immunotherapy product candidate ATA188 is an off-the-shelf EBV-specific T-cell preparation that utilizes a targeted antigen recognition technology that enables the T-cells we administer to selectively identify cells expressing the EBV antigens that we believe are important for the potential treatment of MS. We are also developing an autologous version of this product candidate that we call ATA190. ATA190 utilizes the same approach to targeted antigen recognition as ATA188. These product candidates are designed to selectively target only those cells which are EBV-positive while sparing those that are not. We believe that eliminating only EBV-positive B cells, including plasma cells, has the potential to benefit some patients with MS. In October 2015, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell immunotherapy product candidates targeting EBV, including ATA188, utilizing technology and know-how developed by QIMR Berghofer. In connection with this license, we also received an option to exclusively license the autologous version of EBV-specific product candidates, including ATA190, which we exercised in June 2018.

In the fourth quarter of 2017, we initiated an open label, single arm, multi-center, multi-national Phase 1 trial with allogeneic ATA188 for patients with MS and in January 2018 announced that we received clearance of our investigational new drug, or IND, application from the FDA to proceed with patient enrollment at U.S. sites. In the first quarter of 2018, we initiated this study in the U.S. The primary objective of this Phase 1 trial is to assess the safety of ATA188 in patients followed for at least one year after the first dose. Key secondary endpoints in the trial include measures of clinical improvement such as Expanded Disability Status Scale, or EDSS, and annualized relapse rate, or ARR, as well as MRI imaging. The trial is expected to enroll a total of 60 patients across the United States, Australia and Europe: 30 patients with PMS (either PPMS or SPMS), and 30 patients with RRMS. We expect to have initial results from our ATA188 Phase 1 trial in patients with PMS available in the first half of 2019.

In addition, based on the Phase 1 clinical results observed to date with ATA190, we believe the continued development of ATA190 will enhance our understanding of the potential therapeutic utility of targeting EBV in the treatment of MS and further inform and complement our development of ATA188. We plan to initiate, in 2019, a randomized clinical study of ATA190 in patients with PMS.

ATA621 for BK and JC virus associated diseases

Through our ongoing collaboration with QIMR Berghofer, we developed a T-cell immunotherapy product candidate, ATA621, for BK and JC virus-associated diseases. These two viruses are closely related and there are no available antiviral agents approved for use in BK or JC-associated diseases. JC virus is associated with progressive multifocal leukoencephalopathy, or PML, which occurs in transplant, HIV and cancer patients as well as in patients treated with immunosuppressive therapies, including certain therapies utilized for the treatment of MS. BK virus is associated with hemorrhagic cystitis, or BKVHC, which mainly occurs following HCT or cyclophosphamide treatment as well as BK virus associated nephropathy, or BKVAN, which is a disease most commonly associated with kidney transplant. Recent positive published results support our continued development of ATA621, targeting both JC and BK viruses for patients with progressive multifocal leukoencephalopathy (PML). We are currently conducting IND-enabling manufacturing process development for this program.

ATA520 for hematologic malignancies

Our T-cell immunotherapy product candidate ATA520 is an off-the-shelf WT1 specific T-cell immunotherapy, that targets cancers expressing the antigen WT1 and is currently in Phase 1 clinical trials. WT1 is an intracellular protein that is overexpressed in a number of cancers, including hematological malignances as well as solid tumors. We have decided to prioritize our EBV-related and next-generation CAR T programs ahead of ATA520 at this time.

ATA230 for CMV viremia and disease

Our T-cell immunotherapy product candidate ATA230 is an off-the-shelf CMV-specific T-cell immunotherapy, that is in clinical trials for refractory CMV infection that occurs in some immunocompromised patients, e.g., after HCT. The FDA granted orphan drug designation for ATA230 for the treatment of CMV viremia and disease in immunocompromised patients as well as Rare Pediatric Disease Designation for the treatment of congenital CMV infection. The EMA has also granted us orphan designation for ATA230 for CMV infection in patients with impaired cell-mediated immunity. We have decided to prioritize our EBV-related and next-generation CAR T programs ahead of ATA230 at this time.

Financial Overview

We have a limited operating history. Since our inception in 2012, we have devoted substantially all of our resources to identify, acquire and develop our product candidates, including conducting preclinical studies and clinical trials, acquiring or manufacturing materials for clinical trials, constructing our manufacturing facility and providing general and administrative support for these operations.

We have never generated revenues and have incurred losses since inception. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties.

Our net losses were $150.7 million and $84.2 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $447.3 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. As of September 30, 2018, our cash, cash equivalents and short-term investments totaled $364.5 million, which we intend to use to fund our operations.

Research and Development Expenses

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

We plan to increase our research and development expenses as we continue the development of our product candidates. Our current planned research and development activities include the following:

- continuing to initiate sites and enroll patients in our Phase 3 clinical trials of tabelecleucel for the treatment of patients with EBV+ PTLD after HCT and SOT who have failed rituximab;
- process development, testing and manufacturing of drug supply to support clinical trials and IND-enabling studies;
- continuing to develop product candidates based on our next-generation CAR T programs;
- continuing development of ATA190 and enrolling patients to the Phase 1 trial of ATA188 in MS;
- continuing to develop our product candidates in additional indications, including tabelecleucel for NPC and frontline PTLD;
- continuing to develop other product candidates, including ATA621 for BK and JC virus associated diseases; and
- leveraging our relationships and experience to in-license or acquire additional product candidates or technologies.

In addition, we believe it is important to invest in the development of new product candidates to continue to build the value of our product candidate pipeline and our business. We plan to continue to advance our most promising early product candidates into preclinical development with the objective to advance these early-stage programs to human clinical trials over the next several years.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the availability of qualified drug supply for use in our ongoing Phase 3 or other clinical trials;
- the scope, rate of progress, and expenses of our ongoing as well as any additional clinical trials and other research and development activities;
- future clinical trial results;
- uncertainties in clinical trial enrollment rates or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- changing medical practice patterns related to the indications we are investigating;

- significant and changing government regulation; and
- the timing and receipt of any regulatory approvals, as well as potential post-market requirements.

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The process of conducting the necessary clinical research to obtain approval from the FDA and other regulators is costly and time consuming and the successful development of our product candidates is highly uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section of this report titled "1A. Risk Factors." As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and benefits for legal, human resources, finance, commercial and other general and administrative employees, including stock-based compensation; outside professional service costs, including legal, patent, human resources, audit and accounting services; other outside services and consulting costs, including those related to pre-commercial activities; and allocated information technology and facilities costs. We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount to support our continued research and development and the potential commercialization of one or more of our product candidates.

Interest and Other Income, net

Interest and other income, net consists primarily of interest earned on our cash, cash equivalents and short-term investments.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no significant changes during the nine months ended September 30, 2018 to our critical accounting policies and significant judgments and estimates as disclosed in our management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Income Taxes

On December 22, 2017, the President signed into law new tax legislation, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. As of September 30, 2018, we have made a reasonable estimate of the effects on our existing deferred taxes and related disclosures for the reduction in corporate tax rate and adjustments to the expected deductibility of executive compensation. Due to current year taxable losses and our federal valuation allowance position, we did not recognize any income tax expense or benefit as a result of enactment of the Tax Act. Due to accumulated foreign deficits the Company does not expect a current inclusion in U.S. federal taxable income for the transition tax on earnings of controlled foreign corporations.

The SEC staff has issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We consider the key estimates on the deferred tax remeasurement and the impact of the changes to the deductibility of executive compensation to be provisional due to expected forthcoming guidance from federal and state tax authorities, our continuing analysis of final year-end data and tax positions, as well as further guidance expected for the associated income tax accounting. During the nine months ended September 30, 2018, we did not make any adjustments to the provisional amounts included in the consolidated financial statements for the year ended December 31, 2017. We expect to complete our analysis within the measurement period in accordance with SAB 118.

Emerging Growth Company Status

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements. As an “emerging growth company”,

- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

However, we are choosing to irrevocably opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards. We will be deemed a “large accelerated filer” as of the end of the fourth quarter of 2018, as our public float as of June 29, 2018 was greater than $700 million, and thus we will no longer be classified as an “emerging growth company” as of December 31, 2018.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2018 and 2017

Research and development expenses

Research and development expenses consisted of the following costs, in the periods presented:

	Three months ended September 30,			Nine months ended September 30,		
	2018	2017	Increase (Decrease)	2018	2017	Increase (Decrease)
	(in thousands)			(in thousands)		
Tabelecleucel expenses	$ 12,620	$ 9,121	$ 3,499	$ 33,748	$ 24,020	$ 9,728
ATA188, ATA190 and other program expenses	6,068	2,156	3,912	11,753	6,036	5,717
Employee and overhead costs	24,667	9,321	15,346	59,701	26,379	33,322
Total research and development	$ 43,355	$ 20,598	$ 22,757	$ 105,202	$ 56,435	$ 48,767

Tabelecleucel costs were $12.6 million and $33.7 million in the three and nine-month periods ended September 30, 2018, as compared to $9.1 million and $24.0 million in the comparative 2017 periods. The increases between the periods were primarily due to clinical trial, manufacturing and outside service costs related to the two Phase 3 clinical trials of tabelecleucel in patients with EBV+ PTLD who have failed rituximab, which were initiated in January 2018. We anticipate that tabelecleucel costs will continue to increase in the remainder of 2018 and into 2019 due to enrollment in the two Phase 3 clinical trials as well as initiation of the NPC study.

ATA188, ATA190 and other program costs were $6.1 million and $11.8 million in the three and nine-month periods ended September 30, 2018, as compared to $2.2 million and $6.0 million in the comparative 2017 periods. The increases between the periods were primarily related to clinical trial, manufacturing and other outside service costs related to the Phase 1 clinical trial of ATA188 for patients with MS and the exercise of the option to license ATA190, the autologous version of ATA188. We anticipate that ATA188, ATA190 and other program costs will continue to increase in the remainder of 2018 due to an increase in manufacturing activity, the continued development of our manufacturing processes, clinical trial activities, and development related to our collaborations with QIMR Berghofer and MSK.

Employee and overhead costs were $24.7 million and $59.7 million in the three and nine-month periods ended September 30, 2018 as compared to $9.3 million and $26.4 million in the comparative 2017 periods. The increases between the three-month periods were primarily due to a $9.7 million increase in employee-related costs driven by increased headcount, a $3.6 million increase in facility-related costs, and a $2.0 million increase in professional services costs. The increases between the nine-month periods were primarily due to a $20.0 million increase in employee-related costs driven by increased headcount, a $6.8 million increase in professional services costs and a $6.5 million increase in facility-related costs. The increases between the periods were primarily related to our continuing expansion of research and development activities and we anticipate that employee and overhead costs will continue to increase in future periods as we continue to expand such activities.

General and administrative expenses

	Three months ended September 30,			Nine months ended September 30,		
	2018	2017	Increase (Decrease)	2018	2017	Increase (Decrease)
	(in thousands)			(in thousands)		
General and administrative	$16,865	$11,062	$ 5,803	$ 50,093	$ 29,295	$ 20,798

General and administrative expenses increased to $16.9 million and $50.1 million in the three and nine-month periods ended September 30, 2018 as compared to $11.1 million and $29.3 million in the comparative 2017 periods. The increase between the three-month periods was primarily due to a $3.4 million increase in professional services costs, a $3.0 million increase in employee-related costs driven by increased headcount, partially offset by a $0.6 million decrease in facility-related costs. The increase between the nine-month periods was primarily due to a $11.7 million increase in professional services costs, a $9.4 million increase in employee-related costs driven by increased headcount, partially offset by a $0.3 million decrease in facility-related costs. The increases between the periods were primarily related to the expansion of our operations and we expect that general and administrative costs will continue to increase in the remainder of 2018 as we continue to expand.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012, we have funded our operations primarily through the issuance of common and preferred stock. In January 2018, we completed an underwritten public offering of 7,675,072 shares of common stock at an offering price of $18.25 per share and received net proceeds of $131.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us. Further, in March 2018, we completed an underwritten public offering of 4,928,571 shares of common stock at an offering price of $35.00 per share and received net proceeds of $161.9 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

In March 2017, we entered into the ATM Facility with Cowen for the sale, in our sole discretion, of shares of our common stock, having an aggregate offering price of up to $75.0 million through Cowen, as our sales agent. We pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold under the ATM Facility. The issuance and sale of these shares by us pursuant to the ATM Facility are deemed “at the market” offerings and are registered under the Securities Act of 1933, as amended.

During the nine months ended September 30, 2018, we sold an aggregate of 1,007,806 shares of common stock under the ATM facility, at an average price of approximately $48.52 per share, for gross proceeds of $48.9 million and net proceeds of $47.6 million, after deducting commissions and other offering expenses. No shares were sold under the ATM Facility in the third quarter of 2018. As of September 30, 2018, $6.1 million of common stock remained available to be sold under this facility, subject to certain conditions as specified in the agreement.

We have incurred losses and negative cash flows from operations in each year since inception. As of September 30, 2018, we had an accumulated deficit of $447.3 million. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products. As such, we anticipate that we will continue to incur losses the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash, cash equivalents and short-term investments are held in bank and custodial accounts and consist of money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities. Management expects that existing cash, cash equivalents and short-term investments as of September 30, 2018 will be sufficient to fund our planned operations to mid-2020.

Our cash, cash equivalents and short-term investments balances as of the dates indicated were as follows:

	September 30, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$66,028	$79,223
Short-term investments	298,515	86,873
Total cash, cash equivalents and short-term investments	$364,543	$166,096

Cash Flows

Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table details the primary sources and uses of cash for each of the periods set forth below:

	Nine months ended September 30,	
	2018	2017
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$(122,353)	$(62,564)
Investing activities	(242,357)	56,939
Financing activities	351,515	19,350
Net (decrease) increase in cash, cash equivalents and restricted cash	$(13,195)	$13,725

Operating activities

Net cash used in operating activities was $122.4 million in the 2018 period as compared to $62.6 million in the 2017 period. The increase of $59.8 million was primarily due to a $66.2 million increase in net loss, a $1.9 million increase in the amortization of investment premiums and discounts, and a $0.7 million increase in operating assets and liabilities, partially offset by a $7.3 million increase in stock-based compensation, a $1.6 million increase in depreciation expense, and a $0.2 million increase in non-cash interest expense.

Investing activities

Net cash used in investing activities in the 2018 period consisted primarily of $402.6 million used to purchase available-for-sale securities and $31.8 million in purchases of property and equipment, partially offset by $132.0 million received from maturities and $60.0 million from sales of available-for-sale securities. Net cash provided by investing activities during the 2017 period consisted primarily of $162.1 million received from maturities and $58.2 million from sales of available-for-sale securities, partially offset by $152.8 million used to purchase available-for-sale securities, $10.5 million in purchases of property and equipment and a $1.2 million investment in restricted cash.

Financing activities

Net cash provided by financing activities in the 2018 period consisted of $293.3 million of aggregate net proceeds from the underwritten public offerings in January and March 2018, $47.6 million of net proceeds from the ATM facility and $18.5 million of net proceeds from employee stock transactions, partially offset by $7.5 million of taxes paid related to the net share settlement of restricted stock and $0.4 million on principal payments on our capital lease obligations. Net cash provided by financing activities in the 2017 period consisted of $19.2 million of net proceeds from the ATM facility and $0.5 million of net proceeds from employee stock transactions, partially offset by $0.4 million of taxes paid related to the net share settlement of restricted stock.

Operating Capital Requirements and Plan of Operations

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates, and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need to raise substantial additional funding in connection with our continuing and expected expansion of our operations.

We expect that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations to mid-2020. In order to complete the process of obtaining regulatory approval for our lead product candidate and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidate, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and

uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our ongoing and planned clinical trials and preclinical studies for our product candidates;
- our success in establishing and scaling commercial manufacturing capabilities;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
    - subject to receipt of regulatory approval, costs associated with the commercialization of our product candidates and the amount of revenues received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights;
- the extent to which we in-license or acquire other products and technologies; and
- the timing of capital expenditures.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Contractual Obligations and Commitments

Future minimum payments under our operating, capital and finance leases as of September 30, 2018 was $19.4 million.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

During the nine months ended September 30, 2018, there were no material changes to our interest rate risk disclosures, market risk disclosures and foreign currency exchange rate risk disclosures reported in our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) of the Exchange Act as of September 30, 2018. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2018 to ensure that information required to be disclosed by us in the reports 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 that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure 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.

Inherent Limitations on Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures and our internal controls will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have

been or will be detected. As these inherent limitations are known features of the financial reporting process, it is possible to design into the process safeguards to reduce, though not eliminate, these risks. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. While our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2018, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the nine months ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Investors should carefully consider all of the risk factors and uncertainties described below, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated and combined financial statements and related notes, together with our other filings made from time to time with the SEC before investing in our common stock. This description includes any material changes to, and supersedes, the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017.

The risks described below may not be the only ones relating to our company and additional risks that we currently believe are immaterial may also affect us. If any of these risks, including those described below, materialize, our business, competitive position, reputation, financial condition, results of operations, cash flows and future prospects could be seriously harmed. In these circumstances, the market price of our common stock could decline, and investors may lose all or a part of their investment.

Risks Related to Our Financial Results and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales or otherwise to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the nine months ended September 30, 2018, we reported a net loss of $150.7 million and we had an accumulated deficit of $447.3 million as of September 30, 2018.

We do not expect to generate revenues for the foreseeable future, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, in-license or develop, and potentially begin to commercialize product candidates that may achieve regulatory approval. 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 revenues. If any of our product candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent

periods. We anticipate that our expenses will increase in the future as we continue to invest in research and development of our existing product candidates, investigate and potentially acquire new product candidates and expand our manufacturing and commercialization activities.

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

Our company was formed in August 2012. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights and conducting product development activities for our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials, obtain regulatory approval, consistently manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization for any of our product candidates. In addition, the adoptive immunotherapy technology underlying our T-cell product candidates, including our next-generation CAR T programs, is new and largely unproven. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may not be as accurate as they could be if we had a longer operating history or approved products on the market.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, any of our quarterly or annual periods' results are not indicative of future operating performance.

We currently have no source of revenues. We may never generate revenues or achieve profitability.

To date, we have not generated any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including any of our current product candidates, and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit regulatory submissions to the FDA, EMA or other agencies and obtain regulatory approval for indications for which there is a commercial market;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- develop manufacturing and distribution processes for our novel T-cell immunotherapy product candidates;
- develop commercial quantities of our products at acceptable cost levels;
- establish and maintain adequate supply of our products, including cell lines with sufficient breadth to treat patients;
- establish and maintain manufacturing relationships with reliable third parties or complete our own manufacturing facility such that we can maintain the supply of our products by ensuring adequate, manufacturing of bulk drug substances and drug products in a manner that is compliant with global legal requirements;
- achieve market acceptance of our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property portfolio;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

Our revenues for any product candidate for which regulatory approval is obtained 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 revenues from sales of our products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our T-cell immunotherapy product candidates, and the advancement and expansion of our preclinical research pipeline. We also expect to continue to expend resources for the development and manufacturing of product candidates and the technology we have licensed or have an exclusive right to license from our partners, including ATA188 and ATA190 and any product candidates related to our next-generation CAR T programs. These expenditures will include costs associated with research and development, potentially acquiring or licensing new product candidates or technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. Under the terms of our license agreements with each of our partners, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize on our own. In addition, other unanticipated costs may arise. Because the design and outcome of our ongoing, planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates, if clinical trials are successful, including any costs from post-market requirements;
    - the cost of commercialization activities for our product candidates, if any of these product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to develop, acquire or in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing technologies or other adverse market developments.

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations to mid-2020. As of September 30, 2018, we had total cash, cash equivalents and short-term investments of $364.5 million. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We do not have any committed external source of funds. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

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Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or take other actions that are adverse to our business.

Risks Related to the Development of Our Product Candidates

We are early in our development efforts and have only a small number of product candidates in clinical development. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be materially harmed.

We are early in our development efforts, and only a small number of our product candidates are in clinical development. The majority of our product candidates are currently in preclinical development. We have invested substantial resources in identifying and developing potential product candidates, conducting preclinical studies, clinical trials and manufacturing activities and preparing for the potential commercial launch of our product candidates. Our ability to generate revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on many factors, including the following:

- completion of preclinical studies and clinical trials with positive results;
- receipt of regulatory approvals from applicable authorities;
- protecting our rights in our intellectual property portfolio, including by obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing or making arrangements with third-party manufacturers or completing our own manufacturing facility for clinical and commercial manufacturing purposes;
- developing manufacturing and distribution processes for our novel T-cell product candidates and next-generation CAR T programs;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our products, if approved by applicable regulatory authorities, whether alone or in collaboration with others;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other therapies;
- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

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

Our future success is dependent on the regulatory approval of our product candidates.

We do not have any products that have gained regulatory approval. Currently, our clinical-stage product candidates include tabelecleucel, for which we recently initiated Phase 3 clinical trials in the United States, ATA188, which is in a Phase 1 clinical trial, and ATA190, which is in a Phase 1 clinical trial conducted by QIMR Berghofer. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our product candidates in a timely manner.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or conduct of our clinical trials;
- failure to demonstrate positive benefit/risk of the product candidate for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates, such as our novel T-cell product candidates and next-generation CAR T programs, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied

pharmaceutical or other product candidates. Approvals by the EMA and FDA for existing autologous CAR T therapies, such as Novartis's Kymriah and Gilead's Yescarta, may not be indicative of what these regulators may require for approval of our therapies. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from that have previously been approved, such as existing autologous CAR T therapies. For instance, allogeneic product candidates may result in adverse events not experienced with autologous products.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our T-cell immunotherapy product candidates and our next-generation CAR T programs represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.

Our future success is dependent on the successful development of T-cell immunotherapies and our next-generation CAR T programs in general and our development product candidates in particular. Because these programs, particularly our pipeline of allogenic T-cell product candidates that are bioengineered from donors, represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing our product candidates subject us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of T-cell immunotherapies;
- developing and deploying consistent and reliable processes for procuring blood from consenting third-party donors, isolating T-cells from the blood of such donors, activating the isolated T-cells against a specific antigen, characterizing and storing the resulting activated T-cells for future therapeutic use, selecting and delivering a sufficient supply and breadth of appropriate partially HLA-matched cell line from among the available T-cell lines, and finally infusing these activated T-cells into patients;
- utilizing these product candidates in combination with other therapies (e.g. immunomodulatory approaches such as checkpoint inhibitors), which may increase the risk of adverse side effects;
- educating medical personnel regarding the potential side effect profile of each of our product candidates, particularly those that may be unique to our allogenic T-cell product candidates and to our next-generation CAR T programs;
- understanding and addressing variability in the quality of a donor's T-cells, which could ultimately affect our ability to manufacture product in a reliable and consistent manner;
- developing processes for the safe administration of these products, including long-term follow-up and registries, for all patients who receive these product candidates;
- manufacturing our product candidates to our specifications and in a timely manner to support our clinical trials and, if approved, commercialization;
- sourcing clinical and, if approved by applicable regulatory authorities, commercial supplies for the materials used to manufacture and process these product candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;
- 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 diseases beyond those initially addressed by our current product candidates.

We cannot be sure that the manufacturing processes used in connection with our T-cell immunotherapy product candidates will yield a sufficient supply of satisfactory products that are safe, pure and potent, comparable to those T-cells produced by our partners, historically, scalable or profitable.

Moreover, actual or perceived 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 by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may ask for specific post-market requirements, and additional information informing benefits or risks of our products may emerge at any time prior to or after regulatory approval.

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 therapy, may decide the therapy is too complex to adopt without appropriate training or not cost-efficient, 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.

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidates in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market tabelecleucel, ATA188 or ATA190, any product candidates resulting from our next-generation CAR T programs or any of our other product candidates in any particular jurisdiction.

Tabelecleucel has been predominantly evaluated in single-center trials under investigator-sponsored INDs held by MSK, utilizing different response criteria and endpoints from those we may utilize in later clinical trials. For example, the primary endpoint of both the MATCH and ALLELE trials is “confirmed best objective response rate” defined as the percent of patients achieving either a complete or partial response to treatment with tabelecleucel confirmed after the initial tumor assessment showing a response. In contrast, neither the prior MSK trials nor our EAP trial protocol require response confirmation. The findings may not be reproducible in late phase trials we conduct. For regulatory approvals of tabelecleucel, we plan on using independent radiologist and/or oncologist assessment of responses which may not correlate with the investigator-reported assessments. In addition, the Phase 2 clinical trials with tabelecleucel enrolled a heterogeneous group of patients with a variety of EBV-associated malignancies, including EBV+ PTLD after HCT and EBV+ PTLD after SOT. These Phase 2 trials were not prospectively designed to evaluate the efficacy of tabelecleucel in the treatment of a single disease state for which we may later seek approval. If conditional marketing authorization is granted from the European Commission, we may be subject to obligations, including the need to provide additional clinical data at a later stage to confirm a positive benefit/risk balance.

Moreover, final trial results may not be consistent with interim trial results. Efficacy data from prospectively designed trials may differ significantly from those obtained from retrospective subgroup analyses. In addition, clinical data obtained from a clinical trial with an allogeneic product candidate such as ATA188 may not yield the same or better results as compared to an autologous product candidate such as ATA190. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

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. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and clinical trials.

We may experience delays in our ongoing or future clinical trials and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

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delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;

- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or 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;
- delay or failure in obtaining institutional review board, or IRB, approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;

- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, including because potential trial sites may already be engaged in competing clinical trial programs for the same indication that we are treating;
- failure of our third-party clinical trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new trial sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign authorities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;
- a decision by the FDA, the IRB, comparable foreign authorities, or us, or a recommendation by a data safety monitoring board or comparable foreign authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable benefit/risk profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities and breadth of appropriate partially HLA matched cell lines from among the available T-cell lines to start or to use in clinical trials;
- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the possibility that the rare diseases that many of our product candidates address are under-diagnosed, changing medical practice patterns or guidelines related to the indications we are investigating, the severity of the disease under investigation, the proximity of subjects to clinical sites, the patient referral practices of physicians, the design and eligibility criteria of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out or die before completion, competition for patients from other clinical trials, risk that we do not have appropriately matched HLA cell lines and clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Many of our product candidates are designed to treat rare diseases, and as a result the pool of potential patients with respect to a given disease is small. We may not be able to initiate or continue to support clinical trials of tabelecleucel, ATA188, ATA190 or any other product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

We rely on CROs, other vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

If we experience delays or quality issues in the conduct, completion or termination of any clinical trial of our product candidates, the approval and commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any delays in completing our clinical trials for our product candidates may also decrease the period of commercial exclusivity. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of

regulatory approval of our product candidates.

Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of that product;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Both the FDA and the EMA have granted us orphan designation for tabelecleucel for EBV+ PTLD after HCT or SOT.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not be maintained or effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a new drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Breakthrough Therapy Designation by the FDA may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

Although we have obtained Breakthrough Therapy Designation, or BTD, for tabelecleucel for EBV+PTLD, this may not lead to faster development or regulatory review and does not increase our likelihood of success. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Receipt of a BTD for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited the FDA review procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the conditions for qualification and rescind BTD or decide that the time period for FDA review or approval will not be shortened.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development,

labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our contract manufacturing organizations, or CMOs, and CROs for any post-approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, current Good Clinical Practices, or GCP, current good tissue practices, or cGTP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

Regulations, guidelines and recommendations published by various government agencies and organizations may affect the use of our product candidates.

Changes to regulations, recommendations or other guidelines advocating alternative therapies for the indications we treat could result in decreased use of our products. For example, although treatment with EBV-specific T-cells is recognized as a recommended treatment for persistent or progressive EBV+ PTLD as set forth in the 2017 National Comprehensive Cancer Network Guidelines, future guidelines from governmental agencies, professional societies, practice management groups, private health/science foundations and other organizations could lead to decreased ability of developing our product candidates, or decreased use of our products once approved by applicable regulatory authorities.

We may not successfully identify, acquire, develop or commercialize new potential product candidates.

Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in-license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the

success of our business will depend on our ability to expand our product pipeline through in-licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in-license or acquire them.

We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses.

We may desire to form strategic alliances, create joint ventures or collaborations, enter into licensing arrangements with third parties or acquire products or business, in each case that we believe will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time-consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive benefit/risk profile. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction.

Risks Related to Manufacturing

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

Concurrently with the license of our existing product candidates, we acquired manufacturing process know-how and, in some cases, and inventory of process intermediates and clinical materials, from our partners. Transferring manufacturing processes, testing and associated know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. As a result, there is a risk that all relevant know-how was not adequately transferred to us from our partners.

In addition, we need to conduct significant development work to transfer these processes and manufacture each of our product candidates for various studies, clinical trials and commercial launch readiness. To the extent we elect to transfer manufacturing to our CMO, there is a risk that the know how is not adequately transferred. For example, to facilitate the manufacture of additional drug product for our Phase 3 clinical trials of tabelecleucel using the MSK manufacturing testing and process know-how, we undertook the process of transferring this know-how to our CMO. With respect to tabelecleucel, we cannot be certain that all relevant know-how has been adequately incorporated into the manufacturing process until the completion of studies (and the related evaluations) intended to demonstrate the comparability of material previously produced by MSK with that generated by our CMO. The inability to manufacture comparable drug product by us or our CMO could delay the continued development of our product candidates. Although we believe we have manufactured material that is comparable to that previously produced by MSK, the FDA, EMA, and other comparable regulatory authorities may not agree.

The processes by which our product candidates are manufactured were initially developed by our partners for clinical purposes. We intend to evolve the existing processes with our partners to support advanced clinical trials and commercialization requirements. Developing commercially viable manufacturing processes is a difficult and uncertain

task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidates will be made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, and numerous other factors.

The process of manufacturing cellular therapies is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, impact to key product quality attributes, and other supply disruptions. Product defects can also occur unexpectedly. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, these manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because our T-cell immunotherapy product candidates are manufactured from the blood of third-party donors, the process of manufacturing is susceptible to the availability of the

third-party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. This type of contaminations could result in delays in the manufacture of products which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects. Furthermore, our allogeneic products ultimately consist of many individual cell lines, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell line for therapeutic use in a patient will require close coordination between clinical and manufacturing personnel.

Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug product which could delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

We intend to manufacture at least a portion of our product candidates ourselves. Delays in commissioning and receiving regulatory approvals for our manufacturing facility could delay our development plans and thereby limit our ability to generate revenues.

In June 2018, we opened our Atara T-Cell Operations and Manufacturing, or ATOM, facility in Thousand Oaks, California. The research and development and process and analytical development labs are operationally supporting preclinical development activities. The commissioning and qualification activities required to support ATOM manufacturing capacity will be completed to support clinical production expected in 2019. If the appropriate regulatory approvals for the new facility are delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development activities and our opportunities for growth.

In addition to the similar manufacturing risks described in "Risks Related to Our Dependence on Third Parties," our manufacturing facility will be subject to ongoing, periodic inspection by the FDA, EMA or other comparable regulatory agencies to ensure compliance with cGMP and GTP. Our failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our product candidates. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA, EMA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions,

any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facility. Advances in manufacturing techniques may render our facility and equipment inadequate or obsolete, without further investment.

In order to produce our product candidates in the quantities that we believe will be required to meet anticipated market demand of any of our drug candidates if approved by applicable regulatory authorities, we will need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our product candidates in a sufficient quantity to meet future demand.

If our sole clinical manufacturing facility or our CMO is damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.

If any manufacturing facility in our manufacturing network or the equipment in these facilities is either damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of this facility or equipment, we may not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our commercial product sales.

Currently, we maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our CROs, we may not be able to obtain regulatory approval for or commercialize our product candidates on a timely basis, if at all.

We have relied upon and plan to continue to rely upon third-party CROs and contractors to conduct, monitor and manage data for our ongoing preclinical and clinical programs. For example, our collaborating investigators at MSK managed the conduct, analysis, interpretation and publication of data for the ongoing clinical trials of tabelecleucel, our CRO and our collaborating investigators at QIMR Berghofer manage or managed the conduct of the ongoing and prior clinical trials for ATA190 and ATA188 and we are utilizing a CRO for our EAP trial of tabelecleucel in PTLD, for our exploratory trial of tabelecleucel and pembrolizumab in NPC and for our open Phase 3 trials of tabelecleucel for EBV+ PTLD after HCT and SOT.

We rely on third-party CROs and contractors for the execution of our preclinical studies and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs and contractors are required to comply with federal regulations, GCP, which are international standards meant to protect the rights and health of patients that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development, and cGTP, which are standards designed to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable diseases. Regulatory authorities enforce GCP, GLP and cGTP through periodic inspections of trial sponsors, principal investigators and trial sites. If we, or any of our partners or CROs, fail to comply with applicable GCP, GLP or cGTP, the clinical and preclinical data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies before approving our regulatory applications. We cannot assure that inspection by a given regulatory authority will determine that any of our studies comply with GCP, GLP or cGTP requirements. In addition, our clinical trials must be conducted with product produced under cGMP and cGTP requirements. We are also

required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, clinicaltrials.gov, within a specified timeframe. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process and result in adverse publicity.

Our CROs and partners are not our employees, and except for remedies available to us under our agreements, we cannot control whether or not they devote sufficient time and resources, including experienced staff, to our ongoing clinical, nonclinical and preclinical programs. Our CROs and partners may also have relationships with other entities, some of which may be our competitors. If CROs or partners do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical or preclinical data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Our internal capacity for clinical trial execution and management is limited and therefore we have relied on third parties. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results or data in a timely manner or may fail to perform at all. Unexpected or unreliable data from prior or future studies or trials, including by our partners, may emerge in the future. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees which limits the internal resources we have available to identify and monitor our third party providers.

Our CROs and partners generally have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs and partners have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our preclinical and clinical development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so timely or on commercially reasonable terms.

We have limited experience manufacturing our product candidates on a clinical or commercial scale. We are, and expect to continue to be, dependent on third parties across our supply chain to support manufacturing of our product candidates and if we experience problems with any of these third parties, the manufacturing of our product candidates could be delayed.

We do not currently manufacture our product candidates in our own facilities and we rely on our CMO or our partners for the production of our product candidates and the acquisitions of materials incorporated in or used in the manufacturing or testing of our product candidates. Our CMOs or partners are not our employees, and except for remedies available to us under our agreements with our CMOs or partners, we cannot control whether or not they devote sufficient time and resources, including experienced staff, to the manufacturing of supply for our ongoing clinical, nonclinical and preclinical programs.

To meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of tabelecleucel, ATA188, ATA190, any product candidates resulting from our next-generation CAR T programs or any other product candidates, we will need to transition the manufacturing of these materials to a CMO or our own facility. Regardless of where production occurs, we will need to develop relationships with suppliers of critical starting materials or reagents, increase the scale of production and demonstrate comparability of the material produced at these facilities to the material that was previously produced. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time.

In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We would expect additional comparability work will also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know-how and data has been adequately incorporated into the manufacturing process until the completion of studies (and the related evaluations) intended to demonstrate the comparability of material previously produced with that generated by our CMO. For example, we generated and evaluated data from new material manufactured by our CMO and identified certain assays that need refinement prior to initiating the Phase 3 trials of tabelecleucel. We have generated comparability data from the cell lines produced by our CMO using our refined assays and believe this data supports the demonstration of comparability, and we recently initiated the Phase 3 trials in the U.S. following discussions with FDA.

If we are not able to successfully transfer and produce comparable product candidates, our ability to further develop and manufacture our product candidates may be negatively impacted.

While the addition of the ATOM facility provides us with future flexibility within our manufacturing network, we still may need to identify additional CMOs for continued production of supply for some or all of our product candidates. Given the nature of our manufacturing processes, the number of CMOs who possess the requisite skill and capability to manufacture our T-cell immunotherapy product candidates is limited. We have not yet identified alternate suppliers in the event the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them.

Manufacturing cellular therapies is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our product candidates at costs, or in sufficient quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA or comparable regulatory authorities not agree with our product candidate specifications and comparability assessments for these materials, further clinical development of our product candidate could be substantially delayed and we would incur substantial additional expenses.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial resources to meet its obligations under the manufacturing agreement, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar regulatory jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have limited control over our manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

We depend on third party suppliers for key materials used to produce our product candidates. Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate for an ongoing clinical trial could considerably delay initiation or completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If we or our CMOs are unable to purchase key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which could impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product

candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements – both that we own or possess or that are owned or possessed by our partners that are in-licensed to us – to protect the intellectual property related to our technology and product candidates. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license, many of which are critical to our intellectual property protection and our business. For example, the product candidates and platform technology we have licensed from our partners are protected primarily by patent or patent applications of our partners that we have licensed and as confidential know-how and trade secrets. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office, or USPTO, and non-US patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in these patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable.

Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek a license from a third party who owns intellectual property that may be useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all.

In addition, 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. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction..

We and our partners have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our partners were the first to file any patent application related to a product candidate. We or our partners may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and inter partes and post-grant review proceedings before the USPTO the European Patent Office and other non-U.S. patent offices.

Even if granted, patents have a limited lifespan. In the United States, the natural expiration of a patent generally occurs 20 years after it is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be

unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates.

Furthermore, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government has certain rights to these patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to practice the invention for or on behalf of the United States. These rights may permit the government to disclose confidential information on which we rely to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in any inventions that result from government-funded research may be subject to certain requirements to manufacture products embodying these inventions in the United States.

If we are sued for infringing the intellectual property rights of third parties, the resulting litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and inter partes and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, patent applications covering our product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing their claims.

If we or our partners are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until the relevant patent expired. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us.

We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates.

Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the

course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. In the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any of these license agreement may require us to pay royalties and other fees that could be significant. As a result of all of the foregoing, any actual or threatened intellectual property claim could prevent us from developing or commercializing a product candidate or force us to cease some aspect of our business operations.

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

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the United States, or from selling or importing infringing 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 or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

We have in-licensed a significant portion of our intellectual property from our partners. If we breach any of our license agreements with these partners, we could lose the ability to continue the development and potential commercialization of one or more of our product candidates.

We hold rights under license agreements with our partners, including MSK, QIMR Berghofer and Moffitt that are important to our business. Our discovery and development platform is built, in part, around patent rights in-licensed from our partners. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations, we may be liable to pay damages and our counterparties may have a right to terminate the affected license. The termination of any license agreement with one of our partners could materially adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product candidates and our ability to commercialize the affected product candidates. Furthermore, a disagreement under any of these license agreements may harm our relationship with the partner, which could have negative impacts on other aspects of our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our partners may elect to initiate legal proceedings to enforce or defend our or our partners' intellectual property rights, to protect our or our partners' trade secrets or to determine the validity or scope of our intellectual property rights. Any claims that we or our partners assert against perceived infringers could also provoke these parties to assert counterclaims against us or our partners alleging that we or our partners infringe their intellectual property rights or that our intellectual property rights are invalid.

Interference or derivation proceedings provoked by third parties, brought by us or our partners, or brought by the USPTO or any non-US patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, inter partes review, post-grant review or other preissuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could require us or our partners to cease using the related technology and commercializing our product candidates, 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 or our partners a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Any intellectual property proceedings can be expensive and time-consuming. Our or our partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our partners can. Accordingly, despite our or our partners' efforts, we or our partners may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as in the United States. Even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, 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 proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to seeking the protection afforded by patents, we 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 other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. The T-cell immunotherapy product candidates and platform technology we have licensed from our partners are protected primarily as confidential know-how and trade secrets. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors,

or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved , among physicians, patients, healthcare payors and the medical community, including hospitals and outpatient clinics.

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which the product candidate is approved;
    - acceptance by physicians and patients of the drug as a safe and effective treatment;
- the administrative and logistical burden of treating patients;
- the adoption of novel cellular therapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our products as well as competitive products;
- the development of manufacturing and distribution processes for our product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the United States and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval, and ultimately our ability to successfully commercialize any product candidate for which we obtain regulatory approval.

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

Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by 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, provided incentives to programs that increase the federal government’s comparative effectiveness research and established a new Medicare Part D coverage gap discount program.

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 the U.S. 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 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since its enactment, there have been judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or

replace certain aspects of the Affordable Care Act. For example, the President signed Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While the U.S. Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted and the U.S. Congress may consider and adopt other legislation to repeal and replace all or certain elements of the Affordable Care Act. Any "repeal and replace" legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier. Policy changes, including potential modification or repeal of all or parts of the Affordable Care Act or the implementation of new health care legislation, could result in significant changes to the health care system which may adversely affect our business in unpredictable ways.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product candidates for which we obtain regulatory approval and our ability to set a price that we believe is fair for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product candidates, if any, may be. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, in the United States, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, certain leaders in the U.S. Congress and the presidential administration have indicated that they will continue to seek new legislative or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

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

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Additionally, our commercial opportunities will be reduced or eliminated if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence of our target diseases. Competition could result in reduced sales and pricing pressure on our product candidates, if approved by applicable regulatory authorities. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

There are currently no FDA or EMA approved products for the treatment of EBV+ PTLD. However, some approved products and therapies are used off-label in the treatment of EBV+ PTLD, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing drug candidates for EBV+ PTLD and other EBV-associated diseases including: Cell Medica Ltd., which is conducting Phase 2 clinical trials for baltaleucel-T, an autologous EBV specific T-cell therapy in EBV-related disorders, including PTLD, Viracta Therapeutics, Inc., which is conducting Phase 1b/2 clinical trials for tractinostat (VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV^{+} lymphomas, and Viracyte, which is conducting a Phase 2 clinical trial for Viralym-M™ , an allogeneic, multi-virus T-cell product that targets five viruses including EBV. In addition, Tessa Therapeutics Pte Ltd. is developing TT10, an autologous EBV specific T-cell therapy, which is currently being evaluated in Phase 3 clinical trials for the treatment of nasopharyngeal carcinoma.

Competition in the MS market is high with at least fourteen therapies, including two generics, approved for the treatment of relapsing-remitting multiple sclerosis (RRMS) in the U.S. and European Union. There are many U.S. and international competitors in the RRMS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Ocrevus®, marketed by F. Hoffmann-La Roche, was approved for the treatment of relapsing MS in the U.S. and European Union. There are numerous other development candidates in Phase 3 trials for RRMS including Novartis' anti-CD20 monoclonal antibody ofatumumab; Biogen's BIIB098 (formerly Alkermes' ALKS 8700); and J&J/Actelion's next-generation sphingosine 1-phosphate receptor (S1PR) agonist ponesimod. Celgene recently received a Refusal to File letter from the FDA regarding ozanimod, an S1PR and S1PR5 agonist, in relapsing MS, however, they have stated they will resubmit their regulatory filing in 2019.

Only three therapies have been approved for the treatment of progressive MS. Recently, Ocrevus® was approved in the U.S. and European Union for the treatment of primary progressive MS (PPMS). Extavia® (marketed by Novartis) and Betaseron® (marketed by Bayer AG) are approved in the European Union for the treatment of secondary progressive MS (SPMS). Few therapies have been approved for progressive MS because many candidates have failed during clinical trial testing. In the U.S., there is one drug (mitoxantrone) approved to treat SPMS, which is now generic. Novartis has filed marketing applications for siponimod in SPMS in both the US and EU and is on track for launches in 2019.

The SPMS and PPMS markets have active development pipelines and additional novel agents could be approved in the future. Several development candidates are being evaluated in trials including a number of Phase 3 programs: MedDay's MD-1003, a concentrated form of biotin, and AB Science's masitinib, a tyrosine kinase inhibitor, are pursuing both SPMS & PPMS. Medicinova's MN166(ibudilast) is in Phase 2 trials for PPMS.

A number of companies and institutions are pursuing development programs for relapsed or refractory MM. These development programs include drug candidates being evaluated in clinical trials as a monotherapy or in combination with other approved agents. In addition, many groups are developing novel T-cell therapies such as autologous CAR T-cell or autologous TCR T-cell candidates. These include bluebird bio, Inc., which is conducting Phase 2 clinical trials testing bb2121, an anti-BCMA CAR T; Gilead Sciences, Inc., which is testing KTE-585, an anti-BCMA CAR T in Phase 1 clinical trials; Juno Therapeutics, which is testing an anti-BCMA CAR T in Phase 1 clinical trials; Autolus Limited, which is testing AUTO-2, a bi-specific anti-BCMA/TACI CAR T in Phase 1 clinical trials and Adaptimmune Therapeutics PLC, which is testing an anti-NY-ESO TCR in Phase 1/2 clinical trials.

Many of the approved or commonly used drugs and therapies for EBV+ PTLD and MS, among others, are well-established and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs and nutritional supplements are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. We expect that, if any of these product candidates is approved, it will be priced at a significant premium over competitive generic products. This pricing premium may make it difficult for us to differentiate these products from currently approved or commonly used therapies and impede adoption of our product, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies or if they are acquired by larger companies. These third parties compete with us in recruiting and retaining qualified scientific, commercial and

management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. 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 processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States 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 the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the 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.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We are at any early stage of establishing an organization that will be responsible for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without a sufficiently scaled and trained internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

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

As of September 30, 2018, we had 310 employees. We have made the decision to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates. In particular, we may need to add substantial numbers of additional personnel and other resources to support our development and potential commercialization of our product candidates. As our development and commercialization plans and strategies continue to develop, or as a result of any future acquisitions, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources will increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our preclinical studies and clinical trials effectively;

- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

As our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

Risks Related to Our Business Generally

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our personnel, including Isaac E. Ciechanover, M.D., our President, Chief Executive Officer. Our employment agreement with Dr. Ciechanover is at-will and does not prevent him from terminating his employment with us at any time. The loss of the services of Dr. Ciechanover could impede the achievement of our research, development and commercialization objectives.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute will constrain our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for

payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates;

- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- state and foreign laws and regulations that are analogous to the federal laws and regulations described in the preceding subsections of this risk factor, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our

product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

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

Our business and operations would suffer in the event of computer system failures or security breaches.

Our internal computer systems, and those of our partners, our CROs, our CMOs, and other business vendors on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the President signed into law new tax legislation, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures.

We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse.

Our ability to use net operating loss carryforwards to offset future taxable income, and our ability to use tax credit carryforwards, may be subject to certain limitations.

Our ability to use our federal and state net operating losses, or NOLs, to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

As of December 31, 2017, we reported U.S. federal and state NOLs of approximately $76.0 million and $231.4 million, respectively. Our federal NOLs generated prior to 2018 will continue to be governed by the NOL tax rules as they existed prior to the adoption of the Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Many states have similar laws, and our state NOLs will begin to expire in 2032. Accordingly, these federal and state NOLs could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted Tax Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOL's is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our ability to utilize these NOLs and other tax attributes, such as federal tax credits, in any taxable year may be limited if we have experienced an "ownership change." Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year testing period. Similar rules may apply under state tax laws. We completed a Section 382 study of transactions in our stock through December 31, 2017 and concluded that we have experienced an ownership change that we believe under Section 382 of the Code will result in limitations in our ability to use certain of our NOLs and credits. In addition, we may experience future ownership changes as a result of future offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, the amount of the NOLs and tax credit carryforwards presented in our financial statements could be limited and, in the case of NOLs generated in 2017 and before, may expire unused. Any such material limitation or expiration of our NOLs may harm our future operating results by effectively increasing our future tax obligations.

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

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

Risks Related to Ownership of Our Common Stock

Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance.

Our stock price has fluctuated in the past and can be expected to be volatile in the future. From October 16, 2014, the first date of trading of our common stock, through September 30, 2018, the reported sale price of our common stock has fluctuated between $9.66 and $65.56 per share. The stock market in general and the market for biotechnology

companies in particular have experienced volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or products or our competitors' product candidates or products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other risks described in this "Risk Factors" section.

In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and health care spending and delivery, including the possible repeal and/or replacement of all or portions of the Affordable Care Act or changes in tariffs and other restrictions on free trade stemming from U.S. and foreign government policies, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations may adversely affect the trading price of our common stock.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

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

Our executive officers, directors and significant stockholders own a significant portion of our outstanding common stock. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock. The interests of our significant stockholders may not always coincide with the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the market price for our common stock.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, certain holders of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations

applicable to affiliates.

We are an “emerging growth company” and are taking advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we are taking advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years from the date of our initial public offering. We will cease to be classified as an “emerging growth company” and will be deemed a “large accelerated filer” as of the end of the fourth quarter of 2018.

Our status as an “emerging growth company” under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements currently available to us as an “emerging growth company” we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

Effective December 31, 2018, we will no longer be an “emerging growth company,” and the reduced reporting requirements applicable to “emerging growth companies” will no longer apply, which will increase our costs as a result of being a public company and demands on management.

Effective December 31, 2018, we will no longer be classified as an “emerging growth company” as defined in the JOBS Act. As such, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. As we prepare for no longer being classified as an “emerging growth company”, the cost of compliance with Section 404 has required, and will continue to require, us to 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 or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, 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, in the future, material weaknesses 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 effect on our stated operating results. If we are unable to implement these changes effectively or efficiently, it could harm our operations, financial reporting or financial results and could result in an adverse opinion on internal control from our independent registered public accounting firm.

In addition, we have previously taken advantage of the JOBS Act’s reduced disclosure requirements applicable to “emerging growth companies” regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation. Once we are no longer classified as an “emerging growth

company," we will no longer be eligible for such reduced disclosure requirements and exemptions and as such, we will be required to hold a say-on-pay vote and a say-on-frequency vote at our 2019 annual meeting of stockholders. As a result, we expect that when we are no longer classified as an "emerging growth company," we will require additional attention from management with respect to our disclosures and will incur increased costs, which could include higher legal fees, accounting fees, consultant fees and fees associated with investor relations activities, among others.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of potential gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock in one or more transactions at prices and in a manner we determine from time to time, including pursuant to our ATM Facility with Cowen, or any similar arrangements into which we may enter. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions or in-licenses, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, non-employee directors and consultants. Future grants of RSUs, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock.

Some terms of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation, or Certificate of Incorporation, and amended and restated bylaws, or Bylaws, as well as Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include terms that:

- permit our board of directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our board of directors, including as a result of 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;
- establish that our board of directors is divided into three classes, with each class serving three-year staggered terms, which makes it more difficult to replace a majority of our directors in a short period of time;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and 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 advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by our board of directors, the chairperson of our board of directors or our chief executive officer.

Any of the factors listed above may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management.

In addition, because we are incorporated in Delaware, we are governed by Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or

not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any term of our Certificate of Incorporation or Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. In the event securities or industry analysts who cover us downgrade our stock or publish unfavorable research about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	6/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	6/20/2014	
4.1	Form of Atara Biotherapeutics, Inc. Common Stock Certificate.	S-1/A	333-196936	4.1	7/10/2014	
4.2	Investor Rights Agreement of Atara Biotherapeutics, Inc., dated March 31, 2014.	S-1	333-196936	4.2	6/20/2014	
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification by Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1(1)	Certifications of Chief Executive Officer and Principal Financial and Accounting Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Schema Document					X
101.CAL	XBRL Calculation Linkbase Document					X
101.LAB	XBRL Labels Linkbase Document					X
101.PRE	XBRL Presentation Linkbase Document					X
101.DEF	XBRL Definition Linkbase Document.					X

* Indicates management contract or compensatory plan or arrangement.
† Confidential treatment requested.

(1) The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

ATARA
BIOTHERAPEUTICS,
INC.

Date: November 6, 2018

By:/s/ Isaac Ciechanover
Isaac Ciechanover
President and Chief
Executive Officer
(Duly Authorized Officer
and Principal
Executive Officer)

By:/s/ Utpal Koppikar
Utpal Koppikar
Chief Financial Officer
(Duly Authorized Officer
and Principal
Financial and Accounting
Officer)